NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Relieving symptoms of benign prostatic hyperplasia by inserting implants into the prostate

Benign prostatic hyperplasia is a condition that causes the prostate to increase in size. It can lead to the prostate squeezing the tube that carries urine from the bladder to the tip of the penis (the urethra). This can cause problems with passing urine. Prostatic urethral lift implants are implants that are permanently fitted in the prostate to open up the narrowed or blocked urethra by lifting or holding the enlarged prostate out of the way.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in June 2013 and updated in November 2013.

Procedure name

Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Specialist societies

- British Association of Urological Surgeons

Description

Indications and current treatment

Benign prostatic hyperplasia (BPH) is a common condition that affects older men. It is characterised by an increase in the size of the prostate, which is caused by an increased number of stromal and epithelial cells. BPH can cause lower urinary tract symptoms including hesitancy during micturition, interrupted or decreased urine stream (volume and flow rate), nocturia, incomplete voiding and urinary retention.

Mild symptoms are usually managed conservatively. Drugs such as alpha blockers can be used to relax the smooth muscle of the urethra. Androgen blockers such as 5-alpha-reductase can also be used. If symptoms are more severe, then surgical treatments may be used including transurethral resection of the prostate (TURP) or transurethral vaporisation of the prostate, or holmium laser enucleation of the prostate (see NICE clinical guideline 97).

What the procedure involves

The aim of insertion of prostatic urethral lift implants for lower urinary tract symptoms secondary to benign prostatic hyperplasia is to widen the lumen of the urethra by retracting the enlarged prostate lobes. The procedure is designed to cause less tissue injury than surgical resection or thermal ablation, and it is claimed to reduce the risk of complications such as sexual dysfunction and incontinence.

The procedure is undertaken transurethrally under local or general anaesthesia. A pre-loaded delivery device is passed through a rigid sheath under cystoscopic visualisation. The delivery device is used to compress 1 lateral lobe of the prostate in an anterolateral direction towards the prostatic capsule. A needle is then advanced through the lobe and capsule, and a non-absorbable monofilament implant with 2 end pieces is deployed. One end of the implant is anchored in the urethra and the other on the outer surface of the prostatic capsule, retracting the prostatic lobe away from the urethral lumen. Multiple implants are usually inserted during the same procedure.

Outcome measures

International Prostate Symptom Score (IPSS)

The International Prostate Symptom Score (IPSS) is an 8-item validated questionnaire often used to assess symptoms of BPH (it is also referred to as the American Urological Association BPH Symptom Score Index). It includes questions on incomplete bladder emptying, frequency, intermittency and urgency of micturition, weak urine stream, straining to urinate and nocturia. Higher scores represent worse symptoms. In general, an IPSS symptom score of 0–7 indicates mild symptoms, 8–19 indicates moderate symptoms and 20–35 indicates severe symptoms. An additional quality-of-life question asks men how they feel about their BPH symptoms (ranging from 0 to 6, with 0 representing ‘delighted’ and 6 representing ‘terrible’).

Sexual Health Inventory for Men (SHIM)

A 5-item validated questionnaire used to assess erectile dysfunction. The severity of erectile dysfunction score is from 1 to 25, with 1 being the most severe and 25 being healthy.

Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)

A 4-item validated questionnaire used to assess ejaculatory dysfunction. Three questions relate to ejaculatory function items and 1 relates to ejaculation bother item. Ejaculatory function score is the sum of questions 1 to 3 and scores range from 1 to 15, with lower scores indicating more severe ejaculatory complaints. Bother score range from 0 to 5, with higher scores indicating greater bother.

Benign Prostatic Hyperplasia Impact Index (BPHII)

A 4-item questionnaire used to assess how urinary trouble and problems associated with BPH may impact the patient. Scores range from 0 to 4, with higher score indicating greater impact.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. Searches were conducted of the following databases, covering the period from their commencement to 5 September 2013: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation

or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with lower urinary tract symptoms.
Intervention/test	Prostatic urethral lifts.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 391 patients from 1 randomised controlled trial[1] and 3 case series [2–4].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

Study details

Roehrborn CG (in press 2013)[1]

Randomised controlled trial (LIFT study)

Multi-centre study (Australia, USA and Canada) (19 centres)

Recruitment period: 2011

Study population: men with symptomatic BPH

n = 206 (140 PUL vs 66 sham)

Age: mean 66 years

Patient selection criteria: patients at least 50 years old, with no prior surgical treatment for BPH, AUASI ≥13, Qmax ≤12 ml/s with a 125 ml voided volume and prostate 30–80 cc were included. Patients with median lobe obstruction, retention, PVR >250 ml, active infection, PSA >10 ng/ml (unless negative biopsy), cystolithiasis within 3 months and bacterial prostatitis within 1 year were excluded.

Technique: under general or local anaesthesia, implants (UroLift System, NeoTract) were delivered transurethrally to the target site. Average of 4.9 implants were delivered.

Key efficacy findings

Number of patients analysed: **varied at different time points and outcomes**

Technical success: All procedures were completed successfully.

Mean change at 3 months

Outcomes (PUL vs sham)	PUL mean (SD)		Sham mean (SD)	
	Baseline	Change	Baseline	Change
AUASI[a] (140 vs 66)	22.2 (5.5)	−11.1 (7.7)	24.4 (5.8)	−5.9 (7.7)
BPHII [b] (140 vs 66)	6.9 (2.8)	−3.9 (3.2)	7.0 (3.0)	−2.1 (3.3)
QoL[b] (140 vs 66)	4.6 (1.1)	−2.2 (1.8) Final: 2.4(1.7)	4.7 (1.1)	−1.0 (1.5) Final: 3.6(1.6)
Q_{max} (ml/s)[c] (126 vs 56)	8.0 (2.4)	4.3 (5.2)	7.9 (2.4)	2.0 (4.9)
IIEF-5[d] (132 vs 65)	13.3 (8.4)	0.1 (5.8)	13.7 (8.5)	1.5 (6.4)
MSHQ-EjD (94 vs 50)[d]	8.7 (3.1)	2.2 (2.5)	8.8 (3.1)	1.7 (2.6)
MSHQ-bother [d] (117 vs 60)	2.4 (1.7)	−0.8 (1.5)	2.2 (1.7)	−0.7 (1.6)
PVR (ml)[d] (140 vs 65)	85.5 (69.2)	−9.7 (85.5)	85.6 (70.8)	−22.2 (70.7)

The mean change between the groups: [a]p=0.003; [b]p<0.001; [c]p=0.005; [d]not significant.

Key safety findings

Death (due to unrelated causes) was reported in 1 patient (unclear in which group; timing unclear).

Complications

	0–3 months		3–12 months
	PUL %(n)	Sham %(n)	PUL %(n)
SAEs	5.0(7)	1.5(1)	11.4 (16)
Related SAEs [a]	0.7 (1)	0	0.7(1)
All AEs	87.1 (122)	51.5(34)	52.1 (73)
Related AE	80.7(113)	30.3(20)	25.0 (35)
Dysuria[b]	34.3(48)	16.7(11)	0.7(1)
Haematuria[b]	25.7(36)	4.5(3)	0.7(1)
Pelvic pain/discomfort[b]	17.9(25)	4.5(3)	1.4(2)
Urgency [b]	7.1(10)	0(0)	2.1(3)
Bladder spasm	3.6(5)	0	0.7 (1)
Urge incontinence	3.6(5)	1.5(1)	0.7(1)
UTI	2.9(4)	1.5(1)	0
Retention	0.7(1)	1.5(1)	0.7(1)

[a] The following AEs were reported as 'related to the procedure': clot retention (coincided with reinitiating warfarin therapy; needed an overnight stay); removal of a bladder stone at 12 months (considered to have arisen from confirmed bladder gravel at baseline and not associated with an implant);

[b] considered to be 'mild to moderate' events and

Comments

Follow-up issues:
7 patients were censored because of use of BPH medication, 2 were excluded because of protocol deviations and 1 discontinued participation (reason not reported).

Study design issues:
- Randomisation (2:1) using permuted block generated thorough a central program. Questionnaire administrator and patients were blinded to randomisation until the 3 month end point (except

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

Sham procedure: a rigid cystoscopy was performed and a disposable biopsy device was deployed 4 times to stimulate the UroLift device sounds.

Patients had to undergo washouts of 2 weeks for alpha blockers, 3 months for 5-alpha-reductase inhibitors and 3 days for anticoagulants.

Follow-up:

3 months for both groups (for primary efficacy end point);

12 months for patients treated by PUL.

Conflict of interest/source of funding: not reported

Mean change in score at 12 months (results only reported for patients treated by PUL)

Outcome	Baseline	Follow up
AUASI (n=123)	21.8 (5.4)	11.1(7.0)
QoL(n=123)	4.5(1.0)	2.2(1.6)
BPHII(n=123)	6.6(2.8)	2.7(2.9)
Q_{max} (ml/s) (n=103)	8.1(2.4)	12.1(5.4)
PVR (ml) (n=120)	82(66)	70(98)

The change in AUASI, BPHII, QoL scores and Q_{max} at 12 months were significant (P<0.0001).

Scores for AUASI, BPHII and QoL were also reported at 2 weeks, 1 month, 3 months and 6 months; the change was significant at all time points. In addition to above, Q_{max} and PVR were reported at 3 months only ; change was significant for Q_{max}. Changes for MSHQ-EjD, MSHQ- bother and IIEF-5 scores were not reported.

Retreatment (at 12 months): 5% (7/140)

- 5 patients underwent PUL revision because of insufficient response.
- 2 patients were treated by TURP or laser vaporisation with no complications (reasons for retreatment not reported).

resolved within 2 weeks.

Additional AEs (12 months) [assessed using cystoscopy; undertaken in 94% (131/140) of patients]

Encrustation	14 implants (10 patients). Implants were inadvertently delivered such that part of the implant was exposed inside the bladder. 1 implant was later removed. There were no encrustations on implants delivered within the prostate.
Oedema (mild increase)	5 patients
Inflammation (mild increase)	1 patient

Catheterisation

28.6% (40/140) of patients were catheterised following the procedure. 32% (32/100) of the remaining patients needed catheterisation; mean duration was 0.9 days.

There were no new reports of erectile dysfunction or retrograde ejaculation.

for 4 patients).

- All AEs were independently adjudicated.
- AUASI scale: 8 item questionnaire (7 symptom and 1 QoL item); symptom scores range from 0–35, with higher scores indicating severity. QoL scored on a scale of 0 to 5, with higher scores indicating lower QoL. IIEF-5 rates erectile function. Scores range from 5 to 25, higher scores indicating no erectile dysfunction.
- Protocol for follow-up is on an annual basis for 5 years.

Study population

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.			
			issues: •Baseline demographics reported as being 'similar' between the 2 groups. **Other issues:** •After 3 month end point, patients in sham group were offered treatment. 80% (53/66) of patients subsequently elected to undergo PUL. Results to be published.

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

McNicholas TA (2013)[2]

Case series

UK, Australia, Germany, Italy, Spain, Netherlands

(7 centres)

Recruitment period: not reported

Study population: men with symptomatic BPH, with a mean prostate volume 48 cm^3, IPSS of 23.2, QoL of 4.7 and Q_{max} of 8.7 ml/s.

n=**102**

Age: mean 68 years

Patient selection criteria: authors reported 'typical inclusion criteria' were: prostate volume <60cm^3, IPSS >2, Q_{max} <15 ml/s and PVR<350 ml.

Technique: with patients under general, spinal, or local (17%) anaesthesia, implants (UroLift) were placed transurethrally under cystoscopic guidance to separate the encroaching prostatic lobes. Patients received an average of 4.5 implants (ranging from 2 to 9 for prostate volumes 16 to 149 cm^3.

Follow-up: **12 months**

Conflict of interest/source of funding: Three authors were paid consultants to NeoTract, Inc. Device-specific materials were provided by NeoTract, Inc. The manufacturers reviewed the manuscript.

Number of patients analysed: **varied for outcomes and time intervals**

Technical success: All procedures were completed successfully.

Mean IPSS

	2 weeks (n=56)	3 months (n=82)	12 months (n=51)
Baseline	22.7(5.6)	23.3(6.0)	23.9(6.3)
Follow-up	14.5 (7.2)	10.7(6.3)	11.6(5.6)

The change in mean score was statistically significant at all time points (p<0.001).

Mean QoL

	2 weeks (n=55)	3 months (n=65)	12 months (n=43)
Baseline	4.9(0.9)	4.8(0.9)	4.8(1.0)
Follow-up	3.0(1.6)	2.0(1.4)	2.3(1.5)

The change in mean score was statistically significant at all time points (p<0.001).

Mean BPHII

	2 weeks (n=48)	3 months (n=65)	12 months (n=47)
Baseline	7.3(2.5)	7.6(2.5)	7.7(2.6)
Follow-up	5.5(3.6)	3.3(2.8)	2.9(2.8)

The change in mean score was statistically significant at 2 weeks (p=0.005) and at all remaining time points (p<0.001)

Mean Q_{max} (ml/s)

	2 weeks (n=32)	3 months (n=80)	12 months (n=41)
Baseline	9.6(3.2)	8.6(3.8)	7.8(4.0)
Follow-up	13.3(4.7)	12.9(4.5)	11.9(3.5)

The change in mean score was statistically significant at all time points (p<0.001).

Mean PVR (ml)

	2 weeks	6 months	12 months

Complications (transient and 'mild to moderate')

'Most common' (actual numbers not reported)

Dysuria	25%
Haematuria	16%
Urgency	10%

Three cases each of retention, UTI and orchitis ('all treated routinely'; no further details).

Catheterisation

58% of patients were catheterised overnight.

7 patients who presented with urinary retention at baseline remained catheter free (range 1 to 12 months).

Follow-up issues:

- Follow-up was at 2 and 6 weeks, 3, 6, and 12 months. The authors not all patients were followed up at all times because of practice variations at each centre.
- Data from retreated patients were censored from time of retreatment.

Study design issues:

- The study is a retrospective analysis of prospectively accrued data on consecutively enrolled patients.
- All patients completed IPSS at baseline unless in retention.
- Sexual

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

	(n=28)	(n=37)	(n=29)
Baseline	102(91)	105(86)	103(89)
Follow-up	91(105)	71(86)	106(69)

The change in mean PVR was statistically significant at 6 months (p=0.002)

Sexual function: None of the patients reported a loss of ejaculatory emission.
There were no reports of loss of antegrade ejaculation.

Reduction in symptoms
7 patients who presented with urinary retention at baseline remained catheter free (mean follow-up at 8.3 months).

Retreatment
6.5% (4 patients; denominator not reported) of patients who experienced insufficient improvement were converted to TURP without complication (at 2 weeks, 3 weeks, 6 weeks and 11 months).

function data not collected using validated instruments.

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

Chin PT (2012)[3]

Case series

Australia (6 centres)

Recruitment period: not reported

Study population: men with moderate to severe symptomatic BPH. Duration of LUTS: range 0.5 to 23 years. Prostate volume: range 21 to 149 cm^3

n=**64**

Age: mean 67 years

Patient selection criteria: men ≥55 years with moderate to severe symptomatic BPH, IPSS >13, PVR <250 ml and Q_{max} of 5–12 ml/s were included. Patients with PSA levels >10 ng/ml, a history of urinary retention, previous prostate surgery, obstructive median lobes, compromised renal function or current infection were excluded. Patients had to be free of alpha-blocker medication within 1 week of treatment and 5 alpha-reductase inhibitor medication within 6 months of treatment.

Technique: under local anaesthesia (n=26) or general (n=40) anaesthesia, multiple permanent implants (UroLift System, NeoTract) were delivered transurethrally to secure the prostatic urethra. Two implants were typically placed at both the bladder neck and mid prostate.

Follow-up: **24 months**

Number of patients analysed: **varied at different time points and for the outcomes**

Mean IPSS

	2 weeks (n=59)	6 months (n=62)	12 months (n=55)	24 months (n=33)
Baseline	22.6 (5.4)	22.7 (5.3)	22.5 (5.4)	21.8 (5.3)
Follow-up	13.2 (6.3)	11.6 (7.1)	12.1 (7.1)	12.6 (7.2)

The change in mean score from baseline to follow-up was statistically significant (p<0.001) at all time intervals.

Mean QoL

	2 weeks (n=62)	6 months (n=62)	12 months (n=55)	24 months (n=33)
Baseline	4.9 (0.9)	4.9 (0.9)	4.8 (1)	4.7 (1.1)
Follow-up	2.7 (1.7)	2.3 (1.5)	2.5 (1.6)	2.5 (1.8)

The change in mean score from baseline to follow-up was statistically significant (p<0.001) at all time intervals.

Mean SHIM

	6 weeks (n=30)	6 months (n=33)	12 months (n=26)	24 months (n=13)
Baseline	18.2 (4.9)	17.5 (5.6)	17.9 (5.9)	16.5 (6.8)
Follow-up	19.8 (5.7)	18.4 (5.9)	19.7 (5.2)	17.6 (5.6)

The change in mean score from baseline to follow-up was

Complications	n
Transient urge incontinence	5 (resolved within 8 days)
Rigor (3 days after procedure)	1 (treated without complications; no further details)
Irritative symptoms, dysuria and mild haematuria	Number of patients not reported (resolved within 1 week)
UTI	7 (all resolved with antibiotics)
Symptoms of prostatitis (penile and perineal discomfort, pain on erection and ejaculation)	1 (treated with antibiotics)
Epididymo-orchitis (week after the procedure)	1 (treated by catheterisation and antibiotics)
NSTEMI (in patient with history of heart disease)	1 (developed angina postoperatively, treated medically and had no sequelae)

Blood loss (not needing transfusion) was also reported.

Follow-up issues:

- Follow-up at 2 weeks, 6 weeks, 3, 6, 12 and 24 months.
- Sample size was small at 24 months follow-up as not all patients attended this follow-up visit.
- Data for Q_{max} were not available for all patients at all time intervals because of non-compliance.
- Data from retreated patients were censored from the analysis at retreatment.

Study design issues:

- Prospective study.
- Method of patient

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Conflict of interest/source of funding: Study funded by NeoTract, Inc. Authors are consultants and clinical trial participants for the manufacturer.

statistically significant at 6 weeks (p=0.05), 3 months (p=0.004; data not reported here) and at 12 months (p=0.01).

Mean MSHQ-EjD function and bother scores

Function score	6 weeks (n=26)	3 months (n=28)	6 months (n=28)	12 months (n=22)	24 months (n=10)
Baseline	10.6 (2.1)	10.9 (2.3)	10.6 (2.1)	10.9 (2.4)	10.4 (2.1)
Follow-up	12.3 (2.1)	12.5(2.6)	11.3 (3.5)	11.1 (3.0)	9.3 (2.8)

The change in mean function score from baseline to follow-up was statistically significant (p<0.001) at 6 weeks and 3 months.

Bother score	6 weeks (n=26)	3 months (n=28)	6 months (n=28)	12 months (n=22)	24 months (n=10)
Baseline	1.5 (1.4)	1.4 (1.4)	1.5 (1.5)	1.5 (1.4)	1.6 (1.6)
Follow-up	0.7 (1.2)	0.8 (1.2)	0.6 (1.0)	0.8 (0.9)	1.6 (1.4)

The change in mean bother score from baseline to follow-up was statistically significant at 6 weeks, 3 months, 6 months (p≤0.001), and at 12 months (p=0.002).

Mean Q_{max} (ml/s)

	2 weeks (n=43)	3 months (n=46)	6 months (n=45)	24 months (n=18)
Baseline	8.3 (2.2)	8.1 (2.3)	8.1 (2.3)	7.4 (2.2)
Follow-up	12.0 (7.6)	10.5 (4.1)	10.5 (3.8)	10.3 (4.1)

The change in mean Q_{max} from baseline to follow-up was

Catheterisation

47% (30/64) of patients did not need a catheter. Two catheterised patients had TURP within 30 days. Of the remaining catheterised patients, 75% of catheters were removed the day after the procedure.

There were no encrustation, infection or other abnormalities 6 months after the procedure (assessed using cystoscopy in 22 patients).

There were no adverse events associated with an ejaculation or retrograde ejaculation.

recruitment not reported.

- There was no inclusion criteria related to sexual function or sexual activity. Patients with baseline SHIM scores of <5 (indicating complete erectile dysfunction or a lack of sexual activity) were excluded from analysis.
- The MSHQ-EjD and BPHII instruments were added as protocol amendments after 10 patients had been treated.

Other issues:

- Three different generations of implants

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

	statistically significant at 2 weeks (p=0.001), 6 weeks to 12 months (p<0.001) and at 24 months (p=0.006). 6 weeks and 12 month data not reported above. **Mean PVR (ml)** **3 months (n=61)** / **6 months (n=61)** / **24 months (n=31)** **Baseline**: 90 (86) / 90 (86) / 54 (68) **Follow-up**: 86 (71) / 79 (82) / 89(104) The change in mean PVR was not statistically significant at any time point. **Retreatment** 20% (13/64) of patients had retreatment. • Four patients (who had failed to respond to initial treatment) had TURP or photoselective vaporisation of the prostate within 7 months. • Nine patients who had symptomatic improvement after the initial procedure had TURP (n=4), photoselective vaporisation (n=4) or PUL (n=1) (at mean 13 months because of recurring LUTS).		were used and procedural technique was refined. Later version of device and technique used in patients 25 to 64.IPSS results for these patients were reported separately (not reported here). • 10 patients needing retreatment were in the first 25 patients treated. • Authors noted a learning curve was associated with the procedure.

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

Woo HH (2011)[4]

Case series

Australia (2 centres0

Recruitment period: 2005–07

Study population: men with moderate to severe symptomatic BPH. Duration of LUTS: range 0.5 to 10 years; Prostate volume range 21–97 ml.

n = **19**

Age: mean 66 years

Patient selection criteria: patients with IPSS >13, Q_{max} 5–12 ml/s, prostate volume 20–100 ml, PVR <250 ml and serum PSA level of <10 ng/ml. Patients who had an obstructive median lobe, current infection, history of urinary retention, alpha-adrenergic receptor blocker inhibitor medication within 1 week of treatment or 5-alpha-reductase inhibitor medication within 6 months of treatment, history of significant medical comorbidity or prior surgery that may confound results, or a urological condition that may affect voiding function were excluded.

Technique: under general anaesthesia, the implant (UroLift System, NeoTract) was delivered transurethrally to the target site. Additional implants were delivered as needed.

Mean number of implants per procedure was 3.5.

Number of patients analysed: **19**

Technical success

The procedure was completed in all of the patients.

Mean IPSS scores

	2 weeks (n=15)	3 months (n=15)	12 months (n=13)
Baseline	21.9 (5.5)	21.9 (5.5)	22.1 (5.4)
Follow-up	13.8 (6.9)	9.4 (5.6)	12.5(9.4)

The change in score from baseline to follow-up was statistically significant at 2 weeks and 3 months (p<0.001) and at 12 months (p=0.002). Scores also reported at 6 months was significant (not reported above).

Mean QoL scores

	2 weeks (n=15)	3 months (n=15)	12 months (n=13)
Baseline	4.7 (1.1)	4.7 (1.1)	4.6 (1.2)
Follow-up	2.7 (2.2)	1.9 (1.7)	2.5 (1.7)

The change in score from baseline to follow-up was statistically significant at all time intervals (at 2 weeks: p=0.006; at 3 months: p<0.001and at 12 months: p=0.002).

Mean Q_{max} (ml/s)

	2 weeks (n=10)	3 months (n=11)	12 months (n=9)
Baseline	7.5 (2.4)	7.4 (2.3)	7.4 (2.5)
Follow-up	9.9 (4.3)	10.3 (4.6)	9.9 (4.1)

The change in mean Q_{max} from baseline to follow-up was statistically significant at 3 months (p=0.05).

Mean PVR (ml)

Device related adverse events (within 30 days)

Complication	% (n)	Duration[a] (days)
Haematuria	63 (12)	3
Dysuria	58 (11)	5
Irritative symptoms	47 (9)	28
Transient incontinence (all spontaneously resolved ≤10 days)	16 (3)	5
Bladder spasms	16 (3)	8
Urinary retention	16 (3)	3.5
Erectile dysfunction (all spontaneously resolved)	11 (2)	23 days in 1 patient, 127 days in 1 patient
Spraying	11 (2)	1 day in 1 patient, 3 days in 1 patient
UTI (treated successfully with antibiotics)	5 (1)	25
Prostatitis (treated successfully with antibiotics)	5 (1)	5

There is likely an overlap with patients included in Chin (2012)[1]

Follow-up issues:

- There was a smaller sample size for Q_{max} and PVR analyses as not all patients were compliant with flow study preparation instructions.

Study design issues:

- The primary aims of the study were to evaluate the safety of the procedure and the successful delivery of implants.
- For efficacy outcomes data from

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.

Follow-up: **12 months**

Conflict of interest/source of funding: study funded by NeoTract, Inc.

	2 weeks (n=10)	**3 months (n=11)**	**12 months (n=9)**
Baseline	162 (151)	147 (151)	170 (158)
Follow-up	83 (85)	46 (51)	131 (112)

The change in mean PVR from baseline to follow up was statistically significant at 3 months (p=0.01) and at the 6 month interval (p=0.04) (data not included above).

Insufficient response

TURP was carried out in 3 patients who showed insufficient response (at 11 days, 7 months and 11 months).

Incomplete voiding	5 (1)	42
Weak stream	5 (1)	1
Penile discomfort/pain	5 (1)	7
Suprapubic discomfort/ pain	5 (1)	12
Unspecified pain	5 (1)	3

[a] Median duration listed for AEs with ≥3 patients.

Catheterisation

58% (11/19) of patients had a catheter overnight after the procedure. One patient needed a catheter for 6 days (and successfully passed a voiding trial) and another needed a catheter for 11 days (and later elected to undergo TURP).

There were no reported incidences of retrograde ejaculation.

An open urethral lumen was observed (in 12 patients who underwent follow up cystoscopy) with no encrustation, infection or other abnormalities (timing ranged from 5 to 7 months).

patients who had concomitant procedures were censored and data from patients who had TURP were censored at the time TURP was carried out.

Study population issues:

- 4 patients had concomitant procedures (3 needed urethral and meatal dilatation and 1 needed internal urethrotomy for anterior urethral stricture) to allow treatment with the device

Abbreviations used: AE, adverse event; AUASI, American Urological Association Symptom Index; BPH, benign prostatic hyperplasia; BPHII, Benign Prostatic Hyperplasia Impact Index; IIEF-5, International Index for Erectile Function; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; MSHQ-EjD, Male Sexual Health Questionnaire for Ejaculatory Dysfunction; NSTEMI, non ST-segment elevated myocardial infarction; PUL, prostatic urethral lift; PSA, prostate-specific antigen; QoL, quality of life; PVR, post-void residual; Q_{max}, maximum urinary flow rate; SAE, serious adverse event; SHIM, sexual health inventory for men; TURP, transurethral resection of the prostate; UTI, urinary tract infection.			
			Other issues: • Two versions of the device were used. • Authors reported that 1 surgeon performed the procedures at each of the 2 centres. • Results for serum PSA and creatinine were also reported to be 'stable'. Data not presented here.

Efficacy

American Urological Association Symptom Index (AUASI) score

In a randomised controlled trial (RCT) of 206 patients, 140 treated by prostatic urethral lift (PUL) compared with against 66 patients treated by a sham procedure, there was a significant difference in mean change at 3 months. The mean change in AUASI score was −11.1 in the group treated by PUL and −5.9 for the patients treated by the sham procedure (p=0.003)[1].

International Prostate Symptom Score (IPSS)

A case series of 64 patients reported a significant improvement in IPSS scores between 2 weeks and 24 months after treatment. The mean IPSS score improved from 21.8 at baseline to 12.6 at 2-year follow-up (n=33; p<0.001)[3].

Quality of life

The RCT of 206 patients reported a significant difference in change in AUASI quality-of-life scores (scale 0 to 5; higher score indicating lower quality of life) at 3-month follow-up. The mean quality of life score decreased by 2.2 points (from 4.6 to 2.4) in patients treated by PUL and by 1 point (4.7 to 3.6) in patients treated by the sham procedure[1].

The case series of 64 patients reported an improvement in quality-of-life scores between 2 weeks and 24 months after treatment (with lower scores indicating higher quality of life). The mean quality-of-life score improved from 4.7 at baseline to 2.5 at 2-year follow-up (n=33; p<0.001)[3].

Benign Prostate Hyperplasia Index (BPHI)

The RCT of 206 patients reported a significant difference in mean change in BPHI Index scores at 3-month follow-up. The mean change in BPHI score was −3.9 in patients treated by PUL and −2.1 in patients treated by sham procedure (p<0.001)[1].

Preservation of sexual function

The case series of 64 patients reported Sexual Health Inventory for Men (SHIM) scores (a scale that is used to assess erectile dysfunction, with 1 being the most severe and 25 being healthy). There was a statistically significant improvement in score in 26 patients (for whom results were reported) from 17.9 at baseline to 19.7 at 1-year follow up (p=0.01)[3.]

The case series of 64 patients reported Male Sexual Health Questionnaire-Ejaculatory Dysfunction scores (MSHQ-EjD; a scale for assessing ejaculatory dysfunction; with a function score ranging from 1 to 15, with lower scores indicating more ejaculatory complaints; and a bother score ranging from 0 to 5,

with higher scores indicating greater bother). There was a statistically significant change in the mean function score from 10.9 at baseline to 12.5 at 3-month follow-up (n=28; p<0.001)[3]. There was a significant improvement in the bother score from 1.4 to 0.8 at 3-month follow-up (n=28; p<0.001)[3].

Maximum urinary flow rate

The RCT of 206 patients reported a significant difference in mean improvement in urinary flow rate at 3-month follow-up. The mean change in urinary flow was 4.3 ml/s in patients treated by PUL and 2.0 ml/s in patients treated by the sham procedure (from 8 ml/s at baseline for both groups; p=0.005 difference between the groups)[1].

The case series of 64 patients reported a significant improvement in urinary flow rate at all time points (at 2- and 6-week, 3-, 6-, 12- and 24-month follow-up). The mean urinary flow increased from 7.4 ml/s at baseline to 10.3 ml/s at 2-year follow-up (n=18; p=0.006)[3].

Post-voiding residual volume

A case series of 19 patients reported a significant reduction in the mean post-voiding residual volume, from 147 ml at baseline to 46 ml at 3-month follow up (n=11; p=0.01)[4].

Retreatment

The RCT of 206 patients reported retreatment (at 1 year) in 5% (7/140) of patients treated by PUL. Five patients underwent PUL revision because of insufficient response and 2 patients were treated by TURP or laser vaporisation (reasons for retreatment not reported)[1].

The case series of 64 patients reported that 20% (13/64) of patients had further procedures. Four patients had TURP or photoselective vaporisation of the prostate within 7 months. Nine patients with symptomatic improvement after the initial procedure had either TURP (n=4), photoselective vaporisation (n=4) or prostatic urethral lift (n=1) because of recurrent lower urinary tract symptoms (at a mean of 13 months after procedure)[3].

Safety

Urinary tract infections

Urinary tract infections (within 3 months after the procedure) were reported in 3% (4/140) of patients treated by PUL and 2% (1/66) of patients treated by a sham procedure in the RCT of 206 patients[1] (level of significance not reported).

Urinary tract infections were reported in 7 patients in the case series of 64 patients (all infections were successfully treated with antibiotics)[3].

Orchitis

Orchitis was reported in 3 patients in a case series of 102 patients (treated 'routinely'; timing unclear)[2].

Symptoms of prostatitis

Symptoms of prostatitis (penile and perineal discomfort, pain on erection and ejaculation) were reported in 1 patient in the case series of 64 patients (the condition was treated with antibiotics)[3].

Urinary retention

Urinary retention (within 30 days of the procedure) was reported in 16% (3/19) of patients in the case series of 19 patients (reported as lasting median 3.5 days; no further details given)[4].

Haematuria

Haematuria (within 3 months after the procedure) was reported in 26% (36/140) of patients treated by PUL and 5% (3/66) of patients treated by a sham procedure in the RCT of 206 patients. This was considered to be a mild-to-moderate event and resolved within 2 weeks[1].

Transient incontinence

Transient urge incontinence, which resolved within 8 days, was reported in 8% (5/64) patients in the case series of 64 patients[3].

Incomplete voiding

Incomplete voiding was reported within 30 days of the procedure in 1 patient in the case series of 19 patients (lasting 42 days)[4].

Erectile dysfunction

Erectile dysfunction was reported within 30 days of the procedure in 11% (2/19) of patients in the case series of 19 patients. This spontaneously resolved after 23 days in 1 patient and 127 days in the other patient[3].

Validity and generalisability of the studies

- One study[2] included patients treated in the UK.
- Inclusion criteria for prostate volume (where stated) varied. Prostate volume in included patients ranged from 16 cm^3 to 149 cm^3.
- It is likely that the patients included in Woo (2011)[4] are part of the cohort of patients included in Chin (2012)[3].

- Two studies[3, 4] noted that different generations of devices were used. This was accompanied by changes in technique and operator expertise.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Prostate artery embolisation for benign prostatic hyperplasia. NICE interventional procedure guidance 453 (2013). Available from www.nice.org.uk/guidance/IPG453
- Laparoscopic prostatectomy for benign prostatic obstruction. NICE interventional procedures guidance 275 (2008). Available from www.nice.org.uk/guidance/IPG275
- Holmium laser prostatectomy. NICE interventional procedures guidance 17 (2003). Available from www.nice.org.uk/guidance/IPG17
- Transurethral electrovaporisation of the prostate. NICE interventional procedures guidance 14 (2003). Available from www.nice.org.uk/guidance/IPG14

Clinical guidelines

- Lower urinary tract symptoms: the management of lower urinary tract symptoms in men. NICE clinical guideline 97 (2010) www.nice.org.uk/guidance/CG97

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Professor Tom McNicholas and Mr Mark Speakman (British Association of Urological Surgeons)

- One specialist adviser has performed this procedure regularly and the other specialist adviser has performed this procedure at least once.
- Both specialist advisers described this procedure as the first in a new class of procedures.

- Adverse events reported in the literature: dysuria, haematuria, urgency, retention, urinary tract infection, orchitis, and haemorrhage (not needing transfusion).
- Anecdotal adverse events: bleeding, prostatic swelling, retention (needing catheterisation) and pain.
- Theoretical adverse events: vascular injury and rectal injury.
- Key efficacy outcomes: symptom improvement, improvement in quality of life, reduction or cessation of medical therapy, flow improvement, reduction in post-void residual volume, maintenance of sexual and especially ejaculatory function.
- One specialist adviser stated that the likely speed of diffusion of this procedure depends on the forthcoming data but will have a niche in the range of therapies available for male lower urinary tract symptoms, especially for younger men who wish to preserve ejaculation and fertility and in men with intolerable side effects from drug therapy.
- The specialist advisers noted that if the procedure is safe and efficacious it is likely to be carried out in most or all district general hospitals.
- The potential impact of this procedure, in terms of numbers of patients who are eligible for treatment and use of resources, was considered to be major by 1 specialist adviser and moderate by the other adviser.

Patient commentators' opinions

NICE's Public Involvement Programme received 3 completed questionnaires from patients who underwent the procedure in the UK that were submitted by the manufacturers.

NICE's Public Involvement Programme sent 13 questionnaires to 1 trust for distribution to patients who had the procedure (or their carers). NICE received 7 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Issues for consideration by IPAC

Ongoing trials:

- NCT01533038: BPH-6: Comparison of the UroLift system to TURP for BPH; type: randomised controlled trial; estimated enrolment: 100; location: multinational (4 centres in UK); estimated study completion date: December 2014.

- NCT01876706: LOCAL Study-UroLift system tolerability and recovery when administering local anaesthesia; type: case series; estimated enrolment: 50; location: USA; estimated study completion date: August 2018.

- Published data from the following trial (identified by 1 of the specialist advisers) has been included in table 2: NCT01294150: The safety and effectiveness of UroLift: type: randomised controlled trial; LIFT Pivotal Study (comparing UroLift versus cystoscopy); estimated enrolment: 206; location: multinational; estimated primary completion date: February 2013.

References

1. Roehrborn CG, Gange SN, Shore ND et al. (2013 in press) Multi-center randomized controlled blinded study of the prostatic urethral lift for the treatment of LUTS associated with prostate enlargement due to BPH: the LIFT study The Journal of Urology doi:10.1016/j.juro.2013.05.116

2. McNicholas TA, Woo HH, Chin PT et al. (2013) Minimally invasive prostatic urethral lift: surgical technique and multinational experience. European Urology doi: 10.1016/j.eururo.2013.01.008

3. Chin PT, Bolton DM, Jack G et al. (2012) Prostatic urethral lift: Two-year results after treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Urology 79 (1): 5–11

4. Woo HH, Chin PT, McNicholas TA et al. (2011) Safety and feasibility of the prostatic urethral lift: A novel, minimally invasive treatment for lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). British Journal of Urology International 108 (1): 82–8

Appendix A: Additional papers on insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Woo HH, Bolton DM, Laborde E et al. (2012) Preservation of Sexual Function with the Prostatic Urethral Lift: A Novel Treatment for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. Journal of Sexual Medicine 9 (2) 568–575.	n=64 Follow-up: 12 months	There was no evidence of degradation in sexual function after treatment for lower urinary tract symptoms (LUTS) with the prostatic urethral lift procedure. Erectile function, as measured by the Sexual Health Inventory for Men (SHIM), was slightly increased at all time points compared with baseline. No patient reported retrograde ejaculation at any follow-up visit.	There may be some overlap of patients with studies included in table 2 (Chin 2012)[3] and Woo (2011)[4] .

Appendix B: Related NICE guidance for insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Guidance	Recommendations
Interventional procedures	**Prostate artery embolisation for benign prostatic hyperplasia NICE interventional procedure guidance 453 (2013)** 1.1 Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. 1.2 Prostate artery embolisation for benign prostatic hyperplasia should only be undertaken following consideration of the patients by a multidisciplinary team that includes a urologist and an interventional radiologist. 1.3 Further research in the form of randomised trials or cohort studies (for example, using an appropriate register) should clearly document patient selection criteria and all complications, specifically including disturbance of sexual function. Efficacy outcomes should include measures of urinary function, symptoms and quality of life. Information about longer-term outcomes, including the need for further treatment, would be valuable. 1.4 NICE may review the procedure on publication of further evidence. **Laparoscopic prostatectomy for benign prostatic obstruction. NICE interventional procedure guidance 275 (2008)** 1.1 Current evidence on the safety and efficacy of laparoscopic prostatectomy for

	benign prostatic obstruction (BPO) is inadequate in both quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake laparoscopic prostatectomy for BPO should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, make them aware of alternative treatment options and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 This procedure should only be carried out by surgeons with special training and experience in laparoscopic radical prostatectomy. The British Association of Urological Surgeons (BAUS) has produced training standards. 1.4 Patients should only be offered this procedure if they would otherwise be considered for open prostatectomy, rather than transurethral resection, for BPO. 1.5 Clinicians should submit data on all patients who receive this procedure to the BAUS Cancer Registry & Sections Audit. 1.6 NICE may review the procedure on publication of further evidence. **Holmium laser prostatectomy. NICE interventional procedure guidance 17 (2003)** 1.1 Current evidence on the safety and efficacy of holmium laser prostatectomy appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. 1.2 Clinicians undertaking this procedure require specialist training. The British Association of Urological Surgeons (BAUS) has agreed to produce training

	standards. **Transurethral electrovaporisation of the prostate. NICE interventional procedure guidance 14 (2003)** 1.1 Current evidence on the safety and efficacy of transurethral electrovaporisation of the prostate appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.
Clinical guidelines	**Lower urinary tract symptoms: the management of lower urinary tract symptoms in men. NICE clinical guideline 97 (2010)** In this guidance, 'mild' refers to an International Prostate Symptom Score (IPSS) of 0–7, 'moderate' refers to an IPSS of 8–19 and 'severe' refers to an IPSS of 20–35. **1.5 Surgery for voiding symptoms** 1.5.1 For men with voiding symptoms, offer surgery only if voiding symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are not appropriate. Discuss the alternatives to and outcomes from surgery. 1.5.2 If offering surgery for managing voiding LUTS presumed secondary to BPE, offer monopolar or bipolar transurethral resection of the prostate (TURP), monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). Perform HoLEP at a centre specialising in the technique, or with mentorship arrangements in place. 1.5.3 Offer transurethral incision of the prostate (TUIP) as an alternative to other types of surgery (see 1.5.2) to men with a prostate estimated to be smaller than 30 g. 1.5.4 Only offer open prostatectomy as an alternative to TURP, TUVP or HoLEP (see 1.5.2) to men with prostates estimated to be larger than 80 g. 1.5.5 If offering surgery for managing voiding LUTS presumed secondary to

	BPE, do not offer minimally invasive treatments (including transurethral needle ablation [TUNA], transurethral microwave thermotherapy [TUMT], high-intensity focused ultrasound [HIFU], transurethral ethanol ablation of the prostate [TEAP] and laser coagulation) as an alternative to TURP, TUVP or HoLEP (see 1.5.2). 1.5.6 If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering botulinum toxin injection into the prostate as part of a randomised controlled trial. 1.5.7 If offering surgery for managing voiding LUTS presumed secondary to BPE, only consider offering laser vaporisation techniques, bipolar TUVP or monopolar or bipolar transurethral vaporisation resection of the prostate (TUVRP) as part of a randomised controlled trial that compares these techniques with TURP. **1.6 Surgery for storage symptoms** 1.6.1 If offering surgery for storage symptoms, consider offering only to men whose storage symptoms have not responded to conservative management and drug treatment. Discuss the alternatives of containment or surgery. Inform men being offered surgery that effectiveness, side effects and long-term risk are uncertain. 1.6.2 If considering offering surgery for storage LUTS, refer men to a urologist to discuss: • the surgical and non-surgical options appropriate for their circumstances and • the potential benefits and limitations of each option, particularly long-term results. 1.6.3 Consider offering cystoplasty to manage detrusor overactivity only to men whose symptoms have not responded to conservative management or drug treatment and who are willing and able to self-catheterise. Before offering cystoplasty, discuss serious complications (that is, bowel disturbance, metabolic acidosis, mucus production and/or mucus

	retention in the bladder, urinary tract infection and urinary retention). 1.6.4 Consider offering bladder wall injection with botulinum toxin[a] to men with detrusor overactivity only if their symptoms have not responded to conservative management and drug treatments and the man is willing and able to self-catheterise. 1.6.5 Consider offering implanted sacral nerve stimulation to manage detrusor overactivity only to men whose symptoms have not responded to conservative management and drug treatments. 1.6.6 Do not offer myectomy to men to manage detrusor overactivity. 1.6.7 Consider offering intramural injectables, implanted adjustable compression devices and male slings to manage stress urinary incontinence only as part of a randomised controlled trial. 1.6.8 Consider offering urinary diversion to manage intractable urinary tract symptoms only to men whose symptoms have not responded to conservative management and drug treatments, and if cystoplasty or sacral nerve stimulation are not clinically appropriate or are unacceptable to the patient. 1.6.9 Consider offering implantation of an artificial sphincter to manage stress urinary incontinence only to men whose symptoms have not responded to conservative management and drug treatments. [a] At the time of publication (May 2010), botulinum toxin did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

Appendix C: Literature search for insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	05/09/2013	Issue 9 of 12, September 2013
Database of Abstracts of Reviews of Effects – DARE (CRD website)	05/09/2013	Issue 3 of 4, July 2013
HTA database (CRD website)	05/09/2013	Issue 3 of 4, July 2013
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	05/09/2013	Issue 8 of 12, August 2013
MEDLINE (Ovid)	05/09/2013	1946 to August Week 4 2013
MEDLINE In-Process (Ovid)	05/09/2013	September 04, 2013
EMBASE (Ovid)	05/09/2013	1974 to 2013 Week 35
CINAHL (NLH Search 2.0/EBSCOhost)	05/09/2013	1981 to present
JournalTOCS	05/09/2013	n/a

Trial sources searched on 14 June 2013

- Current Controlled Trials metaRegister of Controlled Trials – mRCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched

- National Institute for Health and Care Excellence (NICE)
- Food and Drug Administration (FDA) – MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- General internet search

MEDLINE search strategy

1	Prostatic Hyperplasia/
2	urethral obstruction/ or urinary bladder neck obstruction/
3	Lower Urinary Tract Symptoms/
4	LUTS.tw.
5	(urin* adj3 tract* adj3 (sympt* or block*)).tw.
6	((urin* or ureth*) adj3 (obstruct* or block*)).tw.
7	(Prostat* adj3 Hyperplas*).tw.
8	(prostat* adj3 hypertroph*).tw.
9	(prostat* adj3 adenoma*).tw.
10	Prostatism/
11	Prostatism.tw.
12	or/1-11
13	urolift.tw.
14	Urologic Surgical Procedures, Male/
15	(urethr* adj3 lift*).tw.
16	(prostat* adj3 lift*).tw.
17	or/13-16
18	12 and 17
19	animals/ not humans/
20	18 not 19