

# UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

Medical technologies guidance

Published: 16 September 2015

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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## 1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

- 1.1 The clinical case for adopting the UroLift system for treating lower urinary tract symptoms of benign prostatic hyperplasia is supported by the evidence. The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). Using the system reduces the length of a person's stay in hospital. It can also be used in a day-surgery unit.
- 1.2 The UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.
- 1.3 The primary cost drivers in the model were the cost of each implant and the number of implants used per treatment (the modelling assumed 4). Compared with monopolar and bipolar transurethral resection of the prostate (done as an inpatient procedure, which is most common), using the UroLift system in a day-surgery unit results in cost savings of around £286 and £159 per patient. There was uncertainty over the procedure duration in the model, but this made little difference to the cost case.

## 2 The technology

### *Description of the technology*

- 2.1 The UroLift system (NeoTract) is used to perform a prostatic urethral lift, a procedure that is an alternative to current standard surgical interventions such as transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP). The UroLift system uses adjustable, permanent implants to pull excess prostatic tissue away so that it does not narrow or block the urethra. In this way, the device is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue.
- 2.2 The UroLift system comprises 2 single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip to which a needle-shaped probe is attached. Each UroLift implant consists of a superelastic nitinol capsular tab, a polyethylene terephthalate monofilament, and a stainless steel urethral end-piece. The surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal); a fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored in the urethra and the other is attached to the firm outer surface of the prostatic capsule, so pulling the prostatic lobe away from the urethra. This is repeated on the other lobe of the prostate. Typically about 4 implants are used. The procedure can be done with the patient under local or general anaesthetic and may be done either on an in-patient or day-case basis.
- 2.3 The UroLift system received a CE mark in November 2009 as a prostatic retraction implant for use in treating urinary outflow obstruction secondary to benign prostatic hyperplasia. The instructions for use specify that it is indicated for use in men aged 50 years and older and is contraindicated in men that have prostates larger than 100 ml. However, the company's training materials recommend that the system should not be used in men whose prostate has an obstructing middle lobe.
- 2.4 The cost of the UroLift system (comprising 1 delivery device and 1 implant) stated in the company's submission was £330 (excluding VAT).

2.5 In the case for adoption presented by the company, the claimed benefits of the UroLift system were as follows:

- Reduction in diminished ejaculatory or sexual function.
- Reduced need for post-operative catheterisation and reduced catheterisation time.
- Quicker return to pre-treatment activities following treatment.
- Reduced risk of hospital-acquired infections and shorter hospital length of stay, because the UroLift procedure can be done as a day surgery.
- Reduction in inpatient resource use, such as theatre operating time and associated staffing costs and resources.
- Fewer follow-up visits after patients are discharged, both in primary care settings and in an outpatient setting.
- Better adverse event profile, leading to savings in the cost of complications associated with other surgical procedures.
- Reduced costs from avoiding conditions that result from neglecting treatment, such as atonic bladder, kidney infection or failure, and detrusor sphincter dyssynergia (by using the UroLift system in men who would not consider more intrusive surgical treatment).

## *Current management*

2.6 NICE guidance on lower urinary tract symptoms defines benign prostatic enlargement as an increase in the size of the prostate gland because of benign prostatic hyperplasia, and states that this is the cause in around half of all patients with lower urinary tract symptoms. Initial treatment options for benign prostatic hyperplasia include conservative management and medication (5 alpha reductase inhibitors and alpha-blockers).

2.7 If conservative management or drug treatment have been unsuccessful or are not appropriate and symptoms are severe, then surgical options are considered. The guideline recommends using monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate or HoLEP. It specifies that HoLEP should only be done at a centre that specialises in the technique, or which has

mentorship arrangements in place. TURP and HoLEP are usually done as inpatient procedures.

- 2.8 Currently, surgical procedures used to relieve lower urinary tract symptoms aim to resect or remove prostatic tissue to open up the blocked urethra. Although this is effective in relieving symptoms, resecting or removing prostate tissue induces a healing response and associated tissue inflammation. Use of a catheter is usual after the operation, which may be uncomfortable. TURP may also be associated with permanent side effects including erectile dysfunction, retrograde ejaculation and urinary incontinence.
- 2.9 TURP is considered to be the standard of care for symptomatic benign prostatic hyperplasia. However, improvements in the outcomes, durability, side effects and safety profiles of other technologies mean that TURP is becoming less widely used. NICE recommends the [TURis system](#), which is a bipolar TURP system as an alternative to monopolar TURP.
- 2.10 NICE interventional procedure guidance on the [insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#) states that current evidence on inserting prostatic urethral lift implants (such as the UroLift system) in this indication is adequate to support their use, provided that normal arrangements are in place for clinical governance, consent and audit. The guidance also recommends that, during the consent procedure, clinicians should advise patients about the range of treatments available and the possible need for further procedures if symptoms recur. The guidance states that the procedure should only be done by clinicians with specific training in inserting prostatic urethral lift implants, and it encourages further research and the publication of results from consecutive case series.

### 3 Clinical evidence

#### *Summary of clinical evidence*

- 3.1 The key clinical outcomes for the UroLift system presented in the decision problem were:
- length of hospital stay
  - need for, or duration of, catheterisation
  - number of follow-on consultations after discharge, both in primary and secondary care
  - re-operation rates and time to re-operation
  - symptoms of benign prostatic hyperplasia (using International Prostate Symptom Score [IPSS])
  - reduction in ejaculatory or sexual function
  - time to return to normal activities
  - quality of life
  - healthcare-associated infection
  - device-related adverse events.
- 3.2 The company's submission of clinical evidence was based on a recently published systematic review, Perera et al. (2014). It did not carry out additional literature searches or evidence synthesis. The company also submitted 2-year follow-up results (Roehrborn et al. 2014) for a study included in the review (Roehrborn et al. 2013).
- 3.3 The External Assessment Centre carried out an independent search of the literature and did not identify any relevant studies other than the 9 used in the systematic review (Cantwell et al. 2013, Chin et al. 2013, Delongchamps et al. 2012, Roehrborn et al. 2013, McVary et al. 2014, McNicholas et al. 2013, Shore et al. 2014, Woo et al. 2011, Woo et al. 2012). It found 1 study, Abad et al. (2013), which had been excluded from the systematic review. However, having reviewed its English abstract, the External Assessment Centre considered the findings (which were published in Spanish) to be potentially relevant and



obtained a translation. It excluded the study by Delongchamps et al. (2012) because it was published in French and included only 4 patients. The External Assessment Centre noted that 2 studies, Chin et al. (2012) and Woo et al. (2012), reported results from the same case series, and that 3 studies, Roehrborn et al. (2013, 2014) and McVary et al. (2014), reported results from the LIFT study.

3.4 Perera et al. (2014) reported a systematic review and meta-analysis of studies which used the UroLift system. The authors conducted a literature search for studies involving the use of the UroLift system and identified 61, of which 23 conference proceedings and 28 editorials were excluded from further analysis. The remaining 10 studies included 2 published papers on a randomised controlled trial (the LIFT study; McVary et al. 2014 and Roehrborn et al. 2013) and 8 uncontrolled before-and-after studies (Abad et al. 2013, Cantwell et al. 2014, Chin et al. 2012, Delongchamps et al. 2012, McNicholas et al. 2013, Shore et al. 2014, Woo et al. 2011 and 2012). These 10 studies were included in the meta-analysis.

3.5 The meta-analysis used data from 88–1298 responses (depending on the score) obtained from 452–680 patients. The results presented the outcome as a compound 'prostate symptom score', which comprised the combined values of IPSS and Benign Prostatic Hyperplasia Impact Index (BPHII). This made it difficult to identify how much IPSS had changed. In the abstract, Perera et al. presented an improvement in IPSS of –8.0 points (95% confidence interval [CI] –8.8 to –7.2) at 12-month follow-up. However the External Assessment Centre noted this value was obtained from the pooled prostate symptom score and represents a smaller IPSS improvement than any individual publication included in the meta-analysis. The External Assessment Centre stated that this method of calculation was unwarranted when actual IPSS values, means and overall changes could have been reported instead. The External Assessment Centre's own calculations of weighted mean IPSS indicated an improvement in IPSS of –11 points. The meta-analysis results also showed quality of life measurements improved by 2.2–2.4 points, and sexual health scores showed a small improvement of 0.3–0.4 points.

3.6 The LIFT study was a randomised controlled trial designed to evaluate the safety and effectiveness of the UroLift system when used in men with symptomatic benign prostatic hyperplasia. It was patient-blinded and the

comparator used was sham cystoscopy. The primary end point was IPSS reduction in the active arm at least 25% more than that in the control arm. The trial was conducted at 19 centres across the USA (14), Canada (2) and Australia (3) in men aged 50 years or older, with prostate volumes of 30–80 ml and an IPSS greater than 12. Patients were randomised 2:1 in favour of the intervention group, resulting in 140 men having the UroLift system and 66 having sham cystoscopy.

- 3.7 Roehrborn et al. (2013) reported the results of the LIFT study and noted that the primary end point was met at 3 months. After 12 months, IPSS, quality of life, peak urinary flow rate ( $Q_{max}$ ) and BPHII score were all improved in patients who had the UroLift system, compared with their baseline measurements. McVary et al. (2014) reported specifically on the preservation of sexual function in patients in the LIFT study, and recorded sexual health outcome scores using the sexual health inventory for men (SHIM) and male sexual health questionnaire for ejaculatory dysfunction (MSHQ-EjD). The results showed that using the UroLift system improved lower urinary tract symptoms and urinary flow without compromising sexual function. There was no evidence of erectile or ejaculatory dysfunction in patients treated using the UroLift system. There was no difference in SHIM or MSHQ-EjD scores at 3 months compared with their baseline values, but these scores improved and were statistically significantly different from baseline after 1 year. An average of 4.9 UroLift implants was used per patient.
- 3.8 At 2-year follow-up, Roehrborn et al. (2014) reported a mean  $42\% \pm 7.6\%$  decrease in IPSS (95% CI  $-48.5\%$  to  $-35.4\%$ ) compared with baseline measurements. Similar improvements were also reported in BPHII score and quality of life. Sexual health outcomes measured by SHIM and MSHQ-EjD scores indicated that improvements in sexual function were preserved throughout the second post-operative year. Within 2 years of first having the UroLift system, 7.5% of patients had a further procedure to treat lower urinary tract symptoms; 5 had further UroLift implants and 5 had transurethral resection of the prostate (TURP) or holmium laser enucleation (HoLEP). All second procedures were done with no complications from the initial UroLift procedure. Cantwell et al. (2013) reported the subsequent use of the UroLift system in men who had been assigned to the control arm of the LIFT study. Of the 66 men who first had the sham procedure, 53 (80%) chose further treatment with the UroLift system after unblinding (mean age=68 years, mean prostate

volume=40.3 cm<sup>3</sup>). Results showed that the UroLift system was statistically significantly more effective than the sham procedure, producing a mean reduction in IPSS at 12 months of 37% (95% CI -46% to -27%). The authors reported that sexual function was maintained, with no notable deterioration after use of the UroLift system: in fact, the UroLift system caused a statistically significant improvement in ejaculatory function at 3 months compared with sham procedure. Adverse events were reported as mild to moderate and no blood transfusions were needed. The authors noted the symptomatic relief, low morbidity and preservation of sexual function associated with the UroLift system.

- 3.9 During consultation, the company submitted a conference abstract (Roerhborn et al. 2015) reporting 3-year follow-up results from the LIFT study. IPSS improvement was 43% after 3 years compared with patients who had sham ( $p < 0.0001$ ). Fewer patients were reported at 3-year follow-up ( $n = 62$ ) than at 2 years ( $n = 104$ ) but the abstract did not describe reasons for drop-outs at any time point. However, the results and adverse events remained consistent with those collected for the 2-year follow-up. Twelve subjects (8.6%) had a secondary procedure over the 3-year period. Sexual function outcomes were not reported in detail in this abstract.
- 3.10 Abad et al. (2013) was an uncontrolled case series of 20 men (mean age=74.3 years, mean prostate volume=42.6 cm<sup>3</sup>) treated in Spain. At 1-month follow-up, IPSS fell by 37.5% and peak  $Q_{max}$  increased from 8.6 ml/s to 13.2 ml/s. The authors noted no cases of urinary incontinence or sexual dysfunction. Minor complications included transient dysuria (70%) and urgency (40%), and slight haematuria (30%). Two patients (10%) needed post-operative catheterisation. The authors stated that longer follow-up times and larger patient numbers were needed before conclusions could be made on the safety and efficacy of the technology. An average of 3.8 UroLift implants was used per patient.
- 3.11 Chin et al. (2012) and Woo et al. (2012) both reported on the same Australian multicentre study of 64 men (mean age=66.9±7.3 years, mean prostate volume=51±23 cm<sup>3</sup>) with moderate to severe lower urinary tract symptoms. The authors reported improvements following use of the UroLift system, using an average of 4 implants per procedure. At 2-year follow-up, IPSS had decreased by 42% in the entire population (95% CI -54% to -31%); at 3 years,

some patients continued to show a 34% symptomatic improvement. Similar improvements were shown in BPHII and quality of life. Results were statistically significant for all of these outcomes at all time intervals. No decrease in sexual function was observed, and the MSHQ-EjD showed significant improvements at some intervals. Adverse events were minor, such as dysuria and haematuria, and typically resolved within 1 week. No blood transfusions were needed. Cystoscopic follow-up at 6 months (n=22) showed no evidence of encrustation or infection. Post-operative catheterisation rate was 53% (for a median of 20 hours). After 2 years, reoperation rate was 20% using TURP, a repeat prostatic urethral lift or photoselective vaporisation of the prostate.

- 3.12 McNicholas et al. (2013) reported an uncontrolled study of 102 men with symptomatic benign prostatic hyperplasia (mean age=68 years, mean prostate size=48 cm<sup>3</sup>, mean IPSS=23.2), which was done in 7 centres across 5 countries. IPSS, quality of life, BPHII, Q<sub>max</sub> and adverse event reports, including sexual function, were used as outcome measures. The authors reported that all procedures were completed successfully with a mean of 4.5 implants per patient. Mean statistically significant improvements at 12 months were noted in IPSS (52%), quality of life (53%) and Q<sub>max</sub> (51%). Adverse events were mild and transient, with no reported loss of antegrade ejaculation. During the follow-up period 6.5% of patients progressed to having TURP without complication. The authors noted the potential advantages of the UroLift system, including its minimally invasive nature, the avoidance of retrograde ejaculation, symptomatic improvement, and the fact that it can be performed under local anaesthesia.
- 3.13 Shore et al. (2014) reported a prospective non-randomised study of 51 patients having the UroLift system, with particular emphasis on their experiences (mean age=66±7.6 years, mean prostate volume=41.3±11.6 cm<sup>3</sup>, mean IPSS=21.5±5.4). Average procedure time was 52±22 minutes, with an average of 3.7 implants per procedure. All procedures were done as day procedures. Post-operative catheterisation was needed in 20% of patients and mean duration was 16 hours. Follow-up was 1 month. Outcomes included IPSS, quality of life, BPHII, Q<sub>max</sub>, post-void residual, SHIM and MSHQ-EjD. In addition, the study looked at quality of recovery, work productivity and activity impairment. IPSS improved by an average of -47.5% at 1-month follow-up (95% CI -56.4% to -38.5%). Average number of days before return to work was 2.8±3.7; 73% of patients did not miss any work days. There were no serious adverse effects

and no reported cases of sexual dysfunction. Ejaculatory function, measured by MSHQ-EjD score, showed statistically significant improvement at 1 month ( $10.3 \pm 2.6$  at baseline to  $11.9 \pm 3.1$ ) after using the UroLift system. There was no statistically significant change in erectile dysfunction after 1 month.

- 3.14 Woo et al. (2011) reported a case series of 19 patients in Australia with benign prostatic hyperplasia (mean prostate volume= $49 \text{ cm}^3$ ) who had the UroLift system. The objective of the study was to assess the safety and efficacy of the technology. All procedures were performed successfully, with a post-operative catheterisation rate of 58%. Some minor side effects were reported (haematuria, dysuria and irritation) but all resolved within a month. No retrograde ejaculation was reported. At 12-month follow-up, 4 patients had had TURP. The authors noted that IPSS improvement was highest at 3 months after the UroLift procedure (57% reduction). They also noted that there was no statistically significant change in  $Q_{\max}$  or post-void residual.
- 3.15 During consultation, the results of the BPH6 trial (Sønksen et al. 2015) became available as an in-process document (Clinicaltrials.gov identifier: NCT01533038). This study most closely matches the scope for this evaluation because it directly compares UroLift with TURP as part of a randomised, multicentre clinical trial. The report described outcomes in patients using the composite BPH6 end point at 12 months; the External Assessment Centre noted that these end points are well justified and supported by published sources. There were no statistically significant differences in baseline parameters except for the MSHQ-EjD function score. The UroLift arm experienced a significant improvement in MSHQ-EjD from baseline ( $p=0.03$ ) whereas the TURP arm experienced a significant deterioration ( $p<0.0001$ ). The UroLift system did not cause any adverse events that needed surgical intervention or revision but further intervention was needed in 2 patients (6%) in the TURP group. patients having the UroLift system also experienced fewer treatment-related infections (7%) than patients having TURP (14%;  $p=0.46$ ).

## External assessment centre synthesis and results

- 3.16 The External Assessment Centre considered that the meta-analysis in Perera et al. (2014) demonstrated the clinical effectiveness of the UroLift system. However, it stated that the reporting of the results from the meta-analysis was

not clear, particularly in the reporting of the methodologies used, patient numbers, and how pooled effect sizes based on multiple outcomes were used.

- 3.17 In order to address this, the External Assessment Centre presented data for each reported outcome measure as changes from baseline and used weighted means to account for cohort sizes. Outcomes were reported at 1, 3, 12 and 24 months follow-up, where available, from the 7 studies identified (LIFT [Roehrborn et al. 2013, 2014; McVary 2014], Cantwell et al. 2013, Abad et al. 2013, combined cohort study [Chin et al. 2012, Woo et al. 2012], McNicholas et al. 2013, Shore et al. 2014 and Woo et al. 2011). The External Assessment Centre also provided context for the results by identifying clinically important effect sizes for each outcome measure. It obtained this information using published and validated differences where available, such as for IPSS; others were based on expert advice.
- 3.18 The External Assessment Centre noted that at the time there was no published evidence directly comparing the UroLift system with the specified comparators. Because of this, it selected a recent systematic review, Li et al. (2014), which reviewed studies comparing TURP with HoLEP from which to derive effect sizes for the comparator interventions. The External Assessment Centre considered the patient populations in these studies to be broadly similar to those found in studies of the UroLift system, with patient ages and IPSS baselines falling within the same range. Prostate volumes were more varied in the studies of TURP and HoLEP, but skewed towards larger prostates and slower flow rates than the studies on the UroLift system.
- 3.19 The External Assessment Centre conducted an evidence synthesis of the outcomes in these studies. It presented changes in baseline outcomes for the comparators similar to the calculations that were done for the UroLift system (table 1). Results showed that both TURP and HoLEP were associated with greater improvements in IPSS than the UroLift system at all time points (-17.34 to -19.7 with TURP and -17.68 to -20.88 with HoLEP, compared with -9.22 to -11.82 with the UroLift system).  $Q_{max}$  and post-void residual improvements were also higher with TURP and HoLEP.
- 3.20 The External Assessment Centre noted that sexual function was poorly reported on in the publications on TURP and HoLEP. This is likely to be because impaired sexual function is a well-recognised complication of these procedures

and so may not be explicitly reported. Clinical advice suggested that 5% of patients having TURP will develop erectile dysfunction, and that 70–80% will experience retrograde ejaculation. One clinical expert stated that the GOLIATH study (Bachmann et al. 2015) reported reliable data on erectile function for TURP. Results of the study (n=119) reported an erectile dysfunction score (based on the international index for erectile dysfunction) of  $13.7 \pm 7.2$  at baseline, rising to  $14.1 \pm 8.2$  at 12 months after having TURP (indicating a higher level of erectile dysfunction). This change was not significant. Another study reporting 6-year follow-up of HoLEP reported a retrograde ejaculation rate of 76% (Gilling et al. 2008).

- 3.21 The External Assessment Centre emphasised that the results of its evidence synthesis did not represent a direct comparison of the UroLift system with either TURP or HoLEP, and that patient populations may vary and outcome measures are dependent on original baseline scores. Nevertheless, it considered that this approach may give an idea of improvements from baseline and complications after TURP and HoLEP, presented in the same format as the UroLift system data.
- 3.22 During consultation, the External Assessment Centre reviewed the additional evidence (see sections 3.9 and 3.15) on the 3-year LIFT study outcomes and on the in-process publication of the BPH6 trial. It concluded that both were supportive of, and consistent with, the findings presented in the UroLift assessment report which formed part of the evidence presented to the Committee.

**Table 1 Weighted means of outcome measures for the UroLift system and comparators**

	Minimally important change	Month	UroLift (based on trials of the UroLift system alone)	TURP (based on trials comparing TURP with HoLEP)	HoLEP (based on trials comparing TURP with HoLEP)

<b>IPSS</b> (Negative is improvement)	Minimum: 3 Moderate: 5.1 Marked: 8.8 <sup>1</sup>	1	-10.35	-17.34	-17.68
		3	-11.82	-19.7	-20.88
		12	-10.49	-18.13	-19.29
		24	-9.22	-17.5	-20.4
<b>IPSS QoL</b> (Negative is improvement)	Minimum: 1-3 <sup>1</sup>	1	-2.27	-2.99	-2.64
		3	-2.48	-2.8	-3
		12	-2.31	-3.18	-3.24
		24	-2.22	N/A	N/A
<b>BPHII</b> (Negative is improvement)	Minimum: 0.5 Moderate: 1.1 Marked: 2.2 <sup>1</sup>	1	-3.29	N/A	N/A
		3	-3.96		
		12	-3.95		
		24	-3.76		
<b>IIEF</b> (Positive is improvement)	Minimum: 4 <sup>2</sup>	1	+0.52	N/A	N/A
		3	+1.34		
		12	+0.8		
		24	N/A		
<b>MSHQ-EjD</b> (Negative is improvement)	Minimum: 1.5 <sup>2</sup>	1	+1.82	N/A	N/A
		3	+1.47		
		12	+0.83		
		24	N/A		
<b>MSHQ-Bother</b> (Negative is improvement)	Minimum: 1 <sup>2</sup>	1	-0.67	N/A	N/A
		3	-0.79		
		12	-0.91		
		24	N/A		



Q <sub>max</sub> (Positive is improvement)	Minimum: 2 ml/s <sup>3</sup>	1	+4.16	+14.58	+15.29
		3	+3.78	+14.11	+18.25
		12	+3.52	+16.69	+17.78
		24	+4.15	+23.20	+23.1
PVR (Negative is improvement)	Minimum: 50 ml <sup>2</sup>	1	-7.0	-137.43	-160.23
		3	-10.34	-89.34	-78.0
		12	-5.72	-127.29	-161.47
		24	N/A	-196.1	-231.4

<sup>1</sup>Barry et al. 1995

<sup>2</sup>Clinical expert opinion

<sup>3</sup>NICE guidance on [lower urinary tract symptoms](#)

Abbreviations: BPHII, benign prostatic hyperplasia impact index; HoLEP, holmium laser enucleation of the prostate; IIEF, international index of erectile dysfunction; IPSS, international prostate symptom scores; MSHQ-Bother, male sexual health questionnaire for bother; MSHQ-EjD, male sexual health questionnaire for ejaculatory dysfunction; PVR, post-void residual; Q<sub>max</sub>, peak urinary flow rate; QoL, quality of life; RCT, randomised controlled trial; TURP, transurethral resection of the prostate.

## Adverse events and complications

- 3.23 The company searched the Medicines and Healthcare Products Regulatory Agency (MHRA) website and the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database to identify reports of adverse events relating to the UroLift system. None were found and the External Assessment Centre confirmed this.
- 3.24 The External Assessment Centre emphasised the difference in reporting complications between studies using the UroLift system and those using the 2 comparators. For example, mild adverse events such as transient dysuria and haematuria are commonly reported with the UroLift system. However, because these events are recognised as common with TURP and HoLEP, they are typically not reported in the literature.

- 3.25 Nevertheless, the External Assessment Centre considered that some comparisons can be made between the procedures in terms of complications and adverse events. The External Assessment Centre reported that incontinence was less prevalent with the UroLift system (5%) compared with TURP (11%) and HoLEP (14%). Reoperation rates were higher with the UroLift system (8%, weighted mean of all studies, 95% CI 3% to 14%) than with TURP (6%) and HoLEP (4%). Follow-up intervals varied, up to a maximum of 2 years.
- 3.26 The External Assessment Centre stated that it was difficult to compare catheterisation rates between the different procedures because policies vary between centres; for example, some hospitals are reported to catheterise after the UroLift procedure as a matter of course. Mean post-procedure catheterisation times were shorter for the UroLift system (22.3 hours) than for TURP (62.7 hours) and HoLEP (44.2 hours), based on Li et al. (2014) and Perera et al. (2014). A clinical expert advised the External Assessment Centre that after both TURP and HoLEP, a urinary catheter is inserted in part to irrigate the bladder, which can increase the patient's recovery time. Another expert stated that the UroLift system removes the need for both catheterisation and the use of irrigation fluid after the operation.
- 3.27 One study (reported by both Chin et al. 2012 and Woo et al. 2012) included data on implant encrustation, which occurs when UroLift implants are placed too close to the bladder and exposed to static urine. The External Assessment Centre sought clinical advice on this issue because of the lack of long-term data. Three experts described encrustation as a significant issue, 2 considered it to be insignificant and a sixth was unsure. All except 1 of the experts advised that removing encrusted implants is a simple procedure.
- 3.28 The External Assessment Centre also sought clarification on any potential difficulties the implants may cause if a patient later has TURP. Clinical experts who have done TURP for patients with UroLift implants advised the External Assessment Centre that implants do not impede any later procedure, including TURP and HoLEP, and that no alteration of the standard surgical techniques is needed.

## Committee considerations

- 3.29 When developing its provisional recommendations, the Committee noted that there was no published evidence comparing the UroLift system with the comparators specified in the scope. It considered that the External Assessment Centre's evidence synthesis was useful in showing that UroLift was slightly less effective in terms of improving IPSS compared with TURP and HoLEP, but nevertheless achieved a marked improvement in symptoms. After consultation, the Committee noted that the results of a recent comparative trial (BPH6) of UroLift against TURP were similar to those in the External Assessment Centre's evidence synthesis, and supported its interpretation of the comparative effectiveness of UroLift and TURP.
- 3.30 The Committee noted the consistent evidence that using the UroLift system does not damage sex function: it considered this to be an important advantage for many men. It noted small improvements in sexual function in some reports. The Committee accepted that damage to sexual function is not commonly reported in studies of TURP and HoLEP, because it is often regarded as an inevitable consequence of the procedures.
- 3.31 The Committee considered that despite some limitations, the clinical evidence was sufficient to demonstrate that the UroLift system provides clinical and patient advantages as an option for treating symptoms of benign prostatic hyperplasia with a lower risk of important complications.
- 3.32 The Committee discussed patient selection for treatment using the UroLift system. It noted that the instructions for use state that the device is indicated for men with benign prostatic hyperplasia who are aged 50 years or older and who have a prostate of less than 100 ml. The clinical experts stated that appropriate prostate shape is also important; in particular, a prostate with a hypertrophic median lobe would preclude the use of the UroLift system.
- 3.33 The Committee was advised that the UroLift system would be appropriate for up to 1 in 4 men needing surgery for lower urinary tract symptoms of benign prostatic hyperplasia. It heard advice from the clinical experts that the UroLift system is most useful for men who wish to preserve sexual function. It also has special advantages for men with blood clotting disorders and for men for whom general anaesthetic would be unsuitable.

- 3.34 The Committee recognised that there was no clinical evidence which included follow-up beyond 3 years. The evidence showed that benefit is maintained up to 3 years, but the Committee heard expert advice that the UroLift system may not offer permanent relief of symptoms. Available information on re-operation rates for the UroLift system suggests that they are similar to those for TURP and HoLEP. The clinical experts also stated that data for re-operation rates could not be directly compared between the UroLift system and its comparators, because the need to re-operate often represents the regrowth of prostate tissue, which is cut away as part of TURP and HoLEP. The UroLift system works in a different way, retracting prostatic tissue rather than removing it.
- 3.35 The Committee noted that no quality of life data were presented, but it considered that the UroLift system was very likely to result in improved quality of life for men in terms of preserving sexual function. The Committee was also advised by the clinical experts that men having UroLift implants typically return to full activity sooner than those having TURP or HoLEP.
- 3.36 The Committee noted that the NICE interventional procedure guidance on [insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#) (a procedure that uses the UroLift system) recommends further research and the publication of results from consecutive case series of patients having the procedure. The Committee concurred with this recommendation, in particular with regard to obtaining more evidence on the effects of UroLift implants on symptoms and quality of life, the duration of benefit, and the need for further procedures in the longer term.

## 4 NHS considerations

### *System impact*

- 4.1 The company claimed that using the UroLift system would reduce hospital length of stay and inpatient resource use, because it can be done as a day procedure. It also claimed that by using the UroLift system, patients would need fewer follow-up visits after being discharged and that there would also be savings associated with a reduced need to treat complications. The company also claimed that using the UroLift system could lead to reduced costs from avoiding conditions that may result from men delaying treatment because they are unwilling to risk sexual dysfunction after transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP).
- 4.2 All the expert advisers stated that training was needed to use the UroLift system. Three of the experts referred to the training provided by the company, which includes a training simulator for the device. Most of the experts stated that simulator training and subsequent mentoring were needed.
- 4.3 The company submission stated that using the UroLift system would allow day surgery and outpatient care rather than inpatient treatment. The External Assessment Centre developed a scenario, based on information from expert advisers who used the technology, which explored the costs and benefits of using the UroLift system in a day-surgery unit (see [section 5.9](#)).

### **Committee considerations**

- 4.4 The Committee was advised that UroLift implants do not preclude the use of other surgical procedures that may be needed subsequently. Clinical experts also stated that UroLift implants are easily removed.
- 4.5 The Committee noted that there was uncertainty about the duration of symptom control after using the UroLift system, but it considered that the current evidence and advice indicated that benefits would be sufficiently prolonged to support adoption of the procedure (see [section 3.34](#)).
- 4.6 The Committee noted that most of the clinical evidence was based on inpatient treatment and this was reflected in the cost model presented by the company.

The External Assessment Centre was advised by clinical experts that the UroLift system could be used in day surgery, and that some NHS hospitals already had implemented this approach. The clinical experts confirmed that there was an increasing trend to use the device as a day-surgery procedure. The Committee concluded that use of the UroLift system was likely to take place in day-surgery units in the NHS.

- 4.7 The Committee recognised the need for training to use the UroLift system and that there is a learning curve associated with its use. It was advised that procedure times and numbers of implants used both decrease with experience, and that increasing experience and confidence with the procedure may enable it to be done under local anaesthetic and without the use of a catheter. Based on all this advice, the Committee concluded that the cost savings associated with the use of the UroLift system may increase as surgeons become more experienced.
- 4.8 The company suggested that, in the future, the UroLift system might be used earlier in the care pathway as an alternative to medication. The Committee noted that this is outside the scope of the current evaluation. It considered that earlier use of the device in the care pathway might form part of a future evaluation with the development of a more mature evidence base for the UroLift system.

## 5 Cost considerations

### *Cost evidence*

- 5.1 The company's searches for economic evidence identified 5 studies that it considered relevant to the decision problem. None of these studies included the UroLift system, but were all economic studies of the comparators. The External Assessment Centre considered that none of these studies were appropriate for inclusion as they did not include the UroLift system. The External Assessment Centre's searches also did not find any relevant economic studies.
- 5.2 The company presented a de novo cost model, in which the intervention was the UroLift system and the comparators were monopolar or bipolar transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP). The population was men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years or older and who have a prostate of less than 100 ml. The model had a decision tree structure with an arm for each technology considered. Post-treatment outcomes were success or failure, with further options for relapse or no relapse after a successful procedure. Both the relapse and failure branches had options for re-treatment (which may succeed or fail) or no re-treatment. The model had an NHS perspective with a 2-year time horizon.
- 5.3 The clinical parameters that the company used were based on data from Chin et al. (2012), Woo et al. (2011) and Roehrborn et al. (2014). The probability of procedural success (defined as a 10% or better improvement in International Prostate System Score [IPSS] at 12 months) varied from 89.08% for the UroLift system to 96.71% for HoLEP. The probability of long-term relapse after a successful procedure ranged from 0% for the UroLift system to 0.99% for bipolar TURP, and the probability of re-treatment within 31 days ranged from 0.21% for HoLEP to 0.75% for UroLift. The model values for UroLift length of stay (0.5 days) and procedure time (30 minutes) were both based on clinical advice.
- 5.4 The company calculated the capital costs for each technology based on an assumed 10-year lifespan and use for 250 patients a year. The UroLift system has a capital cost of £5199, equating to a cost per procedure of £2.50. For HoLEP, with a capital cost of £167,555, the cost per procedure is £80.60. It was

assumed that there were no capital costs associated with monopolar or bipolar TURP. The company assumed that 4 UroLift implants were used per procedure, giving a consumables cost of £1320 per procedure for the system. For bipolar and monopolar TURP the consumable cost was £52.50 for a loop electrode. The consumable cost for HoLEP was £97.18 per procedure based on a reusable fibre and morcellator.

- 5.5 The results of the company's base-case analysis showed that using the UroLift system in an inpatient setting had an incremental cost of £3 per patient compared with monopolar TURP, £40 compared with bipolar TURP and £418 per patient compared with HoLEP. The UroLift system was associated with higher equipment costs but lower costs for clinical supplies and services. It became cost neutral compared with monopolar TURP when the cost per UroLift implant was lowered to £329.

### **Additional work by the External Assessment Centre**

- 5.6 The External Assessment Centre considered the overall model structure to be unwieldy because it included comparators outside the scope, pre- and post-operative tests which were common across the interventions, and perspectives outside the scope (and not referred to in the submission). However, the External Assessment Centre considered the costs included in the model to be thorough, detailed and taken from reliable sources.
- 5.7 The External Assessment Centre agreed with the main assumptions informing the company's model for using the UroLift system in an inpatient setting, but established or revised some parameters as follows:
- It calculated a weighted mean procedural time of 59.6 minutes based on the published literature and used this instead of the 30 minutes in the company submission.
  - It also changed the operating time associated with monopolar TURP from 60 minutes to 66 minutes, based on the published literature.
  - It calculated the weighted mean number of devices per procedure to be 4.4 and revised the value of 4 implants used in the company submission.
  - It increased staffing costs associated with TURP to include an extra band 5 nurse based on clinical advice that the nurse may be needed to deal with irrigation fluid.



- It increased staffing costs associated with HoLEP to include an extra band 5 nurse based on clinical advice that the nurse may be needed as a laser operator.
- It reduced the cost of blood transfusion from £862.17 in the company's model to £329, based on the NHS Blood and Transplant List (2014/15).
- It included a capital equipment cost for TURP of £10 per-procedure cost (bringing the total capital cost to £20,799). There was no capital cost for TURP included in the company's model.
- It assumed a cost of £368.61 for single-use HoLEP fibres (from the NHS supply chain); in the company's model HoLEP fibres were priced at £614.27 for fibres that could be used 20 times.

5.8 When all the External Assessment Centre's parameter revisions were incorporated into the model, the results from the base case showed that the UroLift system, when used in an inpatient setting, costs more than either of the comparators. It costs £227 per patient more than HoLEP, £272 per patient more than monopolar TURP and £400 more than bipolar TURP. The External Assessment Centre identified the cost of the UroLift implants as the key cost driver of the analysis. Analysis showed that the UroLift system becomes cost neutral compared with monopolar TURP if the price per UroLift implant is £268.

5.9 Based on the company's claimed benefits and expert advice, the External Assessment Centre also explored a scenario in which the UroLift system was done in a day-surgery unit. Day surgery was defined as the patient being 'admitted and discharged on the same day, with day surgery as the intended management'. In this scenario, the length of stay in the day unit was 3 hours with a procedure time of 30 minutes, based on clinical expert opinion. It was assumed that the procedure would be done under local anaesthetic and so the cost of a consultant anaesthetist was removed from the model. All of the External Assessment Centre's assumptions for this scenario were supported by published information or by clinical experts who are currently using the UroLift system in the NHS.

5.10 Results from the day-surgery scenario showed that a UroLift procedure costs £2355, HoLEP costs £2315, bipolar TURP costs £2564 and monopolar TURP costs £2691. Therefore, using the UroLift system produced savings of £336 per patient compared with monopolar TURP and £209 per patient compared

with bipolar TURP. It incurred an additional cost of £40 per patient compared with HoLEP.

- 5.11 At its meeting to develop provisional recommendations, the Committee asked the External Assessment Centre to develop an additional day-surgery scenario which included the cost of a consultant anaesthetist (see section 5.14). This added £50 to the cost of the UroLift system, bringing the total to £2405. In this scenario, using the UroLift system produced savings of £286 per patient compared with monopolar TURP and £159 per patient compared with bipolar TURP. It incurred an additional cost of £90 per patient compared with HoLEP.

### Committee considerations

- 5.12 The Committee noted the cost modelling presented by the company and the adjustments made by the External Assessment Centre, and considered these adjustments to be both reasonable and plausible.
- 5.13 The Committee noted that in both the company's and the External Assessment Centre's base-case models of a hospital inpatient setting, the UroLift system was more costly than TURP and HoLEP. The main cost driver was the cost of the UroLift implants.
- 5.14 The Committee was advised by the clinical experts that the External Assessment Centre's base-case analysis was based on evidence from studies done under trial conditions in other countries where procedure times were longer than in UK practice and where catheters were always used. The External Assessment Centre advised that even when the procedure time was reduced to 30 minutes, the UroLift system was not cost-saving in an inpatient setting, with implants at their current price.
- 5.15 The Committee noted that the cost modelling showed the UroLift system to be cost saving only when used in the day-surgery scenario (see section 5.8). The clinical experts advised that a consultant anaesthetist would usually be present when the UroLift system was used in a day-surgery scenario. The Committee asked the External Assessment Centre to update its analysis to include the cost of the consultant anaesthetist (see section 5.10). The clinical experts also stated that the day-surgery scenario is feasible and is current practice in some hospitals.

- 5.16 The Committee noted that the costs of cystoscopy were not included in the cost model. The External Assessment Centre confirmed that the cost of cystoscopy was similar for both the UroLift system and the comparators, and so this cost was not considered in the model.
- 5.17 The Committee considered that preservation of sexual function by using the UroLift system would mean less need for erectile dysfunction consultations and treatments such as sildenafil, compared with current practice, but it noted that these potential cost savings had not been included in the model.
- 5.18 The Committee noted that UroLift incurred an additional cost of £40 per patient in comparison with HoLEP in a day-surgery scenario. However, the Committee was advised by the clinical experts and by the External Assessment Centre that a number of uncertainties remained in the model concerning the lifespan of the HoLEP equipment and the number of uses per year. It was advised that HoLEP is used very little in the NHS. In the light of that information and in view of the clinical advantages of the UroLift system, the Committee considered that this cost difference should not affect the recommendation to adopt UroLift for use in day surgery.
- 5.19 The Committee noted the difference in the cost for TURP in the economic model for this evaluation and that in published NICE medical technology guidance on [the TURis system for transurethral resection of the prostate](#). The External Assessment Centre explained that this was because costs that are common to TURis or TURP (for example theatre overheads and some theatre staff costs) were excluded from the cost model used in the TURis evaluation. The cost model for comparing the UroLift system with TURP includes many of these costs because the interventions do not share so many common cost consequences.

## 6 Conclusions

- 6.1 The Committee concluded that the UroLift system is effective in relieving symptoms of benign prostatic hyperplasia. It noted that the degree of symptom relief outcomes is slightly less than that after transurethral resection of the prostate (TURP) or holmium laser enucleation (HoLEP), but it is sufficient and clinically important. The Committee recognised that the duration of symptom relief after using the UroLift system is uncertain. It concluded that it is similar in the medium term (up to 3 years) to the comparators but that further evidence on durability and the need for subsequent procedures would be useful.
- 6.2 The Committee considered the evidence that the UroLift system does not damage sexual function to be convincing. This contrasts with a substantial risk to erectile and ejaculatory function after TURP or HoLEP and represents a significant advantage for men who wish to preserve their sexual function.
- 6.3 The Committee noted that evidence for avoiding catheterisation after the UroLift system was sparse, but accepted expert advice that catheterisation time would be reduced and in many cases catheterisation would be avoided, especially as surgeons gain experience with the procedure. It also concluded that it was reasonable and likely that the UroLift system would be used as a day-surgery procedure, often under local anaesthetic.
- 6.4 Based on the day-surgery scenario in the cost model, and assuming a maximum of 4 implants are used, the Committee concluded that using the UroLift system is likely to be cost saving compared with TURP. However, the Committee also concluded that at the current costs of implants, using the system in an inpatient setting was likely to be more costly than either TURP or HoLEP.

Andrew Dillon  
Chief Executive  
September 2015

## 7 Committee members and NICE lead team

### *Medical Technologies Advisory Committee members*

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

#### **Professor Bruce Campbell (Chair)**

Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

#### **Dr Peter Groves (Vice Chair)**

Consultant Cardiologist, Cardiff and Vale University Health Board

#### **Ms Susan Bennett**

Lay member

#### **Professor Nigel Brunskill**

Professor of Renal Medicine, University of Leicester

#### **Mr Matthew Campbell-Hill**

Lay member

#### **Professor Daniel Clark**

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

#### **Dr Fiona Denison**

Reader/Honorary Consultant in Maternal and Fetal Health, University of Edinburgh

#### **Professor Tony Freemont**

Professor of Osteoarticular Pathology, University of Manchester

**Professor Shaheen Hamdy**

Professor of Neurogastroenterology, University of Manchester

**Dr Jerry Hutchinson**

Independent Medical Technology Adviser

**Dr Cynthia Iglesias**

Health Economist, University of York

**Professor Mohammad Ilyas**

Professor of Pathology, University of Nottingham

**Dr Greg Irving**

GP and Clinical Lecturer, University of Cambridge

**Professor Eva Kaltenthaler**

Professor of Health Technology Assessment, School of Health and Related Research (SchARR), University of Sheffield

**Dr Paul Knox**

Reader in Vision Science, University of Liverpool

**Dr Rory O'Connor**

Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

**Mrs Karen Partington**

Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

**Mr Brian Selman**

Managing Director, Selman and Company Limited

**Professor Wendy Tindale**

Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

**Professor Allan Wailoo**

Professor of Health Economics, School of Health and Related Research (SchARR), University of Sheffield

**Mr John Wilkinson**

Director of Devices, Medicines and Healthcare Products Regulatory Agency

**Professor Janelle Yorke**

Lecturer and Researcher in Nursing, University of Manchester

**Dr Amber Young**

Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

***NICE lead team***

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

**Ailish Higgins, Kimberley Carter**

Technical Analysts

**Bernice Dillon**

Technical Adviser

**Professor Raj Persad**

Lead Expert Adviser

**Mr Neil Barber**

Expert Adviser

**Mr Andrew Thorpe**

Expert Adviser

**Dr Paul Knox**

Non-Expert MTAC Member

**Dr Alistair Ray and Dr Grace Carolan-Rees**

External Assessment Centre Representatives

## 8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Cedar:

- Alistair Ray, Helen Morgan and Grace Carolan-Rees, External Assessment Centre report: The UroLift system for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia, February, 2015

Submissions from the following sponsor:

- NeoTract

The following individuals gave their expert personal view on the UroLift system by providing their expert comments on the draft scope and assessment report.

- Mr Neil Barber, ratified by the British Association of Urological Surgeons – clinical expert
- Professor Mark Emberton, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Hashim Hashim, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Francis Keeley, ratified by the British Association of Urological Surgeons – clinical expert
- Professor Tom McNicholas, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Gordon Muir, ratified by the British Association of Urological Surgeons – clinical expert
- Professor Raj Persad, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Mark Speakman, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Andrew Thorpe, ratified by the British Association of Urological Surgeons – clinical expert

The following individuals gave their expert personal view on the UroLift system in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Professor Mark Emberton, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Mark Feneley, ratified by the British Association of Urological Surgeons – clinical expert



- Debbie Gordon, nominated by the Bladder and Bowel Foundation – patient expert
- Mr Hashim Hashim, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Francis Keeley, ratified by the British Association of Urological Surgeons – clinical expert
- Professor Tom McNicholas, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Gordon Muir, ratified by the British Association of Urological Surgeons – clinical expert
- Mr Mark Speakman, ratified by the British Association of Urological Surgeons – clinical expert
- Hannah Winter, nominated by Prostate Cancer UK – patient expert

## About this guidance

This guidance was developed using the NICE [medical technologies guidance process](#).

We have produced a [summary of this guidance for the public](#). [Tools](#) to help you put the guidance into practice and information about the evidence it is based on are also available.

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ISBN: 978-1-4731-1449-4

## Accreditation

