

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

UroLift for treating the symptoms of benign prostatic hyperplasia

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company's submission of evidence and with the EAC report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 7, following the summaries of the clinical and cost evidence.

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations

Please note changes were made to figures in table 6 and to references to them in the text in accordance with corrections made in the updated assessment report (Version 2 19/3/2015).

1 The technology

The UroLift is used to perform a prostatic urethral lift, a novel procedure that relieves lower urinary tract symptoms by moving enlarged prostate tissue so it does not block the urethra. This provides an alternative to current standard surgical interventions, such as transurethral resection and holmium laser enucleation of the prostate. The UroLift uses adjustable implants to move excess prostatic tissue, and so is intended for symptomatic relief of urinary outflow obstruction without cutting or ablation of tissue.

The UroLift comprises a handheld pistol-grip and 2 single-use components: the delivery device and the implant. The delivery device is a needle-shaped probe designed to allow access to the prostatic urethra (the widest part of the urethral canal). The probe is attached to the grip, which is operated by the clinician and used to deploy and secure a single implant. The UroLift implant consists of a superelastic nitinol capsular tab, a polyethylene terephthalate monofilament, and a stainless steel urethral end-piece. One end of the implant is anchored in the urethra and the other is attached to the outer surface of the prostatic capsule, thus pulling the prostatic lobe away from the urethra. Typically about 4 implants are used during the same procedure. The procedure can be performed with the patient under local or general anaesthetic.

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 the UroLift is for use in men aged 50 and older.

2 Proposed use of the technology

2.1 *Disease or condition*

The UroLift system is intended to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH), when conservative management options have not been successful or are not appropriate and surgery is indicated.

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The prevalence of BPH increases with age; around 60% of men aged 60 or older and over 80% of men aged 70 or older experience some symptoms due to BPH. BPH is the most common cause of lower urinary tract symptoms, which include poor urinary stream, frequent urination and nocturia (the need to wake and urinate at night). If untreated, BPH can result in urinary tract infection, acute or chronic urinary retention and kidney failure. Lower urinary tract symptoms secondary to BPH do not usually cause severe illness, but they may affect normal daily activities and sexual function, and may indicate more serious urogenital problems.

2.2 Patient group

Moderate to severe lower urinary tract symptoms are present in about 40% of men aged 50 or older, rising to 90% of men aged 80 or older. They are estimated to affect up to 3.4 million men in the UK. Each year, around 15,000 men in England and Wales have transurethral resection of the prostate (TURP) to relieve symptoms.

The UroLift is indicated for use in men with lower tract urinary symptoms secondary to BPH, who are both aged 50 or older and whose prostate is no larger than 100 cm³.

2.3 Current management

NICE guidance on [lower urinary tract symptoms](#) recommends that surgery is offered only if voiding symptoms are severe or if drug treatment and conservative management options have been unsuccessful or are inappropriate. The guideline defines benign prostatic enlargement as an increase in the size of the prostate gland because of BPH, and states that this affects around half of all patients with BPH. Initial treatment options for BPH include watchful waiting and medication (5 alpha-reductase inhibitors and alpha-blockers).

For surgical management of voiding symptoms presumed secondary to BPH, the guideline recommends using monopolar or bipolar TURP, monopolar transurethral vaporisation of the prostate (TUVP) or holmium laser enucleation of the prostate (HoLEP). It specifies that HoLEP should only be done at a centre that specialises in the technique or which has mentorship arrangements in place.

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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). The post-operative period is often uncomfortable and associated with catheterisation irritable voiding symptoms. TURP is also associated with permanent side effects such as urinary incontinence, erectile dysfunction and retrograde ejaculation.

TURP is considered to be the gold standard of care for symptomatic BPH. However, improvements in the outcomes, durability, side effects and safety profiles of other technologies have meant that it is becoming less widely used in favour of techniques such as HoLEP.

NICE interventional procedure guidance on the [insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to BPH](#) states that current evidence on inserting prostatic urethral lift implants (such as the UroLift) 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 possible range of treatments and need for potential 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 encourages further research and the publication of results from consecutive case series.

NICE is currently producing guidance on the transurethral resection in saline (TURis) system, a bipolar electrosurgery system designed for use when surgical intervention is indicated for prostatic enlargement. This is due to be published in March 2015.

2.4 Proposed management with new technology

Based on the company's proposed case for adoption, the Medical Technologies Evaluation Programme is considering the UroLift as an alternative option to TURP and HoLEP. It would be used at the same point in the care pathway as these technologies, most likely after pharmaceutical treatment has failed or is no longer

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appropriate. Using the UroLift system does not preclude the subsequent use of other surgical procedures, such as TURP. A prostatic urethral lift can be done as a day surgery, and it is proposed that using the UroLift system would lead to fewer inpatient stays than TURP or HoLEP (which both require at least 1 overnight stay). In this way, the UroLift may allow for patient care to be better structured around day surgeries and subsequent outpatient care. There would be a potential reduction in complications associated with inpatient BPH procedures, such as nosocomial infection, urinary tract infections related to post-operative catheter use, and general population risk for anaesthesia administration.

There may also be a reduced need for community care nursing and physician follow-up after patients are discharged, because of potential improved recovery times and less post-operative morbidity.

2.5 Equality issues

No equality issues were identified in the company's submission. The EAC noted that the UroLift may be of benefit to people for whom blood transfusions may not be acceptable, for example Jehovah's Witnesses.

3 Company's claimed benefits

The benefits to patients claimed by the company compared with standard care are:

- Reduction in diminished ejaculatory or sexual function.
- Reduced need for post-operative catheterisation and reduced catheterisation time.
- A quicker return to pre-treatment activities following treatment.
- Reduced risk of hospital-acquired infections (because using the UroLift is a day procedure which does not require inpatient hospitalisation).

The benefits to the health system claimed by the company compared with standard care are:

- Reduction in hospital length of stay, because using the UroLift is a day procedure.
- Reduction in inpatient resource use, such as theatre operating time and associated staffing costs and resources.

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- Fewer follow-up visits after patients are discharged, both in primary care outpatient settings, thus saving physician resources.
- 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, or detrusor sphincter dyssynergia (through using the UroLift in men who would not consider more intrusive surgical treatment).

4 Decision problem

Table 1 Summary of the decision problem

Population	Men with LUTS secondary to BPH aged 50 or over, and with prostate volumes no greater than 100 cm ³ .
Intervention	The UroLift system
Comparators	Current practice varies and is changing. As a result, there are 2 comparators: <ul style="list-style-type: none"> • Monopolar or bipolar TURP • HoLEP
Outcomes	The outcome measures to consider include: <ul style="list-style-type: none"> • length of hospital stay • need for, or duration of, catheterisation • number of post discharge follow-on consultations, both in primary and secondary care • time to re-operation and re-operation rates • symptoms of BPH (using International Prostate Symptom Score) • reduction in ejaculatory or sexual function • time to return to normal activities • quality of life • healthcare-associated infection • device-related adverse events.
Cost analysis	Two comparators will be considered: monopolar or bipolar TURP and HoLEP Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be done to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.

Subgroups to be considered	Men for whom TURP or HoLEP is unsuitable because of difficulties with blood loss or sedation.
Special considerations, including issues related to equality	None

5 The evidence

5.1 Summary of evidence of clinical benefit

The company's submission of clinical evidence was based on a recently published systematic review by a separate group, Perera et al. (2014), rather than its own literature search and review. The company also submitted 2-year follow-up results (Roehrborn et al. 2014) for a study included in the review (Roehrborn et al. 2013).

The EAC carried out an independent search of the literature and did not identify any additional studies (page 40 of the assessment report). However, having reviewed the English abstract, the EAC considered the findings of the Abad et al. (2013) study (which was published in Spanish) to be potentially relevant; for completeness, the EAC obtained a translation. The EAC noted that Chin et al. (2012) and Woo et al. (2012) reported results from the same case series, and that Roehrborn et al. (2013, 2014) and McVary et al. (2014) all reported results from the LIFT study.

Systematic review

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 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 blinded, sham-controlled 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 then included in the meta-analysis.

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The EAC assessed the quality of the systematic review by Perera et al. (2014). Although some aspects of the review were reasonable, there was insufficient methodological detail to fully explain the meta-analysis. Furthermore, some of the included studies had a high risk of bias; indeed, 8 of the 9 conducted studies (the meta-analysis included 2 papers on the same randomised controlled trial) were uncontrolled before-and-after studies. It was also evident that some patients were common to more than 1 study; patients from the Chin et al. (2012) and Woo et al. (2012) studies were counted twice, despite comprising the same patient cohort.

Perera et al.'s systematic review suggested a change in IPSS score of -7.2 to -8.7 (back-calculated from the effect size in the meta-analysis). This is a worse IPSS improvement than any individual publication included in the meta-analysis and the EAC's own calculations of weighted mean IPSS score (-11 points).

The potential for double-counting patients in these studies shows a lack of methodological clarity. This combined with the somewhat short-form nature of a journal publication suggests a lack of transparency in the authors' methodology.

LIFT

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 (BPH). 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% greater 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 $30-80 \text{ cm}^3$ 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.

Roehrborn et al. (2013) reported that the primary end point was met at 3 months. After 12 months, IPSS, quality of life, Q_{\max} and Benign Prostatic Hyperplasia Impact Index (BPHII) score were all improved in patients that had the UroLift compared with baseline measurements (IPSS 95% confidence interval [CI] -42% to -55% ; Q_{\max} Assessment report overview: UroLift for treating the symptoms of benign prostatic hyperplasia

95% CI 41% to 77%; quality of life 95% CI -45% to -58%; BPHII 95% CI -49% to -68%).

McVary et al. (2014) reported specifically on the preservation of sexual function in all patients in the LIFT study, and recorded sexual health outcome scores using the sexual health inventory for men (SHIM) and MSHQ-EjD. The results showed that the UroLift improved lower urinary tract symptoms and urinary flow without compromising sexual function. There was no evidence of erectile or ejaculatory dysfunction in patients having the UroLift. There was no difference between SHIM and MSHQ-EjD scores at 3 months, but these were improved and statistically significantly different from baseline after 1 year.

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 changes were also reported in BPHII score and quality of life. Within 2 years of first having the UroLift, 7.5% of patients had an additional procedure to address lower urinary tract symptoms (extra UroLift implants, n=5; TURP or laser vaporisation, n=5). All were done routinely, with no complications from the initial procedure. The sexual health outcomes discussed by Roehrborn et al. indicate that sexual function was preserved throughout the second post-operative year.

Cantwell et al. (2013) reported on the use of the UroLift system in men who had been assigned to the control arm of the LIFT study. Of the 66 men who had first had the sham procedure, 53 (80%) chose further treatment with UroLift after unblinding (mean age=68, mean prostate volume=40.3 cm³). Results showed that the UroLift system was statistically significantly more effective than the sham procedure; the UroLift produced a mean 37% reduction in IPSS at 12 months (95% CI -46% to -27%). At 12 months, 48 patients (with 215 implants) had cystoscopy; the authors reported that sexual function was maintained, with no notable degradation after use of the UroLift. Indeed, the UroLift caused a statistically significant improvement in ejaculatory function at 3 months (where the sham procedure decreased ejaculatory function). 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.

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Observational studies

Abad et al. (2013) is a Spanish study which reported on 20 patients (mean age=74.3, mean prostate volume=42.6 cm³). It was an uncontrolled case series, assessing key outcomes in patients with benign prostatic hyperplasia before and after using the UroLift system. At 1-month follow-up, IPSS fell by 10 points (26.7 to 16.7) 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 dysuria (70%) and an urgent need to urinate (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.

Chin et al. (2012) and Woo et al. (2012) both reported on the same Australian multicentre study of 64 men with moderate to severe lower urinary tract symptoms (mean age=66.9±7.3, mean prostate volume=51±23 cm³). A mean of 4 implants were used per procedure. The authors reported improvements following use of the UroLift system. At 2-year follow-up, IPSS 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 at all intervals for all of these outcomes. 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 haemuria, and typically resolved within 1 week. No blood transfusions were needed, and cystoscopic follow-up at 6 months (n=22) showed no evidence of encrustation or infection. Post-operative catheterisation rates were 53% (for a median of 20 hours). After 2 years, reoperation rates using TURP, a repeat prostatic urethral lift or photoselective vaporisation of the prostate were 20%.

McNicholas et al. (2013) reported on an uncontrolled study of 102 men with symptomatic benign prostatic hyperplasia (mean age=68, mean prostate size=48 cm³, mean IPSS=23.2), which was done in 7 centres across 5 countries. Important outcome measures were IPSS, quality of life, BPHII, Q_{max} and adverse event reports, including sexual function. The authors reported that all procedures were completed

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successfully (mean number of implants was 4.5). Mean improvements at 12 months were noted in IPSS (52%), quality of life (53%) and Q_{max} (51%; $p < 0.001$). Adverse events were mild and transient, with no reported loss of antegrade ejaculation, and 6.5% of patients progressed to TURP without complication. The authors noted the potential 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.

Shore et al. (2014) reported on a prospective non-randomised study of 51 patients having the UroLift, with particular emphasis on their experiences (mean age = 66 ± 7.6 , mean prostate volume = $41.3 \pm 11.6 \text{ cm}^3$, mean IPSS = 21.5 ± 5.4). Average procedural 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 (mean duration was 16 hours). Follow-up was 1 month. Outcomes assessed included IPSS, quality of life, BPHII, Q_{max} , 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%). Improvements in quality of life and BPHII were comparable. 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 actually improved slightly following use of the UroLift system.

Woo et al. (2011) reported on a case series of 19 patients in Australia whose benign prostatic hyperplasia was treated with the UroLift system (mean prostate volume = 49 cm^3). 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 reduction peaked at 3 months after the first procedure (57% reduction). They also noted that there was no statistically significant change in Q_{max} , PVR or prostate-specific antigen.

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Table 2 Studies included as clinical evidence by the EAC

Study	Study design (country)	Population	Intervention and comparator	Primary end points
LIFT study				
Roehrborn et al. 2013	Randomised control trial (LIFT; included in meta- analysis)	≥50 years of age, no prior BPH surgical treatment, washout of 2 weeks for α- blockers, 3 months for 5-α-reductase inhibitors, 3 days for anticoagulants, IPSS>13, Q _{max} ≤12 ml/s, 125 ml voided volume, 30–80 cm ³ prostate volume. Mean age=67±8.6 years (intervention), 65±8 years (control)	UroLift group, n=140. Control group, n=66 (randomisation 2:1)	Reduction in IPSS 3 months after PUL (at least 25% better than sham cystoscopy)
McVary et al. 2014				Changes in IPSS and sexual health measures (IIEF and MSHQ)
Cantwell et al. 2013	Multicentre before-and- after study to assess the UroLift system in patients	≥50 years old with no prior surgical BPH treatment, washed out or naive to α-blockers or 5 α-reductase inhibitors.	The UroLift system, following a	Symptom scores Quality of life Sexual health questionnaire

Study	Study design (country)	Population	Intervention and comparator	Primary end points
	who had previously been assigned to the sham arm of the LIFT study (Australia, Canada, USA; included in meta-analysis)	Prostate volume of 30–80 ml without an obstructing median lobe. Mean age±SD: 64±8 years	previous sham cystoscopy (n=53)	scores <i>Follow-up:</i> IPSS, IPSS QoL, BPHII, IIEF-5 and MSHQ at 2 weeks, and 1, 3, 6 and 12 months. Q _{max} and PVR assessed at 3 and 12 months. Safety assessed at each visit.
Observational studies				
Chin et al. 2012	Multicentre uncontrolled before-and-after study (Australia; included in meta-analysis)	≥55 years of age with symptomatic BPH, IPSS>13, PVR<250ml, peak Qmax of 5–12 ml/s. Washout of α-blockers for 1 week and 5 α-reductase inhibitors within 6 months of treatment. Mean age=66.9±7.3 years	The UroLift system (n=64)	Longer-term effectiveness of PUL in relieving LUTS <i>Follow-up:</i> 2 weeks, and 2, 6, 12 and 24 months.
Woo et al. 2012				Effect of PUL on erectile and ejaculatory function <i>Follow-up:</i> 2 weeks, 3, 6 and 12 months
McNicholas	Retrospective analysis of	Prostate volume <60 ml, IPSS>12,	The UroLift	To evaluate safety and efficacy

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Study	Study design (country)	Population	Intervention and comparator	Primary end points
et al. 2013	prospective data from consecutive multicentre uncontrolled before-and-after study (5 countries, not clearly stated; included in meta-analysis)	$Q_{max} < 15$ ml/s, PVR < 350 – described as ‘typical inclusions’. Mean age: 68 ± 10 years	system (n=102)	<i>Follow-up:</i> 2 and 6 weeks, 3, 6 and 12 months
Shore et al. 2014	Uncontrolled before-and-after study (locations not reported; included in meta-analysis)	≥ 50 years no prior surgical BPH treatment, washed out or naive to α -blockers and 5- α -reductase inhibitors. IPSS ≥ 13 . $Q_{max} < 12$ ml/s, prostate volume 30 to 80 cm ³ , no obstructing median lobe. Mean age: 66 ± 7.6 years	The UroLift system (n=51)	80% of patients achieve a score of ≥ 80 on QoR VAS <i>Follow-up:</i> 2 weeks, and 1 month
Woo et al. 2011	Prospective non-randomised uncontrolled before-and-after study, assessing safety and feasibility (Australia; included in meta-analysis)	IPSS ≥ 13 , Q_{max} 5–12 ml/s, prostate volume 20–100 cm ³ , PVR < 250 ml, PSA < 10 ng/ml, no median lobe obstruction. Mean age = 66 ± 6 years	The UroLift system (n=19)	Number and severity of serious adverse events up to 12 months follow-up Feasibility of delivering sutures to increase urethral lumen <i>Follow-up:</i> IPSS and QoL at 2

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Study	Study design (country)	Population	Intervention and comparator	Primary end points
				weeks, 3, 6 and 12 months
Abad et al. 2013	Retrospective uncontrolled before-and-after study (Spain; excluded from meta-analysis)	Age ≥50 IPSS >20 Q _{max} ,15 ml/s PSA <10ng/ml	The UroLift system (n=20)	Effectiveness of the UroLift system Number and intensity of side effects post-procedure.
Abbreviations: BPH, benign prostatic hyperplasia; BPHII, benign prostatic hyperplasia impact index; IIEF, international index of erectile dysfunction; IPSS, international prostate symptom scores; LUTS, lower urinary tract symptoms; MSHQ-EjD, male sexual health questionnaire for ejaculatory dysfunction; PUL, prostatic urethral lift; PVR, post-void residual; Q _{max} , peak urinary flow rate; QoL, quality of life; QoR, quality of recovery; VAS, visual analogue scale.				

EAC synthesis of clinical outcomes

The meta-analysis reported pooled estimates of outcome measures at 1, 3, 6 and 12 months after the UroLift procedure (see pages 37–40 of the assessment report). Results were shown as standardised mean gains which allow direct comparisons across studies if the same index of effect is used. The prostate symptom scores (IPSS and BPHII) were pooled and reported together, as were the sexual health scores. Results for the prostate symptom score indicated a large improvement in symptoms. The authors converted their reported standardised mean gains into IPSS improvements from baseline as follows:

- -7.2 (95% CI -7.9 to -6.5) at 1 month
- -8.3 (95% CI -9.1 to -7.5) at 3 months
- -8.7 (95% CI -9.4 to -7.9) at 6 months
- -8.0 (95% CI -8.8 to -7.2) at 12 months.

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. Q_{\max} showed a small improvement of 3.8–4.0 ml/s. The authors state that post-void residual results vary due to inconsistent reporting, with high heterogeneity estimates.

The EAC considered that the meta-analysis in Perera et al. (2014) demonstrated the clinical effectiveness of the UroLift system. However, it stated that the meta-analysis lacked transparency, which was particularly evident in the reporting of the methodologies used, the lack of clarity about patient numbers, and in its using pooled effect sizes based on multiple outcomes, instead of simply reporting the outcomes measures as stated.

So, EAC presented data for each reported outcome measure as changes from baseline and used weighted means to account for cohort sizes (see pages 54–53 of the assessment report). Outcomes were reported at 1, 3, 12 and 24 months follow-up, where available, from the 7 studies presented in table 3 (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 EAC also provided context for the results by identifying clinically important changes for each outcome measure. Some were available as published and validated differences, such as IPSS. Others were obtained by consulting a range of clinical experts.

Because no studies of the UroLift system included an active comparator (that is, TURP or HoLEP), the EAC also presented changes from baseline with TURP and HoLEP, as reported from randomised controlled trials selected for a systematic review (Li et al. 2014). The EAC emphasised that these results do not provide 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.

Table 3 Weighted means of outcome measures for the UroLift system, TURP and HoLEP

	Minimally important change	Month	UroLift (based on trials of the UroLift alone)	TURP (based on trials comparing TURP with HoLEP)	HoLEP (based on trials comparing TURP with HoLEP)
IPSS (Negative is improvement)	Minimum: 3	1	-10.35	-17.34	-17.68
		3	-11.82	-19.7	-20.88
	Moderate: 5.1 Marked: 8.8 ¹	12	-10.49	-18.13	-19.29
		24	-9.22	-17.5	-20.4
IPSS QoL (Negative is improvement)	Minimum: 1-3 ¹	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
BPHII	Minimum:	1	-3.29	N/A	N/A

(Negative is improvement)	0.5	3	-3.96		
	Moderate:	12	-3.95		
	1.1	24	-3.76		
	Marked: 2.2 ¹				
IIEF (Positive is improvement)	Minimum: 4 ²	1	+0.52	N/A	N/A
		3	+1.34		
		12	+0.8		
		24	N/A		
MSHQ-EjD (Negative is improvement)	Minimum: 1.5 ²	1	+1.82	N/A	N/A
		3	+1.47		
		12	+0.83		
		24	N/A		
MSHQ-Bother (Negative is improvement)	Minimum: 1 ²	1	-0.67	N/A	N/A
		3	-0.79		
		12	-0.91		
		24	N/A		
Q_{max} (ml/s) (Positive is improvement)	Minimum: 2ml/s ³	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 (ml) (Negative is improvement)	Minimum: 50 ml ²	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

¹ Barry et al. 1995

² Clinical expert opinion

³ 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_{max}, peak urinary flow rate; QoL, quality of life; RCT, randomised controlled trial; TURP, transurethral resection of the

prostate.

The EAC considered the patient populations in the UroLift studies and the trials comparing TURP and HoLEP to be broadly similar, with patient ages and IPSS baselines falling within the same range. Prostate volumes were more varied in the TURP and HoLEP studies, but skewed towards larger prostates. Q_{\max} baselines were skewed slightly towards slower flow rates (see page 55 of the assessment report).

The EAC noted that at all time points, both TURP and HoLEP were associated with greater improvements in IPSS than the UroLift system (-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). Q_{\max} and post-void residual improvements were also higher with TURP and HoLEP.

The EAC noted that sexual function is poorly reported in the TURP and HoLEP papers. The primary aim of these procedures is symptomatic improvement, not the preservation of sexual function. Issues with sexual function are perceived as secondary and so tend to be reported as complications. This made it difficult for the EAC to calculate the interventions' effects on issues such as erectile and ejaculatory function. Clinical advice suggests that 5% of patients having TURP will develop erectile dysfunction, and 70–80% will experience retrograde ejaculation. One clinical adviser pointed out that the GOLIATH study (Bachmann et al. 2015) reported reliable data on erectile function for TURP. The GOLIATH study ($n=119$) reported an erectile dysfunction score (based on the international index for erectile dysfunction) of 13.7 ± 7.2 at baseline, rising to 14.1 ± 8.2 at 12 months after having TURP. 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).

Adverse events and complications

The company searched the Medicines and Healthcare Products Regulatory Agency (MHRA) and US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) systems to identify surveillance reports relating to the UroLift system. No results were found and the EAC confirmed this.

Extensive data on complications are well reported in all studies of the UroLift system and the comparators (see pages 59–65 of the assessment report). As with the clinical outcome measures, the EAC advised that these data should be interpreted with caution because of the lack of true comparative data. It emphasised the difference in reporting complications between studies using the UroLift system and those using TURP or HoLEP. For example, common complications reported with the UroLift system are mild, such as transient dysuria and haematuria; these are so common with TURP and HoLEP that they are typically not reported in the literature..

The EAC considered that some comparisons can be made between the technologies in terms of complications and adverse events. The EAC 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 (8%) than with TURP (6%) and HoLEP (4%).

The EAC found it difficult to compare catheterisation rates across interventions because procedures vary locally; for example, some hospitals seem to catheterise after the 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). The EAC emphasised that these rates may be driven more by local procedures rather than patient need or a genuine difference between the surgical procedures. A clinical expert advised the EAC that both TURP and HoLEP are usually followed by inserting a urinary

catheter to irrigate the bladder, which limits patient recovery. Another expert echoed this point, stating that the UroLift system removes the need for both catheterisation and the use of irrigation fluid after the operation.

The EAC highlighted this perceived inconsistency between published evidence and clinical opinion. It observed that many complications and additional processes which are reported in the UroLift literature are not widely reported in studies of TURP or HoLEP, because they are considered to be normal consequences of the procedure.

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 EAC sought clinical advice on this issue because of the lack of long-term data. Three experts described encrustation as significant issue, 2 considered it to be insignificant and a sixth was unsure because of the lack of data. There was general agreement that removing encrusted implants was a simple procedure, although 1 expert disagreed.

The EAC also sought clarification on any potential complications the implants may cause if a patient later has TURP. Clinical advisers who have done post-UroLift TURP procedures assured the EAC that implants do not impede any later procedure, including TURP or HoLEP, and that no alteration of the standard surgical technique is needed.

EAC conclusions on the clinical evidence

The EAC reported that the studies used in the company's submission showed the UroLift system to be clinically effective in treating benign prostatic hyperplasia. Looking solely at symptomatic improvement in terms of IPSS, the UroLift system showed a weighted mean IPSS improvement of -9.22 to -11.82 (in the context of a published minimally important change of -3 [Barry et al. 1995]). However, the EAC's systematic review to assess the same outcomes for TURP and HoLEP in patients with similar baseline characteristics (Li et al.

2014) showed better symptomatic improvement with both comparator technologies.

Evidence shows that sexual function is not negatively affected after using the UroLift system' in fact, small improvements (albeit statistically significant) may be achieved. Sexual function is poorly reported in studies of TURP and HoLEP, which focus primarily on symptomatic improvement. This makes it difficult to accurately assess the effect of these technologies on sexual function, although expert advice indicates that it is often badly affected.

The EAC concluded that the mild complications associated with the UroLift system – mainly dysuria and haematuria – may make the device appealing to some patients. There is no reported incidence of a blood transfusion being needed as a result of the procedure, and no related risk of TURP syndrome (a rare but serious complication associated with TURP). The EAC considered that the technology's low adverse event profile, combined with its clinical benefits and potential improvements sexual function, may support the UroLift system being used as an alternative to TURP or HoLEP, depending on patient preference and suitability.

5.2 Summary of economic evidence

The company's searches identified 5 studies that it considered relevant to the decision problem. None of these studies included the UroLift system; all were economic studies of the comparators. The EAC considered that none of these studies was appropriate for inclusion, although they may contain relevant input data for an economics model. The EAC's searches also did not find any relevant economic studies (see page 71 of the assessment report).

De novo analysis

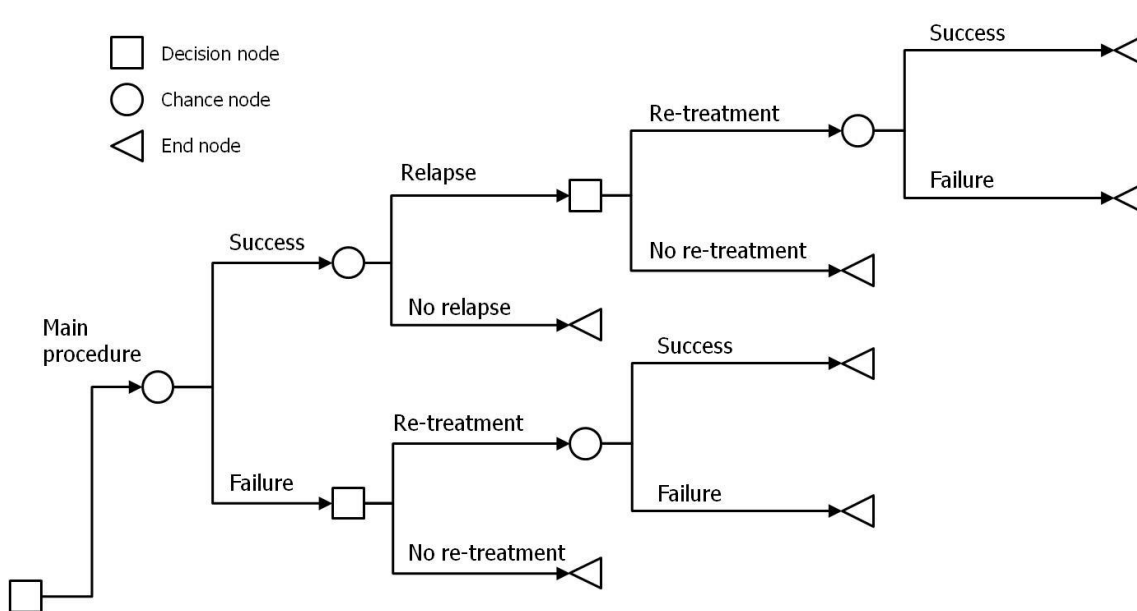
The patient population considered in the company's model was men with lower urinary tract symptoms secondary to benign prostatic hyperplasia, who are both aged 50 years or older and have a prostate volume no greater than 100 cm³. The intervention considered was the UroLift system. The

comparators used in the model included not only TURP and HoLEP (the specified comparators), but also bipolar TURP, laser vaporisation, transurethral vaporization of the prostate (TUVP) and bipolar TUVP. Only the specified comparators are discussed in the company’s submission.

The model was structured as a decision tree with 7 executable arms, 1 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 can succeed or fail) or no re-treatment.

Part of the model structure is shown in figure 1. The company’s submission is based on an NHS perspective with a 2-year time horizon, which it considered adequate to assess most differences in outcomes, adverse events and re-interventions. It is also the length of time for which published clinical data are available for the UroLift system.

Figure 1. Structure of the company’s de novo economic model: single-technology arm



The EAC considered the overall model structure to be unwieldy because it included comparators outside the scope, pre- and post-operative tests which are irrelevant and perspectives outside the scope (and not referred to in the submission). However, the EAC considered the costs included in the model to be thorough, detailed and taken from reliable sources.

A list of 21 assumptions from the company's model is shown on page 74 of the assessment report, with commentary from the EAC. The EAC agreed with the model's main assumptions but revised some of the parameters (such as operation times and length of hospital stay) as described below.

Clinical parameters and variables

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% improvement in 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.

A table summarising the probability of adverse effects associated with each procedure, with EAC analysis, is shown on page 77 of the assessment report.

The model values for length of stay (0.5 days) and procedure time (30 minutes) were both based on clinical advice. The EAC calculated a weighted mean procedural time of 59.6 minutes based on the published literature, although 1 adviser stated that operative times in published literature (59.6 minutes) may reflect trial conditions, and that a 30-minute procedure time was more usual.

The EAC could not identify a reported mean length of stay from published data, and therefore considered it appropriate for the company to use clinical opinion. The EAC considered it important that sensitivity analyses reflected uncertainty around this estimate. Expert advice to the EAC regarding length of stay was varied, but most considered the UroLift to be a day case procedure.

Costs

The company calculated the capital costs for each technology based on an assumed 10-year lifespan and use by 250 patients a year. Using the UroLift system (with a capital cost of £5199) equates to £2.50 per procedure. For HoLEP, with a capital cost of £167,555, the cost per procedure is £80.60. It was assumed that there is no capital costs associated with monopolar or bipolar TURP. Table 4 outlines the consumable costs included in the company's model.

Table 4 Consumable costs included in the company's model

Technology	Details	Cost per procedure	EAC comment
The UroLift system	4 implants (£330 each)	£1320	This is the largest component in the cost of UroLift.
mTURP	1 loop electrode (£52.50)	£52.50	Assume use of 1 loop electrode and 1 roller/ball in 100% of cases. Based on NHS supply chain list of diathermy equipment costs: Covidien E7506 Diathermy plate standard (solid) with leadwire, £4.04; loop electrode (models suitable for mTURP), £26.40; roller/ball electrode (models suitable for mTURP), £26.40. Total=£56.84
HoLEP	Reusable fibre (£614.37, 20 uses) Reusable morcellator (£664.63, 10 uses)	£97.18	EAC investigated single-use fibre (£368.61 from NHS supply chain)
Bi-TURP	1 loop electrode (£52.50)	£52.50	Change to £56.84 as above
Abbreviations: Bi-TURP, bipolar transurethral resection of the prostate; HoLEP, holmium laser enucleation of the prostate; mTURP, monopolar transurethral resection of the prostate.			

Results of company's cost analysis

The results of the company's base-case analysis show that using the UroLift has an incremental cost of £3 per patient compared with monopolar TURP and £418 per patient compared with HoLEP. The UroLift system is associated with higher equipment costs but lower costs for clinical supplies and services. It becomes cost-neutral compared with monopolar TURP when the cost per UroLift implant is changed to £329.

Table 5 Company's breakdown of base case per-patient costs (£)

Item	UroLift system	mTURP	HoLEP	Bi-TURP
Medical ¹	342	423	457	410
Nursing	64	113	137	105
Drugs ²	22	21	20	21
Clinical supplies and services ³	549	1358	923	1222
Equipment cost per procedure	1325	56	97	56
Other ⁴	40	369	290	487
Total	2342	2339	1924	2302
¹ Consultant staff costs. ² Cost of anaesthetic doses, saline, and antibiotics. ³ Includes cost of tests pre- and post- procedure and hospital bed day costs. ⁴ Includes costs of complications and capital costs.				

The company's approach to sensitivity analysis involved varying certain parameters (device cost, probability of treatment failure at 12 months, operation duration and length of stay) by 20% either way. The main drivers of the cost case identified by the company were device cost, length of stay post-procedure and the number of devices used per patient.

EAC revisions to the model parameters

The EAC made a number of changes to the company's base-case model. These are described in pages 85–91 of the assessment report, and summarised here.

The company assumed that 4 devices were used per procedure in its base-case model, based on Chin et al. (2012) and clinical expert opinion. The EAC calculated the weighted mean number of devices per procedure to be 4.4 and used this value in its revised model.

The EAC changed the operating time associated with the UroLift system to 60 minutes (rather than 30 minutes in the company's submission), based on weighted mean procedure time from the published studies. It also updated the operating time associated with monopolar TURP from 60 minutes to 66 minutes, based on the published literature.

The UroLift's base-case length of stay value of 0.5 days remains uncertain and was based solely on clinical opinion. The EAC's sensitivity analysis showed that if length of stay were 0.25 days, the cost per procedure of the UroLift system decreases (from £2342 to £2256) and the UroLift becomes cost saving compared with monopolar TURP (£83, with a threshold cost of £351 per implant).

The EAC updated staffing costs associated with TURP after receiving clinical advice that an extra nurse (band 5) may be needed to handle irrigation fluid. Similarly, some experts advised that an extra nurse would be needed as a laser operator during HoLEP.

The EAC considered that the cost of blood transfusion in the company's model – £862.17 – was an overestimate. It revised the cost downwards to £329, based on the NHS Blood and Transplant List (2014/15).

The EAC included a £10 per-procedure cost for capital equipment for TURP which was not incorporated in the base case (bringing the total capital cost to £20,799). The company's model includes the option to not reuse HoLEP consumables, but this does not affect the price. The EAC considered it unlikely that single- and multi-use HoLEP fibres would have price parity, or that multi-use fibres would only be used once before disposal. The EAC

assumed a cost of £368.61 for single-use HoLEP fibres (from the NHS supply chain), and applied this to its revised model.

The effects of the EAC's revisions to the model are presented in table 6. Shaded rows of the table highlight where the UroLift system is cost saving.

Table 6 Effect of EAC revisions to company's cost model

Parameters	UroLift	mTURP	HoLEP	BiTURP
Company's base case	£2342	£2339	£1924	£2302
No. of implants changed from 4.0 to 4.4	£2474	£2339	£1924	£2302
Operation time for UroLift changed from 30 minutes to 60 minutes	£2496	£2339	£1924	£2302
Operation time for mTURP changed from 60 minutes to 66 minutes	£2345	£2371	£1924	£2302
Addition of urological theatre overhead costs	£2532	£2671	£2372	£2611
Cost of transfusion changed from £862.17 to £329.00	£2338	£2294	£1913	£2255
Addition of £10 capital cost per procedure for TURP	£2343	£2349	£1924	£2312
Cost of TURP consumables=£56.84	£2343	£2343	£1924	£2306
Single-use HoLEP fibres=£368.61	£2342	£2339	£2262	£2302
Additional band 5 nurse for HoLEP	£2342	£2339	£2033	£2302
All above changes	£2979	£2707	£2762	£2579
Additional scenario				
UroLift in day surgery unit	£2355	£2691	£2315	£2564

If all the EAC revisions are incorporated into the model, the UroLift system remains the most costly option of the comparators specified in the scope: it costs £272 more per patient than monopolar TURP, £217 more than HoLEP and £400 more than bipolar TURP. The UroLift system only becomes cost saving compared with monopolar TURP when the price for each implant is decreased to £268.

Additional scenario: day surgery unit

After consulting clinical experts, the EAC ran the model using an 'optimistic but realistic' scenario, in which the UroLift system is cost saving compared

with TURP when done in a dedicated 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' (Verma et al. 2011). 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. Local anaesthetic is used for the procedure and so the cost of a consultant anaesthetist was removed from the model.

In this scenario, the UroLift was cost saving by £336 per patient compared with monopolar TURP and by £209 compared with bipolar TURP. It remains more expensive than HoLEP (£40 per patient).

EAC conclusions on the economic evidence

The EAC considered the company's economic submission to be overly complex but thorough. It felt a major limitation of the model to be that the UroLift system is not cost-saving compared with any comparators. There is only limited scope to change this, because the high cost per procedure is a result of the high costs associated with UroLift. In contrast, comparator costs are driven mainly by length of stay.

6 Ongoing research

The company's submission noted 3 ongoing studies. BPH6 (Clinicaltrials.gov identifier: NCT01533038) is a multicentre, randomised, non-blinded trial being conducted in the UK, Denmark and Germany, comparing the UroLift system with TURP. It appears to be the only study directly comparing these 2 technologies. The estimated study completion date is December 2015.

LIFT (Clinicaltrials.gov identifier: NCT01294150) is a single-blinded, randomised study currently completing 3-year follow-up results (earlier results are discussed in this overview). The study is expected to complete in February 2017.

LOCAL (Clinicaltrials.gov identifier: NCT01876706) is an open-label feasibility study of tolerability and surgical recovery after using the UroLift system under

local anaesthesia. Short-term results have been published, and the expected completion date is sometime in 2018.

7 Issues for consideration by the Committee

The Committee may wish to consider the following issues in its discussion.

Clinical evidence

- The UroLift appears to offer some symptomatic relief from lower urinary tract symptoms secondary to benign prostatic hyperplasia. Although this relief is clinically significant, it is less than that offered by the surgical comparators (namely TURP and HoLEP). However, the UroLift system appears to be associated with fewer complications than these comparators. There is no risk of TUR syndrome or need for blood transfusion with the UroLift system. Treatment with the UroLift also allows sexual function to be better preserved than with more invasive procedures.
- Expert advice suggests that treatment with the UroLift system can be done as a day procedure. It is not always necessary to catheterise patients following use of the UroLift system.
- There is a lack of direct comparative evidence between the intervention and comparators. There is also a lack of long-term data, including data on the likelihood of men needing TURP or HoLEP after the UroLift stops adequately relieving symptoms.

Cost evidence

- The technology appears to be cost-incurring compared with TURP and HoLEP in both the company's base case and in the EAC's revised base-case analysis. Only 1 scenario was identified by the EAC in which the device was cost-saving compared with TURP, and no scenario was identified in which the technology was cost-saving compared with HoLEP.
- This inability to show a clear cost-saving may lead to considering methodological issues surrounding the Medical Technologies Evaluation

Programme. MTEP is a cost-efficiency based programme and does not recommend technologies that are cost-incurring.

8 Authors

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Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- Ray A, Morgan H and Carolan-Rees G. The UroLift System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. February 2015.

B Submissions from the following sponsors:

- NeoTract.

C Related NICE guidance

- [The TURis system for transurethral resection of the prostate](#). NICE medical technologies guidance 23, February 2015
- [Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia](#). NICE interventional procedure guidance 475, January 2014
- [Lower urinary tract symptoms in men](#). NICE quality standard 45, September 2013
- [Lower urinary tract symptoms secondary to benign prostatic hyperplasia: tadalafil](#). NICE evidence summary: new medicine 18
- [Prostate artery embolisation for benign prostatic hyperplasia](#). NICE interventional procedure guidance 453, April 2013
- [Lower urinary tract symptoms in men](#). NICE pathway
- [LUTS in men, age-related \(prostatism\)](#). NICE clinical knowledge summary, August 2010
- [The management of lower urinary tract symptoms in men](#). NICE clinical guideline 97, May 2010
- [Laparoscopic prostatectomy for benign prostatic obstruction](#). NICE interventional procedure guidance 275, November 2008

- [Holmium laser prostatectomy](#). NICE interventional procedure guidance 17, November 2003.
- [Transurethral electrovaporisation of the prostate](#). NICE interventional procedure guidance 14, October 2003

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Li S, Zeng XT, Ruan XL et al. (2014) Holmium laser enucleation versus transurethral resection in patients with benign prostate hyperplasia: an updated systematic review with meta-analysis and trial sequential analysis, *PLoS One*. 9(7): e1016165

McVary KT, Gange SN, Shore ND et al. (2014) Treatment of LUTS secondary to BPH while preserving sexual function: randomized controlled study of the prostatic urethral lift. *Journal of Sexual Medicine*. 11: 279–87

Perera M, Roberts MJ, Doi SAR et al. (2014) Prostatic urethral lift improves urinary symptoms and flow while preserving sexual function for men with benign prostatic hyperplasia: a systematic review and meta-analysis. *European Urology*. Published online 15 November 2014

Roehrborn CG, Gange SN, Shore ND et al. (2014) Durability of the prostatic urethral lift: two year results of the L.I.F.T. Study. *Urology Practice*. 2: 1–7

Roehrborn CG, Gange SN, Shore ND et al. (2013) Multi-center randomized controlled blinded study of the prostatic urethral lift for the treatment of LUTS associated with prostate enlargement due to BPH: the L.I.F.T. study. *Journal of Urology*. 190: 2162–7

Verma R, Alladi R, Jackson I, et al. (2011) Day case and short stay surgery: 2. *Anaesthesia*. 66: 417–34

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 hypertrophy. *Journal of Sexual Medicine*. 9: 568–75

Appendix B: Comments from professional bodies

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

Mr Neil Barber

Consultant Urologist, British Association of Urological Surgeons

Professor Mark Emberton

Consultant Urologist, British Association of Urological Surgeons

Mr Mark Feneley

Consultant Urologist, British Association of Urological Surgeons

Mr Hashim Hashim

Consultant Urological Surgeon, British Association of Urological Surgeons

Mr Francis Keeley

Consultant Urologist, British Association of Urological Surgeons

Professor Thomas McNicholas

Consultant Urological Surgeon, British Association of Urological Surgeons

Mr Gordon Muir

Consultant Urologist, British Association of Urological Surgeons

Professor Raj Persad

Consultant Urological Surgeon and Uro-oncologist, Royal College of Surgeons in England

Mr Mark Speakman

Consultant in Urology, British Association of Urological Surgeons

Mr Andrew Thorpe

Consultant in Urology British Association of Urological Surgeons

Personal experience with technology

Six of the 10 experts contacted had direct experience with the technology. Four did not, but all said they would like to. One cited the results of a recent randomised control trial as the primary reason for their interest, while another had used it on models at conferences. Five of the experts who had direct involvement with the technology also had research-based involvement with it.

The technology

Nine of the 10 expert advisers classified the technology as novel. One described it as a significant modification, and 2 commented that the concept is derived from earlier interventions, namely urethral lifts. Several expert advisers commented on the ease of use of the technology, its safety and good outcomes.

The most common clinical group in which the UroLift would be used are in men with symptomatic benign prostatic hyperplasia for whom medical management is not effective or inappropriate, and who would prefer a minimally invasive treatment or a treatment that allows them to maintain sexual function. A second group would be older men who would be at high risk for traditional surgical intervention due to potential bleeding or medical comorbidities.

Comparators

The most commonly mentioned comparators were TURP, laser TURP (GreenLight, thulium or holmium) and medical therapy. Other experts mentioned transurethral needle ablation of the prostate, transurethral microwave therapy and bladder neck incision.

In terms of direct comparators, most experts said there was nothing directly comparable. Two referenced prostatic stents, but acknowledged that these are rarely used. One expert mentioned that their a colleague is attempting to set up a trial with a similar device. Another mentioned the Medi-Tate temporary implantable nitinol device.

Patient benefits

Patient benefits identified were all related to maintained sexual function and fertility, rapid recovery, a less invasive procedure and the avoidance of long-term drug therapy.

It was agreed that these benefits could be realised in practice. Potential obstacles included a perception that the technology is not durable, or that it does not offer sufficient symptom improvement relative to the comparator technologies. Several experts mentioned cost and pricing, and another referenced the lack of long-term data. One specified the need for a flexible cystoscopy before surgery to rule out a median lobe.

Appropriate outcomes suggested were patient-reported outcome measures, clinical audit data (of costs and outcomes), quality of life, incidence of adverse events and perioperative catheterisation, length of stay and readmission rates.

The experts generally agreed that there was a strong (if limited) evidence base, although 1 considered the evidence base to be weak.

Generally, the experts agreed that the UroLift is a less invasive alternative to traditional procedures. They felt it is particularly suitable for men who wish to maintain sexual function, who are unsuited to medical therapy (high risk patients, or those on anticoagulants), and for whom comorbidities preclude the use of more aggressive surgery. Experts agreed that it is not suitable for men with very large prostates (over 75 cm³) and large median lobes, but that the UroLift is associated with quick return to normal function, has no effect on sexual function, and is reversible.

There was some doubt over the long-term efficacy of the intervention, because it does not actually affect the size of the prostate gland. However, it can be offered repeatedly and does not preclude standard therapy at a later stage. Safety and a lack of serious adverse events were agreed upon. The experts also noted the need for specific surgical training to maximise patient benefits.

Healthcare system benefits

Benefits to the healthcare system were based on less resource use and the related cost savings. Other benefits included a reduced complication rate. The waiting list for TURP could be reduced by using the UroLift for some patients. The experts agreed that these benefits can be realised in practice, but obstacles include those traditionally associated with adoption such as a lack of awareness and budget limitations.

Appropriate outcomes suggested included a health economic evaluation, as well as measurement of length of stay, readmission rates and 5-year reoperation rates. The existing data on these long-term outcomes appear to be insufficient. One expert mentioned pilot studies that are planned in certain NHS trusts.

Facilities, training and functioning

The experts were generally positive about the training model (both surgical and nursing staff need computer simulation, training and mentorship). Many experts were complimentary about the training offered by the company, including the video tutorial and simulator. Standard day surgery units were described as appropriate and sufficient. One expert suggested that skills can be developed in a 1-day workshop.

One expert pointed out that the UroLift system is more subjective than standard TURP, and so the scope for error may be greater. Another suggested that the device would be better if a multiple clip applicator were developed, which would be preferable to the current single-use device. Those who commented on the device's functioning were positive. One expert stated that the kit is not interchangeable with current cystoscope kits.

Costs

Experts presented a range of views on the costs. It was pointed out that much would depend on the durability of the intervention to accurately assess long-term costs relative to comparators. Other experts suggested that the potential market for the device is huge – there are currently 1.2 million interventions for

enlarged prostates per year – so costs may fall if a move is made to mass production.

The experts also highlighted potential savings associated with day-case surgeries, avoiding long-term drug treatment and disease-related consequences (such as urinary tract infections).

One expert cited a device cost of £1400 per procedure, and another suggested a cost saving of £1000 per case compared with TURP. One expert considered the cost to be greater than that of a TURP, and suggested that TURP may still be needed after the UroLift procedure, further increasing costs. The relatively low level of investment needed for uptake was noted.

General advice

Almost all the experts agreed that there is no controversy associated with the technology, and that it would be very useful if more widely available. One stated that there is no consensus on where in the pathway the technology would be best placed.

Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. The following patient and carer organisations responded:

- Bladder & Bowel Foundation
- Prostate Cancer UK

The Bladder & Bowel Foundation stated that the UroLift system had the potential to offer relief from symptoms affecting quality of life, such as discomfort and embarrassment, as well as painful ejaculation. No other technology for the treatment of benign prostatic hyperplasia was identified as being more suitable for NICE guidance development. The foundation noted the importance of NICE guidance as a point of reference and as a benchmark.

Prostate Cancer UK stated that the UroLift could provide an alternative treatment option for men who have not had meaningful symptomatic improvement following lifestyle changes, conservative management or medication. The organisation also felt that the UroLift procedure was minimally invasive, well tolerated and improved symptoms with a risk of only mild complications.

Prostate Cancer UK stated that there may be particular patient benefits for men who are currently undergoing a 'watchful waiting' approach, but who are struggling with symptomatic benign prostatic hyperplasia. It may also relieve the social stigma associated with dealing with symptoms, for example increased urgency and frequency or sexual dysfunction. The organisation felt that the UroLift procedure would be of most benefit to men with prostate volumes of 80–100 cm³, because current options comprise only open prostatectomy and HoLEP.

The organisation also noted that the UroLift procedure can be done quickly and under local anaesthesia, offering particular advantages to older patients. It also noted that reduced catheterisation rates could benefit patients. Prostate Cancer UK also stated that the preservation of sexual function was a major benefit associated with the UroLift procedure.

Funding was identified as a potential barrier to access although it was pointed out that some 'hidden' costs associated with benign prostatic hyperplasia, such as absenteeism, will be offset.