

**MT241 UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia**

**National Institute for Health and Care Excellence**

**Medical Technologies Evaluation Programme**

**MT241 UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia**

**Consultation Comments table**

**MTAC date: 16 July 2015**

There were 37 consultation comments from 13 consultees (6 NHS professionals, 4 patients, 2 manufacturers, and 1 professional society). The comments are reproduced in full, arranged in the following groups – provisional recommendations, comparator, costs, patient population, patient benefit and other.

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<b>Provisional recommendations</b>				
1	7. Olympus KeyMed Group Companies Ltd	1.1	The comparator mentioned as TURP is recommended to be specified and considered separately: e.g. monopolar TURP (M-TURP), bipolar TURP (B-TURP), and TURis (cf. NICE MTG23). See below comment on section 1.3 regarding the evidence base of M-TURP, comparator selection, as well as comparison in day surgery scenario. The evidence available for the technology has significant limitations, as noted by the EAC: “The External Assessment Centre noted that there was no published evidence directly comparing the UroLift system with the specified comparators. (...) 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.” (section 3.17), or section 3.20 “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.”. These limitations on the clinical evidence regarding the lack of direct comparison and prostate size are recommended to be mentioned explicitly.	<p>Thank you for your comment.</p> <p>Both monopolar and bipolar TURP were specified as comparators in the scope.</p> <p>The Committee decided not to change section 1.1 to add information on the lack of direct comparative evidence, or considerations on prostate size because these issues were adequately covered in sections 3.29 (direct comparative evidence) and 1.2 (prostate size).</p>
2	7. Olympus KeyMed Group Companies Ltd	1.2	The present assessment takes extensive consideration of the advice provided by the clinical experts. The clinical experts expressed more stringent selection of population in section 3.30, namely “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.” Patient population in line with the advice of the clinical experts is recommended.	<p>Thank you for your comment.</p> <p>The Committee considerations on prostate shape, including expert advice, are described in section 3.32.</p> <p>The Committee decided to change section 1.2 to further clarify the recommendation on patient selection.</p>

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3	7. Olympus KeyMed Group Companies Ltd	1.3	<p>The goal of the treatment of LUTS secondary to BPH/BPE is to guarantee the functional outcomes of the patients while minimising safety issues and maximising operating efficiency (e.g. cost-saving) in the NHS setting. In patients where conservative treatment or medical therapy has failed, the standard of care today in England and Wales is the monopolar TURP (M-TURP). NICE has published in February 2015 a medical technology guidance (MTG23) on the TURis system for transurethral resection of the prostate, in which the TURis system was recommended as safer, equally effective, and cost-saving alternative to M-TURP (i.e. dominant technology). The scope of the present evaluation (GID-MT241), namely men with LUTS secondary to BPH aged 50 or over, and with prostate volumes no greater than 100 cc, corresponds to that of MTG23 since most of studies include patient above 50 years old or over, and prostate volume smaller than 100cc (cf. MTG23). Evidence base of M-TURP From the above viewpoint, comparative effectiveness as well as economic value of a novel medical technology for the treatment of LUTS symptoms of BPH have to be based on most up-to-date, best available pool of evidence for a fair comparison. The assessment of GID-MT241 as well as assumptions in the model considered do not seem to reflect such evidence base available, that is, not consistent with that assessed in MTG23 although the scope overlaps in large majority, specifically around the current standard of care, i.e. M-TURP. In MTG23, the EAC considered synthesised evidence based on 10 unique randomised studies (1870 patients) comparing M-TURP and the TURis system (MTG23 section 3.3). In the absence of direct comparison between UroLift and existing comparators, the best available source should be used for indirect comparison. Alignment with evidence assessed in MTG23 is recommended given an overlapping scope.</p>	<p>Thank you for your comment.</p> <p>Please see response to comment 1 for information about the comparator specified in the scope for this evaluation.</p> <p>The decision problem for each MTEP assessment is based on the claimed patient and healthcare system benefits associated with each technology. The evidence base for each technology is considered separately by the Committee. In the case of UroLift the EAC did not present an indirect comparison because of the limitations of the evidence and the heterogeneity of the patient populations. It presented a qualitative evidence synthesis which presented improvements from baseline and complications after TURP and HoLEP in the same format as the UroLift system data. It also reported estimates of clinically important effect sizes for each outcome measure. The Committee understood the limitations of the evidence and accepted the EAC's approach (see section 3.29).</p>

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4	7. Olympus KeyMed Group Companies Ltd	1.3	<p>Comparator selection</p> <p>Likewise, the de novo economic model of GID-MT241 does not consider the TURis system as a comparator, when it has been recommended as dominant alternative to M-TURP in the recently published MTG23. In particular, the recommendation 1.3 in MTG23 is neither used as comparison or referenced in the present assessment, which is not consistent with the principle of using most up-to-date best available evidence: “Using the transurethral resection in saline (TURis) system instead of monopolar transurethral resection of the prostate (TURP) results in an estimated saving of £71 per patient for hospitals that already use an Olympus monopolar system and an estimated additional cost of £20 per patient for other hospitals. However, there is some evidence of a reduction in readmissions with the TURis system compared with monopolar TURP. If this evidence is included, using the TURis system results in an estimated saving of £375 per patient for hospitals that already use an Olympus monopolar system and an estimated saving of £285 per patient for other hospitals.” Referencing MTG23 and the TURis system is recommended.</p>	<p>Thank you for your comment.</p> <p>Please see response to comment 1 for information about the comparator specified in the scope for this evaluation.</p> <p>Both the company’s cost consequences model and the revised model presented by the EAC considered the costs and benefits of UroLift compared with bipolar TURP such as the TURis system as well as monopolar TURP.</p> <p>Section 1.3 summarizes the conclusions from the Committee considerations of the cost evidence for the UroLift system. NICE guidance on the TURis system (MTG23) is referenced in section 2.9.</p> <p>The Committee discussed whether further reference to the cost modelling results for the TURis system should be included. Due to the differences between the models it decided that such data would not provide additional relevant information.</p>
5	7. Olympus KeyMed Group Companies Ltd	1.3	<p>Comparison in day surgery</p> <p>Assumptions on the feasibility in ambulatory setting are based on the opinion of the clinical experts. It has to be noted that it is also becoming an increasing trend in practice that TURP, bipolar or TURis, is performed in day-case setting. This is suggested to be confirmed with the clinical experts. For a fair comparison of scenarios, day surgery with UroLift should also be compared with day surgery with the other comparators, notably TURis and bipolar TURP. Inclusion of a scenario is recommended that incorporates TURis or bipolar TURP in day surgery.</p>	<p>Thank you for your comment.</p> <p>Expert advice received at the time of the evaluation (please see pages 17–22 <a href="#">EAC Correspondence</a>) suggested that it was not routine practice to perform TURP, bipolar or TURis in an NHS day-case setting. The EAC sought additional expert advice on the issues raised by the consultee which is reported in Appendix 1 of this document.. The cost evidence submission for MTG 23</p>

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				(TURis) did not include the use of TURP (monopolar or bipolar) in a day-case setting.
6	7. Olympus KeyMed Group Companies Ltd	1.3	Details Regarding the assumptions, the discrepancy as mentioned above includes but is not limited to: Probability of TUR syndrome (EAC report page 77). The probability of TUR syndrome is not consistent with MTG23 (EAC report page 105). Namely the value for TURis, or bipolar TURP in general, should be 0% since the use of saline negates the occurrence of glycine absorption. Probability of blood transfusion (EAC report page 79). The probability of blood transfusion is not consistent with MTG23 (EAC report page 105). It should be lower in M-TURP, and even more so for TURis or bipolar technology. Clot retention is not considered as outcome. Alignment with evidence assessed in MTG23 is recommended.	<p>Thank you for your comment.</p> <p>The decision problem for medical technologies guidance is based on the claimed patient and healthcare system benefits associated with each technology.</p> <p>In response to this comment the EAC noted that reductions in TUR syndrome and probability of blood transfusion would have a minimal impact on the cost saving because these risks are zero with UroLift.</p> <p>The Committee decided not to change the guidance.</p>
7	12. British Association of Urological Surgeons (BAUS)	general	<p>Overall BAUS is satisfied with the conclusions regarding the use of Urolift and believe all relevant information available at the time the assessment was produced, has been considered although further information from BPH-6 has subsequently been produced.</p> <p>BAUS agree with the conclusions regarding cost effectiveness as a day case procedure based on the unit costs quoted in the report.</p> <p>The three provisional recommendations seem fair and reasonable.</p>	<p>Thank you for your comment.</p> <p>The consultee refers to an in-process paper for the BPH-6 trial (UroLift vs. TURP), a summary of which by the EAC is included at appendix 2. The Committee decided to change sections 3.15, 3.22 and 3.29 to include reference to the new data.</p>
<b>Comparator</b>				

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8	7. Olympus KeyMed Group Companies Ltd	2.9	NICE Medical Technology Guidance 23 (MTG23) has been published including best available evidence for both M-TURP and the TURis system for the treatment of LUTS symptoms of BPH. Alignment with evidence assessed in MTG23 is recommended. The gold standard for the care for symptomatic BPH today is M-TURP. It is recommended to be rephrased.	<p>Thank you for your comment.</p> <p>The Committee decided to change section 2.9 to state: 'TURP is considered to be the standard of care for symptomatic benign prostatic hyperplasia.' This section already references the publication of MTG23.</p>
9	7. Olympus KeyMed Group Companies Ltd	3.3, 3.17	Alignment with evidence assessed in MTG23 is recommended based on systematic literature review of randomised studies for M-TURP and TURis.	<p>Thank you for your comment.</p> <p>The decision problem for each MTEP assessment is based on the claimed patient and healthcare system benefits associated with each technology. Please see the response to comment 3.</p>
10	7. Olympus KeyMed Group Companies Ltd	5.2	The comparator mentioned as TURP is recommended be specified and considered separately: e.g. monopolar TURP (M-TURP), bipolar TURP (B-TURP), and TURis (cf. NICE MTG23). Alignment with evidence assessed in MTG23 is recommended given an overlapping scope. Referencing MTG23 and the TURis system is recommended in evaluating the economic value of the technology for the treatment of LUTS symptoms of BPH.	<p>Thank you for your comment.</p> <p>Section 5.2 describes the company's economic model which includes monopolar TURP, bipolar TURP and HoLEP as separate comparators. In the model TURis would be considered as a bipolar TURP procedure.</p>
11	8. Neotract® International	general	The committee and expert felt that HoLEP was not a comparator as this procedure is truly novel	<p>Thank you for your comment.</p> <p>In this evaluation, UroLift is being compared to surgical interventions treating benign prostatic hyperplasia and HoLEP is an ablative procedure intended for this patient population. The Committee was advised by clinical experts that HoLEP is a less commonly carried out than TURP in NHS practice.</p>
<b>Costs</b>				
12	9. Olympus KeyMed	4.6, 6.4	Inclusion of a scenario is recommended that incorporates	Thank you for your comment.

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	Group Companies Ltd		TURis or bipolar TURP in day surgery.	Please see response to comment 5.
13	9. Olympus KeyMed Group Companies Ltd	6.1	Alignment with evidence assessed in MTG23 is recommended given an overlapping scope. Referencing MTG23 and the TURis system is recommended in evaluating the economic value of the technology for the treatment of LUTS symptoms of BPH.	Thank you for your comment.  Please see response to comment 3.
14	9. Olympus KeyMed Group Companies Ltd	5.3	The statement “The probability of long-term relapse after a successful procedure ranged from 0% for the UroLift system to 0.99% for bipolar TURP.” contradicts with prior statements on re-operation such as in section 3.10 “After 2 years, reoperation rate was 20% using TURP, a repeat prostatic urethral lift or photoselective vaporisation of the prostate” or section 3.23 “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.”. The statement is recommended to be deleted or rephrased.	Thank you for your comment.  In response top this comment the EAC noted that “long-term relapse rate” is not equivalent to “2-year reoperation rate”, which may account for the difference. However, these data are reported as in the individual sources.  The statement “The probability of long-term relapse after a successful procedure ranged from 0% for the UroLift system to 0.99% for bipolar TURP” describes the assumptions in the company’s economic model which has a 2-year time horizon. The EAC considered these assumptions appropriate and did not revise the probability of long-term relapse. The Committee accepted the EAC’s view and decided not to change section 5.3.
15	9. Olympus KeyMed Group Companies Ltd	5.7, 5.9	Alignment with evidence assessed in MTG23 is recommended given an overlapping scope. Referencing MTG23 and the TURis system is recommended in evaluating the economic value of the technology for the treatment of LUTS symptoms of BPH.	Thank you for your comment.  Both sections 5.7 and 5.9 report UroLift costs compared with bipolar TURP. The cost model used in MTG23 was designed to address a different decision problem and was not considered part of this

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				assessment. Because of this, the Committee decided not change sections 5.7 or 5.9.  Please also see the response to comment 3.
16	9. Olympus KeyMed Group Companies Ltd	5.1	Alignment with evidence assessed in MTG23 is recommended given an overlapping scope. Referencing MTG23 and the TURis system is recommended in evaluating the economic value of the technology for the treatment of LUTS symptoms of BPH. Inclusion of a scenario is recommended that incorporates TURis or bipolar TURP performed as day surgery.	Thank you for your comment.  Please see response to comment 5.
17	8. Neotract® International	5.4	No capital costs are included in this calculation for HoLEP underestimation in complexity and cost of hosts	Thank you for your comment.  The capital cost of £167,555 is described in the company's cost model (section 5.4). This cost is derived from a resource document from CG97 ( <a href="http://www.nice.org.uk/guidance/cg97/resources/costing-report2">http://www.nice.org.uk/guidance/cg97/resources/costing-report2</a> section 3.9.1), where a cost of £150,000 was used. This was than inflated to 2014/2015 prices.  The £80.60 cost per operations assumed a lifespan of 10 years and 250 operations per year, as described in section 5.4. The Committee decided not to change section 5.4
18	9. Consultant urological surgeon (expert adviser)	5.4	Surprising! It would be interesting to check your costings for Holep. We have not been able to implement Holep in the NHS here due to the cost, especially the high initial purchase costs (£140-170k)	Thank you for your comment.  Please see response to comment 17.
19	8. Neotract® International	5.9	Again no capital costs associated with HoLEP and no morcellation procedure time included in calculated costs	Thank you for your comment.  Please see response to comment 17.



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20	8. Neotract® International	5.6	The mean procedure time in multiple experiences has been less than 20 minutes and was consistently fed back by the expert group	<p>Thank you for your comment.</p> <p>The experts advised a range of procedure times, 7 mins–40 mins, (please see pages 17–22 <a href="#">EAC Correspondence</a>). Procedure durations from studies were also considered but were not included in the day-surgery scenario due to differences in international practices. The EAC confirmed that changes in the procedure duration made little difference to the cost case for the day-case scenario. The Committee decided to note these uncertainties in section 1.3.</p>
21	8. Neotract® International	3.24	Catheter Associated UTIs are a well know source of approx. 7500 deaths globally- recent presentations at BAUS concluded that in the UK each UTI is associated with a cost of 1000 pounds and 1-4 days extra stay	<p>Thank you for your comment.</p> <p>The need for, or duration of, catheterisation and the number of post discharge follow-on consultations, both in primary and secondary care settings were outcomes in the scope. Section 3.26 summarises the comparative evidence identified on catheterisation rates.</p> <p>In response to this comment the EAC noted that no evidence was submitted on the clinical or cost consequences of catheter-associated UTIs.</p> <p>The Committee decided not to change section 3.24.</p>
22	8. Neotract® International	5.16	Interesting papers appearing regarding 5Alpha reductates and causing permanent sexual dysfunction	Thank you for your comment.
<b>Patient population</b>				
23	9. Consultant urological surgeon	3.31	“The Committee was advised that the UroLift system would be appropriate for about 10–15% of men with lower	Thank you for your comment.

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	(expert adviser)		urinary tract symptoms of benign prostatic hyperplasia.” Whose opinion is that? What evidence for that? It's a crucial point and the strength of the “evidence” for that suggestion should be made clear so it can be tested or at least assessed by the reader.	In the absence of any published evidence or information the Committee relied on expert advice for estimates of the proportion of men with BPH who would be suitable for UroLift. The MTEP methods guide describes the contribution of expert advisers in the development of medical technologies guidance and notes expert advice may be used as a part of evidence synthesis (please see section 6.4.). The Committee heard additional expert advice, recommending ‘up to 1 in 4 men needing surgery’ as an estimation of the patient population, and decided to update section 3.33.
24	8. Neotract® International	3.31	User base globally suggest a larger cohort of suitability than 10-15% of men	Thank you for your comment.  Please see response to comment 23.
25	9. Consultant urological surgeon (expert adviser)	2.1	I appreciate that this MTEP review is comparing urolift to existing surgical options but in the introduction it should be recorded that there are other options as well, albeit ones that are not being compared in this current process. The place of this technology is broader than your introduction implies. I would suggest: This provides an alternative to current standard surgical interventions, such as transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP) where medical therapy fails or is unacceptable due to side effects or patient choice.	Thank you for your comment.  Section 2.1 states that UroLift provides an alternative to current standard surgical interventions such as transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP).  The Committee decided not to change section 2.1 because it was already clear that UroLift is intended as an alternative to other surgical options.
26	7. Olympus KeyMed Group Companies Ltd	2.3	The clinical experts expressed more stringent selection of population in section 3.30, namely “The clinical experts stated that appropriate prostate shape is also important; in	Thank you for your comment.  Please see response to comment 2.

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			particular, a prostate with a hypertrophic median lobe would preclude the use of the UroLift system.” Patient population in line with the advice of the clinical experts is recommended.	The Committee decided to change section 2.3 to state that UroLift should not be used in men whose prostate has an obstructing middle lobe.
<b>Patient benefit</b>				
27	9. Consultant urological surgeon (expert adviser)	3.32	“It heard expert advice that the UroLift system is not likely to offer permanent relief of symptoms” Was that one expert or more? I have read the expert evidence and saw only 1 comment to this effect from 10 experts. It is a reasonable opinion but your words make it sound a generally held view (or prejudice, as there is little or no evidence to back it up. After all – many drugs work without affecting the size of the prostate or the natural history of the disease). Many of us agreed that long term follow up would show the long term efficacy. Why not say “One opinion was...” or “The experts agreed that prolonged follow up would be necessary to show long term efficacy.”	<p>Thank you for your comment.</p> <p>The basis of this expert advice is that because UroLift is not an ablative procedure, some patients will eventually experience prostate growth that is beyond the capability of UroLift to contain.</p> <p>The Committee decided to change section 3.34 to further clarify its consideration of long-term efficacy.</p>
28	8. Neotract® International	3.32	LIFT study recently reached 3 year follow up with sustained effects of improvement	<p>Thank you for your comment.</p> <p>A summary and critique of the new data, by the EAC, is attached in appendices 3 and 4 respectively.</p> <p>The Committee decided to change section 3.34 to reflect the new findings.</p>
29	6. Psychosexual nurse specialist	3.1	To actually ascertain the true incidence of post BPH treatment sexual dysfunction is very difficult. My clinical expertise has enabled me to see huge variation in how it is addressed. Some of the questionnaires mentioned in this document will give some details but certainly not all. Whether a man is single or in a relationship the psychological impact is significant. The cost of failed relationships and the breakdown of a family unit can have significant financial implications. Quality of life is a	<p>Thank you for your comment.</p> <p>Reduction in ejaculatory or sexual function was listed as an outcome in the scope. The evidence on sexual function is described in section 3 of the guidance.</p>

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			contributory factor for psychological wellbeing. Sexual difficulties can impact physiologically as a consequence of treatment, socially and psychologically. Sexual activity is an important component of overall quality of life in majority of men over 50.	
30	1. Patient	general	This comment consists of a two-part article published in The Independent newspaper in 2014. MTEP team note: the comment is reproduced in full, in is presented in appendix 5 for ease of reading.	Thank you for your comment. MTEP team note: the NICE guidance referred to in the article is Interventional Procedures Guidance 475 which stated that current evidence on the efficacy and safety of insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
31	2. Patient	general	This comment has been reproduced in full in appendix 6 for ease of reading.	Thank you for your comment.
32	3. Patient	general	Excellent! Excellent! Excellent! Urolift operation brought back my quality of life. Day time I can go 7 hours without having the need to urinate. This means no more embarrassing meetings braking to go the gents! I get a good nights sleep uninterrupted. I am fresh mind in the morning not tired as before Urolift operation. As a bonus which I did not expect my sexual life has been enhanced enormously having come out of the Tamsulosin. Super savings will result for the NHS as no hospital stay is required. Savings from medication. Savings from no further complications. It has been three years now and I am delighted with the results. Professor [redacted] was extremely professional and comfortable. I recommended Urolift and professor	Thank you for your comment.

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			[redacted] it to many friends and family some of whom had it done as well with impeccable results.	
33	11. Patient	general	<p>After seeing the results and affects of my Fathers TURP operation several years before, I was desperate not to have the same procedure and relied fairly unsuccessfully on drugs until I heard of the Urolift. My Father was off work for at least a month and suffered terrible bleeding and was catheterised at home and visited by nurses each day for two weeks.</p> <p>On Friday 7th March 2014 I had the Urolift procedure in the morning and was discharged in the afternoon. Although bleeding when I passed urine, I was amazed to see the flow itself. Heavy, consistent and uninterrupted. I'd forgotten what that looked like as I had gotten used to a very poor, interrupted flow that 'was never quite finished' and often a 'shilling stain' on my trousers afterwards. I did not have the confidence to go too far from the loo on that weekend but I resumed work on Monday with only a light pink urine.</p> <p>100mg of Paracetamol 4 times a day kept the stinging away when passing urine for about 5/6 days and my urine was clear from pink on day 3/4. I stopped taking the tablets (can't remember the name) straight after the procedure.</p> <p>15 months later and I am still delighted with the result.</p> <p><b>DISCLOSURE:</b> Subsequent to my procedure, a 68 year old friend of mine had a TURP despite my urging him to pay for a Urolift. He was confined to the house for some two weeks afterwards still bleeding and has impotence problems today, some 6 months later.</p>	Thank you for your comment.
34	13. Patient	general	I would like to say that the logistics involved in my normal life, like to organise constant access to toilets is extreme examples are "normal bus journeys" – "golf" can be very embarrassing.	Thank you for your comment.

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<b>Other</b>				
35	4. Consultant Urologist	general	<p>This evaluation is well written and largely makes sense. I have undertaken a number of cases in the private sector but had difficulty in setting this up in the NHS. Cases I have undertaken have all taken under 30 minutes and would on average take 15 minutes. All patients have been undertaken as day case with no patients staying overnight. I have undertaken one case under a local anaesthetic on the patient's request with no difficulties. In the NHS, we undertake bipolar TURP and HoLEP. At least 30-40% of these patients stay in overnight. The evaluation does not seem to take into account the morcellation time involved in HoLEP which adds between 30-60 minutes per case.</p> <p>It is important to highlight to patients that the long term outcome and duration of efficacy with this procedure remains unknown.</p>	Thank you for your comment.
36	5. Senior Partner/GP	general	<p>This is a very welcome development in the treatment of BPH and LUTS in men – which accounts for the majority of male urology problems in primary care. Urolift is a minimally invasive option to the usual treatments of surgery or medication with no cutting, heating or removal of prostate tissue. All current data shows that Urolift is an extremely effective way of relieving LUTS due to BPH and can be performed under local anaesthesia. Typically no catheter is required – a massive plus for most men – and no overnight stay is required. Costs are therefore much lower than normal and there are no problems with erectile dysfunction following treatment. The sooner this option becomes available to all CCGs and used routinely, the better.</p>	Thank you for your comment.
37	10. Department of Health	general	<p>Thank you for the opportunity to comment on the evaluation documents for the above medical technology.</p> <p>I wish to confirm that the Department of Health has no</p>	Thank you for your comment.

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			substantive comments to make, regarding this consultation.	

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."*

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Appendix 1: Additional expert advice

**Comment 5** *“It is becoming an increasing trend in practice that TURP, bipolar or TURiS, is performed in day-case setting” Is this the case? Are there any increased risks or compromises made if they are done as a day case?*

<b>Expert Adviser</b>	<b>Comment</b>
<b>Mr Andrew Thorpe</b>	<i>Although we would like this to be the case, most TURP’s are not daycase, TURiS is feasible as a daycase, but it is variable around the UK as to whether they are daycase or not – on my unit they are at least an overnight stay and I think this will be the case throughout most of the country</i>
<b>Mr Neil Barber</b>	<p><i>I think it is true to say that it an increasing aim to try to perform TURP/ TURiS and other procedures as day case – however, it isn’t as simple as that – lists generally have to be in the morning, there will likely be restrictions in which patients this may be considered suitable / possible for this eg younger, fitter men with smaller prostates – ie it will likely be a select group of patients rather than an option for all. Furthermore, the patients would all be going home with a catheter and will either have to return to hospital for removal or arrangements made to do so in the community (not that easy as you might imagine). Most TURiS enthusiasts I know are more realistically looking at reducing the in patient stay to 1 night, patients again either being discharged home with a catheter to be removed on readmission the day after or remove the next morning after surgery with the aim of discharge within roughly 24hours (this is what americans and much of the literature refer to as day case surgery). There is no data to know if such a change in practice will come with extra risk - particularly in terms of reattendance to hospital A and E with problems = my gut feeling is that this will be the case if surgeons really push the concept to a greater proportion of patients.</i></p> <p><i>At my hospital where we are not driving daycase TURiS but probably do things in the ‘normal manner’ – the average length of stay for TURiS was 2.7 days in 2013.</i></p>
<b>Prof. Mark Emberton</b>	<p><i>Day case TURP by any means is still a very minority event.</i></p> <p><i>Not sure there are any national data but doubt whether it represents even 5-10% of the TURP cases done nationally.</i></p> <p><i>TURiS increases the possibilities but still rare.</i></p>
<b>Mr Hashim Hashim</b>	<p><i>That is true. We have changed to day-case TURPs and certainly other Trusts have done so too.</i></p> <p><i>No increased risk, however if it was felt they needed to stay in for medical or social reasons then they will be admitted.</i></p> <p><i>We have been using bipolar for at least the last 5 yrs. The monopolar can in theory also be done as daycase but majority stay in overnight.</i></p>



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<i>Mr Frank Keeley</i>	<i>Yes, there has been a push for daycase TURP since the tariff provided a huge financial incentive a few years ago. I have no great sense of how common it has become. many of our patients are relatively unfit and have been in retention so are not appropriate to be done as a daycase. I do not believe there is a huge risk so long as there are good ways to sort out postop problems</i>
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## MT241 UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia

### Appendix 2: LIFT 3-year follow-up abstract

#### PD5-01 THREE YEAR DURABILITY OF THE PROSTATIC URETHRAL LIFT FOR BPH: RESULTS OF A PROSPECTIVE, MULTI-CENTER, RANDOMIZED STUDY

Roehrborn et al. *The Journal of Urology*. Available: [http://www.jurology.com/article/S0022-5347\(15\)00611-4/fulltext](http://www.jurology.com/article/S0022-5347(15)00611-4/fulltext)

#### INTRODUCTION AND OBJECTIVES

To present an update of the pivotal, multi-center, randomized, blinded trial of the Prostatic Urethral Lift (PUL) through 3 years.

#### METHODS

Men were eligible for enrollment if they were  $\geq 50$  years and had symptomatic lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) with American Urological Association Symptom Index (AUASI)  $\geq 13$ , peak flow (Qmax)  $\leq 12$  ml/s, and prostate volume 30 - 80 cc. During PUL, small permanent metallic implants were placed to hold lateral lobes in a retracted position and open the prostatic urethra. Randomized data (2:1) from PUL and sham were compared through 3 months, and then subjects in the PUL arm were followed for 3 years.

#### RESULTS

From February to December of 2011, 140 men were treated with PUL in the USA, Canada and Australia. AUASI reduction was 44% by 1 month and sustained at 43% through 3 years (p-value  $< 0.0001$ , refer to Table 1). Adverse events were typically mild and transient, with the most frequent being hematuria, dysuria, pelvic pain, urgency and urge incontinence. Sexual function was preserved with no incidence of de novo, sustained erectile or ejaculatory adverse events. Further, sexual function assessments show stable erectile function (Sexual Health Inventory for Men) score and statistically improved ejaculatory (Male Sexual Health Questionnaire for Ejaculatory Dysfunction) scores. There was a low incidence of LUTS retreatment, with only 12 subjects seeking PUL or other procedure over the course of 3 years.

#### CONCLUSIONS

The Prostatic Urethral Lift offers a clinically meaningful improvement in LUTS and urinary flow that can be sustained to 3 years. The procedure is associated with low morbidity and preservation of sexual function. This randomized study protocol provides the longest follow up of PUL to date and will continue to assess durability to 5 years.

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**Table 1: Baseline, follow-up, and change in outcome measure for PUL subjects through 3 years.**

	2 Weeks	1 Month	3 Months	1 Year	2 Years	3 Years
AUA SI						
N (paired)	135	135	136	123	104	62
Baseline	22.3 ± 5.5	22.3 ± 5.5	22.3 ± 5.5	22.1 ± 5.6	21.9 ± 5.6	21.4 ± 6.1
Follow-up	18.0 ± 7.9	12.3 ± 6.9	11.2 ± 7.7	11.5 ± 7.3	12.6 ± 7.8	12.0 ± 7.3
Change	-4.3	-10.0	-11.1	-10.6	-9.2	-9.4
% Change	-18%	-44%	-50%	-47%	-42%	-43%
95% CI	-12 to -23%	-39 to -49%	-44 to -55%	-42 to -53%	-35 to -48%	-34 to -52%
p-value	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Quality of Life						
N (paired)	136	135	136	123	104	62
Baseline	4.6 ± 1.1	4.6 ± 1.1	4.6 ± 1.1	4.6 ± 1.0	4.5 ± 1.0	4.5 ± 1.0
Follow-up	3.6 ± 1.7	2.6 ± 1.7	2.4 ± 1.7	2.3 ± 1.6	2.3 ± 1.6	2.2 ± 1.5
Change	-1.0	-2.0	-2.2	-2.3	-2.2	-2.3
% Change	-18%	-42%	-47%	-51%	-48%	-50%
95% CI	-11 to -26%	-36 to -49%	-40 to -53%	-44 to -57%	-40 to -55%	-40 to -59%
p-value	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
BPH Impact Index						
N (paired)	136	135	136	123	104	62
Baseline	6.9 ± 2.8	6.9 ± 2.8	6.9 ± 2.8	6.8 ± 2.8	6.5 ± 2.9	6.4 ± 3.2
Follow-up	7.0 ± 3.5	4.0 ± 3.1	2.9 ± 3.0	2.8 ± 2.9	2.8 ± 2.9	2.5 ± 2.6
Change	0.1	-2.9	-4.0	-4.0	-3.8	-3.9
% Change	29%	-33%	-56%	-57%	-55%	-50%
95% CI	8 to 50%	-20 to -46%	-48 to -64%	-49 to -66%	-45 to -65%	-33 to -68%
p-value	0.005	< 0.0001	< 0.0001	< 0.0001	< 0.0001	< 0.0001
Peak flow (mL/s)						
N (paired)			122	102	87	39
Baseline			8.0 ± 2.4	8.0 ± 2.4	8.3 ± 2.4	8.3 ± 2.3
Follow-up			12.3 ± 5.3	12.1 ± 5.3	12.5 ± 5.4	11.3 ± 4.5
Change			4.3	4.0	4.2	3.0
% Change			64%	59%	59%	44%
95% CI			50 to 79%	43 to 74%	41 to 77%	24 to 65%
p-value			< 0.0001	< 0.0001	< 0.0001	< 0.0001

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### Appendix 3: EAC summary of BPH-6 in-process paper and LIFT 3-year follow-up abstract

#### Urolift EAC review of new evidence

16<sup>th</sup> July 2015

#### LIFT Study 3 year results (appendix 4 of consultation comments)

Urolift 3-year durability of the Prostatic Urethral Lift (Urolift) is the latest reporting from the LIFT Study by Roerhborn et al., recently presented at the American Urological Association (AUA). The 1 and 2 year results are already included in the Assessment Report and in the weighted means calculations by the EAC.

From February to December of 2011, 140 men were treated with UROLIFT in the USA, Canada and Australia. IPSS improvement was 43% at 3 years compared to sham-treated control subjects. ( $p < 0.0001$ ). Fewer patients were reported at 3 years follow-up: 104 patients at 2 years compared to 62 at 3 years for IPSS, IPSS QoL and BPHII. The abstract does not detail reasons for drop-outs at any time point.  $Q_{max}$  was measured in 87 patients at 2 years and 39 patients at 3 years follow-up. However, this does not impact the reporting, and results remain consistent with the 2 year follow-up reported. Results from all follow-up time points are shown in Table 1 Change from baseline and percentage change from baseline in each metric are presented in bold numbers for emphasis.

Adverse events were not reported in detail as part of this conference abstract. However, it is stated that adverse events were mild and transient, e.g. haematuria, dysuria, pelvic pain, urgency and urge incontinence. 12 subjects (8.6%) required a secondary procedure over the 3-year period. Sexual function results were not reported in detail as part of this abstract, but 1 and 2 year results gave a small, non-statistically significant improvement in IIEF scores. The consistency of the other results at 3 years indicates that at the least, Urolift preserves erectile and sexual function at this time point.

Table 1

	1 Year	2 Years	3 Years
<b>IPSS</b>			
N (paired)	123	104	62
Baseline	22.1 ± 5.6	21.9 ± 5.6	21.4 ± 6.1
Follow-up	11.5 ± 7.3	12.6 ± 7.8	12.0 ± 7.3
<b>Change</b>	<b>-10.6</b>	<b>-9.2</b>	<b>-9.4</b>

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<b>% Change</b>	<b>-47%</b> <b>(-42 to -53%)</b>	<b>-42%</b> <b>(-35 to -48%)</b>	<b>-43%</b> <b>(-34 to -52%)</b>
p-value	< 0.0001	< 0.0001	< 0.0001
<b>IPSS QoL</b>			
N (paired)	123	104	62
Baseline	4.6 ± 1.0	4.5 ± 1.0	4.5 ± 1.0
Follow-up	2.3 ± 1.6	2.3 ± 1.6	2.2 ± 1.5
<b>Change</b>	<b>-2.3</b>	<b>-2.2</b>	<b>-2.3</b>
<b>% Change</b>	<b>-51%</b> <b>(-44 to -57%)</b>	<b>-48%</b> <b>(-40 to -55%)</b>	<b>-50%</b> <b>(-40 to -59%)</b>
p-value	< 0.0001	< 0.0001	< 0.0001
<b>BPH Impact Index</b>			
N (paired)	123	104	62
Baseline	6.8 ± 2.8	6.5 ± 2.9	6.4 ± 3.2
Follow-up	2.8 ± 2.9	2.8 ± 2.9	2.5 ± 2.6
<b>Change</b>	<b>-4.0</b>	<b>-3.8</b>	<b>-3.9</b>
<b>% Change</b>	<b>-57%</b> <b>(-49 to -66%)</b>	<b>-55%</b> <b>(-45 to -65%)</b>	<b>-50%</b> <b>(-33 to -68%)</b>
p-value	< 0.0001	< 0.0001	< 0.0001
<b>Peak flow (mL/s)</b>			
N (paired)	102	87	39
Baseline	8.0 ± 2.4	8.3 ± 2.4	8.3 ± 2.3
Follow-up	12.1 ± 5.3	12.5 ± 5.4	11.3 ± 4.5

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<b>Change</b>	<b>4.0</b>	<b>4.2</b>	<b>3.0</b>
<b>% Change</b>	<b>59%</b>	<b>59%</b>	<b>44%</b>
<b>(95% CI)</b>	<b>(43 to 74%)</b>	<b>(41 to 77%)</b>	<b>(24 to 65%)</b>
<b>p-value</b>	<b>&lt; 0.0001</b>	<b>&lt; 0.0001</b>	<b>&lt; 0.0001</b>

### **BPH6 Trial Results (appendix 2 of consultation comments)**

The results of the BPH6 trial are now available as an in-process document. This study most closely matches the scope for this Assessment Report, as it directly compares Urolift with TURP as part of a randomised, multi-centre clinical trial. It should be noted that TURP is not defined as monopolar or bipolar in the methods, but TURP is performed “in accordance with [the sites] own standards and practices”.

The aim of the study is non-inferiority of prostatic urethral lift (Urolift) when compared to TURP, using the composite BPH6 endpoint at 12 months. The BPH6 thresholds are as follows:

- LUTS relief: Reduction of  $\geq 30\%$  in IPSS at 12 months compared to baseline
- Recovery experience: Quality of Recovery (QoR) visual analogue scale  $\geq 70$  by 1 month follow-up.
- Erectile function: Reduction of  $< 6$  points for IIEF-5 compared to baseline during 12-month follow-up.
- Ejaculatory function: Response to MSHQ-EjD question 3 indicating emission of semen during 12-mo follow-up.
- Continence preservation: Incontinence Severity Index (ISI) score of  $\leq 4$  points at all follow-up intervals.
- Safety: No treatment-related adverse event greater than grade I on the Clavien-Dindo classification system at any time during the procedure or follow up.

The EAC note that these points have sound justification and are backed by published sources.

Secondary analyses included comparison of treatment groups using:

- International Prostate Symptom Score (IPSS)
- IPSS QoL
- BPH impact index (BPH II)
- Peak flow rate ( $Q_{\max}$ )
- Post-void residual volume (PVR).
- Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD)

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The EAC note that this more closely matches what was done in prior publications and the Urolift Assessment Report.

### Results:

80 patients (45 Urolift, 35 TURP) were enrolled. Recruitment was prospective, and randomised in 10 centres, 3 countries. There were no statistically significant differences in baseline parameters except for the MSHQ-EjD function score. Results for individual metrics are shown in Table 2 below.

- Statistically significant improvements from baseline in IPSS, IPSS QoL, BPH II, and  $Q_{max}$  were observed in both Urolift and TURP
- IPSS,  $Q_{max}$ , and PVR were better after TURP than after Urolift ( $p < 0.05$ ). This is in accordance with the results presented in the Assessment Report
- IPSS QoL at 1, 3 and 12 months was not statistically significant between the two arms. Therefore, patients were satisfied with their symptom improvements regarding quality of life after both TURP and Urolift, despite a greater improvement in the TURP arm of the trial.
- Proportion of patients achieving the BPH6 recovery endpoint by 1 month was 82% in the Urolift group, and 53% in the TURP group ( $p = 0.008$ ).
- 74% of the TURP group had a catheter for more than 24 h, compared to just 45% of the Urolift group ( $p = 0.01$ )
- The average number of days to discharge was significantly lower in Urolift than TURP (1.0 vs. 1.9 days,  $p$  value not reported)
- Return to preoperative activity levels was significantly faster (11 vs. 17 days,  $p$  value not reported) for Urolift than for TURP patients
- Erectile function (IIEF-5) was preserved in both Urolift and TURP groups
- The Urolift group experienced an statistically significant improvement in average ejaculatory score (MSHQ-EjD) from baseline ( $p = 0.03$ ), but the TURP group suffered from a significant decline ( $p < 0.0001$ )

### Complications and adverse events:

- An independent external clinical events committee comprising three board-certified urologists who were blinded to the enrolment arm adjudicated on adverse events. Medical history caused unblinding for 6% of events.
- No significant differences were observed for erectile dysfunction, incontinence, or grade II+ adverse events. However, the authors note that this may be a result of insufficient study power for detection of differences in these elements of the BPH6.
- Re-intervention for failure to cure occurred in 6.8% (3/44) of Urolift and 5.7% (2/35) of TURP patients (no significant difference).
- Urolift did not cause any adverse events that required surgical intervention or revision (0%).
- Two patients (6%) in the TURP group required surgical intervention for adverse events.
- Urolift patients experienced fewer treatment-related infections (7%) than TURP patients did (14%;  $p = 0.46$ ).

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Table 2

	1 mo		3 mo		12 mo	
	PUL	TURP	PUL	TURP	PUL	TURP
<b>IPSS</b>						
<i>n</i> (paired)	44	33	42	34	41	32
BL, mean (SD)	22.1 (5.7)	22.8 (5.8)	22.3 (5.8)	22.6 (6.0)	22.0 (5.6)	22.8 (5.9)
FU, mean (SD)	10.5 (7.6)	12.9 (5.9)	10.5 (7.4)	10.8 (8.4)	10.7 (8.1)	7.3 (6.3)
Δ, mean (SD)	-11.6 (9.3)	-10.0 (7.9)	-11.7 (8.5)	-11.8 (9.5)	-11.4 (8.4)	-15.4 (6.8)
DΔ, mean (95% CI)	1.6 (-2.4, 5.7)		-0.1 (-4.2, 4.1)		-4.0 (-7.7, -0.4)	
<i>p</i> value	0.3		1		0.02	
<b>IPSS QoL</b>						
<i>n</i> (paired)	44	33	43	34	40	32
BL, mean (SD)	4.6 (1.1)	4.8 (1.2)	4.7 (1.1)	4.8 (1.2)	4.7 (1.0)	4.6 (1.2)
FU, mean (SD)	2.2 (1.8)	3.0 (1.9)	2.1 (1.5)	2.4 (2.0)	1.9 (1.6)	1.5 (1.5)
Δ, mean (SD)	-2.5 (2.0)	-1.8 (1.9)	-2.6 (1.7)	-2.4 (2.0)	-2.8 (1.8)	-3.1 (1.6)
DΔ, mean (95% CI)	0.7 (-0.2, 1.6)		0.3 (-0.6, 1.1)		-0.3 (-1.1, 0.5)	
<i>p</i> value	0.1		0.5		0.4	
<b>BPH II</b>						
<i>n</i> (paired)	43	32	42	33	40	30
BL, mean (SD)	7.3 (2.5)	7.3 (3.1)	7.4 (2.4)	7.3 (3.1)	7.3 (2.4)	7.0 (3.1)
FU, mean (SD)	4.0 (3.1)	5.3 (3.0)	2.6 (2.8)	3.8 (3.4)	2.3 (2.8)	1.8 (2.6)
Δ, mean (SD)	-3.4 (4.3)	-2.0 (3.6)	-4.8 (3.6)	-3.4 (3.5)	-5.0 (3.7)	-5.2 (3.2)
DΔ, mean (95% CI)	1.4 (-0.5, 3.3)		1.4 (-0.3, 3.0)		-0.2 (-1.9, 1.5)	



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<i>p</i> value	0.06		0.05		0.8	
<b>Q<sub>max</sub></b>						
<i>n</i> (paired)			33	21	32	29
BL, mean (SD)			9.4 (3.5)	9.2 (3.2)	9.6 (3.5)	9.5 (3.3)
FU, mean (SD)			13.6 (5.3)	22.6 (9.0)	13.6 (5.5)	23.2 (10.5)
Δ, mean (SD)			4.2 (5.0),	13.4 (9.9)	4.0 (4.8)	13.7 (10.4)
DΔ, mean (95% CI)			9.2 (5.1, 13.3)		9.7 (5.6, 13.7)	
<i>p</i> value			<0.0001		<0.0001	
<b>PVR</b>						
<i>n</i> (paired)			39	32	41	32
BL, mean (SD)			87.6 (74.1)	98.6 (84.9)	86.3 (73.2)	103.5 (89.7)
FU, mean (SD)			77.3 (74.4)	47.6 (48.7)	93.7 (156.5)	33.6 (38.6)
Δ, mean (SD)			-10.3 (56.2)	-51.0 (78.7)	7.4 (115.2)	-70.0 (79.0)
DΔ, mean (95% CI)			-40.6 (-72.6, -8.6)		-77.4 (-124.9, -29.8)	
<i>p</i> value			0.002		0.002	
<b>IIEF-5</b>						
<i>n</i> (paired)	36	20	38	27	32	27
BL, mean (SD)	20.3 (4.3)	17.6 (6.2)	20.4 (4.0)	19.2 (5.0)	20.8 (4.0)	18.6 (5.4)
FU, mean (SD)	20.9 (4.3)	17.2 (7.3)	19.7 (5.6)	18.2 (6.5)	20.7 (5.2)	17.7 (6.3)
Δ, mean (SD)	0.6 (2.5)	-0.4 (4.9)	-0.7 (5.2)	-1.0 (5.0)	-0.1 (4.7)	-0.9 (4.3)
DΔ, mean (95% CI)	-1.0 (-3.0, 1.0)		-0.2 (-2.8, 2.3)		-0.8 (-3.2, 1.5)	
<i>p</i> value	0.3		0.9		0.5	
<b>MSHQ-EJd function</b>						
<i>n</i> (paired)	36	18	38	27	32	27

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BL, mean (SD)	10.6 (2.6)	8.6 (2.5)	10.8 (2.7)	9.3 (2.4)	10.6 (2.7)	9.3 (2.1)
FU, mean (SD)	12.3 (3.4)	7.7 (5.0)	11.5 (3.5)	6.3 (4.5)	11.9 (3.0)	5.6 (4.0)
$\Delta$ , mean (SD)	1.7 (4.3)	-0.9 (5.0)	0.7 (3.9)	-3.0 (4.1)	1.3 (3.3)	-3.7 (4.1)
D $\Delta$ , mean (95% CI)	-2.6 (-5.3, 0.0)		-3.7 (-5.7, -1.7)		-5.0 (-6.9, -3.1)	
<i>p</i> value	0.03		0.0002		<0.0001	

<b>MSHQ-EjD bother</b>						
<i>n</i> (paired)	36	18	38	28	32	27
BL, mean (SD)	1.8 (1.8)	1.9 (1.7)	1.7 (1.8)	1.9 (1.5)	1.7 (1.8)	2.0 (1.5)
FU, mean (SD)	1.0 (1.3)	1.7 (1.3)	1.1 (1.4)	2.1 (1.4)	1.2 (1.1)	2.0 (1.3)
$\Delta$ , mean (SD)	-0.8 (1.9)	-0.2 (2.3)	-0.7 (2.1)	0.2 (1.5)	-0.5 (2.2)	0.0 (1.5)
D $\Delta$ , mean (95% CI)	0.6 (-0.6, 1.7)		0.9 (0.1, 1.8)		0.5 (-0.5, 1.5)	
<i>p</i> value	0.1		0.01		0.2	

### Notes on BPH6 trial results concerning the Urolift Assessment Report:

Urolift and TURP both give satisfactory improvements in symptoms and functional measurements. This agrees with the findings in the Assessment Report and the expert opinion on minimum clinical significance thresholds for each metric.

As shown in the EAC's pragmatic Urolift/TURP comparison, IPSS,  $Q_{max}$ , and PVR improvements from baseline were greater after TURP than after Urolift. However, this direct, randomised comparison shows that the difference is statistically significant, but by a smaller marginal IPSS improvement than the Assessment Report's comparison. At 12 months, Urolift delivered an average IPSS decrease of  $11.4 \pm 8.4$  (The EAC report showed an improvement of -9.22 to -11.82). The IPSS improvement after TURP was  $15.4 \pm 6.8$  (the EAC pragmatic comparison showed this as -17.34 to -19.70).

One discussion point is the use of the BPH6 metric. A benefit of this BPH6 is the multi-factorial measurements that are taken into account. Rather than symptomatic improvements alone, BPH6 factors in recovery time, sexual health and adverse events. The rationale for the selection of each point and thresholds employed is reasonable and well supported by published sources.

However, it could be argued that BPH6 is weighted more towards these other factors than symptomatic improvement (which makes up on 1 of 6 metrics) and therefore is more likely to favour Urolift.

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### Conclusions:

The 3 year LIFT Study results and the publication of the BPH6 trial are both supportive of the findings presented in the Urolift Assessment Report.

Both publications show that Urolift provides clinically significant improvements from baseline with minimal adverse events.

The 3-year LIFT Study results are very similar to that shown in the 1 and 2 year LIFT Study publications and show that Urolift continues to be effective 3 years post-operatively, with less severe adverse events. The results do not change significantly from those presented in at 1 and 2-year follow-up, as shown in the Assessment Report.

The BPH6 trial results are the only directly comparative, randomised results on Urolift vs TURP. In agreement with the Assessment Report's pragmatic comparison, it shows that TURP provides better IPSS,  $Q_{max}$  and PVR improvements than Urolift, with statistical significance in a randomised comparative study. However, this study shows that the difference in improvements between TURP and Urolift is smaller than shown in the Assessment Report comparison. The reason for this is most likely differences in the Assessment Report comparison populations at baseline, as these were separate studies with overlapping (but not necessarily statistically non-significant) population baselines. Interestingly, although Urolift resulted in a smaller IPSS improvement than seen in TURP, it gave no statistically significant differences in patients' IPSS QoL scores. This may be due to the shorter length of stay, quicker recovery times, and preservation of ejaculatory function post-Urolift, all demonstrated in the results of this trial.

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### Appendix 4: Full text of comment 30

#### PART ONE (Published in The Independent June 13th 2014 print edition)

**Along with half of all males over 50, psychosexual therapist Phillip Hodson has an enlarged prostate that plays havoc with his bladder – and his life. And as treatment can mean saying goodbye to sex, what, he asks, is a man to do?**

Nobody quite knows why the prostate grows throughout a man's life, but this irritating behaviour is a fact. Doctors suggest that if all men lived long enough, the organ would become preposterously proportioned. What's commonly called an "almond-shaped gland" doesn't exactly turn into a coconut, but over time the central core tends to thicken and swell. Since the prostate encircles the outlet to the bladder in exactly the same way that Chief Crazy Horse once surrounded General Custer, obstruction becomes inevitable. Yes, the Battle of the Little Bighorn can be refought in the discomfort of your very own perineum.

**As a result, approximately 50 per cent of men over the age of 50 acquire symptoms of urinary discomfort from what's sweetly termed "benign" prostatic enlargement or BPH. From personal experience, I suggest this enlargement is entirely malicious.**

All my adult life I've sympathised with women's reproductive plight. My various female friends have suffered from infertility, miscarriage, stillbirth, pre-menstrual syndrome, irregular periods, pelvic inflammation, endometriosis, fibroids, prolapse, breast pain, backache, stress incontinence, cystitis, vaginitis and cervicitis. I haven't even mentioned contraception or cancer. Then there's the menopause. By contrast, men's parts have escaped practically scot free. We've twiddled our thumbs in doctors' waiting rooms while our partners adopt the position. The main male worry has been to avoid erectile disorder or a random kick in the goolies.

Until now.

I finally understand in living detail why women think gynaecology is a bloody nuisance. For Nature's gender bias belatedly tilts a little backwards. Women do not possess a prostate and they should thank the Good Lady for her foresight. The irony is that men past middle age tend to "ache in the places that they used to play" (a phrase from Leonard Cohen, who at 79 probably knows). For 30 years, that seminal organ, the prostate, has given me unadulterated joy. Now I am considering having it shot.

How did I discover my BPH? Haemospermia, in a word. The first time you ejaculate blood, it's unnerving and does nothing for your social life, though fortunately on this occasion I was alone. You certainly resolve to consult a GP although the risk of cancer is low (unlike finding blood in the urine). Haemospermia in late middle age doesn't always indicate BPH, but can be general evidence that the prostate's gone on manoeuvres, though isn't about to kill you. Crazy Horse is leaving the reservation but not on the warpath.

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Your doctor will then ask endless questions about your peeing habits. Ever since I was potty-trained, urination has been pretty much off my conscious agenda. As a non-beer-drinker, I have never felt the need to unload in a hurry or, God help us, in the street. As a psychotherapist, I have sat through hours giving therapy sessions, never once thinking my bladder needed support or even counselling. Like many foolish males, I almost prided myself on not going often enough. In my catchment area, it was once a day if you were lucky.

So when I developed further symptoms of BPH it was more than annoying. From being Mr Ironsides who didn't need the loo all day long, I became Mr Desperate who was almost hyper-conscious of the nation's inhibited investment in public conveniences. In a nutshell, the problem is that you have to go when you feel you need to go, within some 20 seconds – and you'd no idea you needed to go until a moment ago, turning motorway journeys into cliffhangers of mind over bladder. Next time you sit in a few miles of M-way traffic jam, do think of the older chaps wondering whether now's the moment to break out the emergency receptacle in front of the daughter-in-law. Or buy a leg bottle.

I've always prided myself on facing facts when they're unavoidable. Nor am I typically squeamish about medical exams. I quite like operations! I've had six on my eyes, surrendered the appendix and been multi-scoped from both ends.

But yet – this fortitude also contains the seeds of its own rebellion. I refuse anaesthetics and drugs where possible; have stitches with a stick between my teeth; and cycle to and from the eye clinic for cataract and vitrectimal surgery. This may be slightly neurotic of me and I wouldn't deny the charge. But it sadly means that in the ejaculation zone, I end up just as treatment-resistant as almost every other guy. Once I'd visited London's Prostate Centre where former colleagues work and with enormous relief tested negative for cancer, I faced the recommended next steps in a spirit of revolt.

For what they said was: "Right. You have normal PSA test results; no malignant cells, no calcification, kidneys are normal, flow is reasonable but there is moderate BPH change and a large residual volume. Sleep is shallow and constantly interrupted. What we'd like you to do is swallow a pill that will shrink the prostate gland – although you may notice a drop in libido..." It was all spoken casually. But further investigation elicited further info: "This drop in libido is commonly accompanied by breast enlargement and tenderness, ejaculation problems, feeling dizzy and impotence." It was the "commonly" that got me.

Now I don't know about you, but some of my reason for living is very much summed up by trying to promote the opposite of these outcomes. I am not sure that doctors quite appreciate the nature of a choice between mere urinary embarrassment on the M25 and not being able to fuck properly while sporting pendulous boobs. Or contemplating invasive surgery.

So, personally, there it sits. Growing as I write. Irritating, but just about tolerable. To be completely fair, there are already sexual consequences. In some dire cases of BPH, men cannot ejaculate at all, or develop "retrograde" ejaculation where semen is sent backwards into the bladder. In my own case, you never can tell what trick the damn system's going to pull next. The best term for it is "sometimes saves on the laundry; sometimes doesn't".

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The over-50s are 43 per cent of the population and rising, so the chances are you know someone to whom this article applies. Despite my ironic tone (to help me manage my problem), I universally urge those with any BPH symptoms to seek medical help All the more because my research for this piece did turn up one piece of great news. Speaking to an endlessly helpful urologist, I learn there's a brand new but Nice-approved, clinically researched "Urolift" treatment ([urolift.co.uk](http://urolift.co.uk)) which, without going into all the ins and outs, offers a local op to "staple" the prostate out of harm's way so the lobes cease to bear down on the urethra and dramatic relief may ensue.

Existing remedies for the full range of prostate issues involve drugs to improve sphincter function; drugs to shrink the organ; surgery to reduce prostate size or you can try the full "Andrew Lloyd Webber". Our musical peer had his prostate completely removed in 2009 to avoid cancer, as told to the nation via Piers Morgan. It made him completely impotent.

And there's the rub. Alpha blockers can cause "dry or weakened orgasm". Shrink drugs can cause "loss of libido, impotence and abnormal or absent ejaculation". Surgery such as resection "prevents normal ejaculation in over 80 per cent per cent of patients" while removal means spending more time with your piano.

Consultant urologist Professor Tom McNicholas says: "Urolift is the only treatment for BPH that preserves men's sexual function. Now that it has gained Nice-approval, it should be routinely offered on the NHS. It improves symptoms nearly as much as surgery and more than drugs."

I don't know whether Urolift's for me, but I am certainly going to find out. If it is, I will report back to you with my findings. Because there's one thing I've learnt as a psycho-sexual therapist over the past 30 odd years: the majority of men, whether they ever go to bed with another partner again, do not wish to swallow drugs that negate their masculinity. Nor have potentially nerve-cutting surgery in their sexual heartlands. They'd prefer to keep their peckers up for as long as possible.

### **PART TWO (Published in the Independent October 3rd 2014)**

Every two hours, I have an urgent appointment en suite. For three years, I've suffered from benign prostatic enlargement (BPH) affecting most older men.

In a previous article I mocked the word "benign" but – according to one reader – embarked on a 1200-word whinge about the unfairness of father nature. With strong email support from fellow-sufferers, I explored the possibility that a new 'urolift' procedure to pin the prostate back with stainless steel clips might do the trick. I didn't fancy the alternatives – having to buy bras after swallowing emasculating pills or likely impotence following radical surgery.

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Urologist Tom McNicholas said: “Urolift is the only treatment for BPH that reliably preserves men’s full sexual function”. Hodson thought: “I’ll definitely have some of that”.

Not that I didn’t receive online food for thought. Dr Wendy from Australia tweeted that the article would help women understand why men were always grumpy. Samira Ahmed wrote that she “loved a man who explains prostate trouble with a General Custer analogy”. A Singapore medic recommended cooking the prostate with microwaves.

One osteopath told me to eschew diets involving red meat; a second told me to chew pills containing Saw Palmetto extracted from an Arkansan palm tree. Warren offered to keep my seminal ducts open by kindly sending a month’s supply of anti-microbial peptides.

An interventional radiologist endorsed ‘embolisation to cut off the prostate’s blood supply’. Nurse Terry praised a plumbing implement called “Paul’s Tubing” for safe relief on motorways. A firm called Stressnomore generously despatched an anal stimulator with electric probe to buttress my perineum provided I regularly sat on it.

A Mr Anonymous thanked me for clearing up a potential mystery in what was happening to him and “why the doctors are doing what they are doing as they haven’t been communicative”. (He added that his grandfather suffered the condition for 35 years during which he was humiliated in his job on the GLC Water and Sewage Executive by colleagues who christened him “Walter Works”).

A reader boasted of getting intense Reiki massage from his wife so he could “just about pee over a five-barred gate at the age of 68”. Finally the 82-year-old President of the General Custer Association of Great Britain ticked me off for suggesting that the US Cavalry were ever technically “surrounded” by Chief Crazy Horse at the Battle of the Little Bighorn.

My own doctor, a personal friend, said he wondered why I bothered at all since he found it perfectly normal to urinate every two hours “at our age” and, in his scientific opinion, “doctors only make things worse”. Even so he gave me a referral to the same Professor McNicholas who sank his digits and probes deep into my dilemmas and gave me a mix of statistical readouts and old-fashioned wisdom by which I was both succoured and impressed.

The good news – my prostate does NOT have an obstructive central lobe which would rule out the new stapling process. But with the organ “on the large size of what we we’d ideally like to treat” he suggested alternative interim strategies, including some changes to lifestyle, to make the object less irritated and hopefully smaller. Although I neither drink alcohol nor smoke, for that matter I don’t abuse chilli or snort turmeric, he was frankly horrified by my habit, shared with the late Tony Benn, of drinking tea whenever possible, day and night.

I genuinely had never imagined this to be a relevant issue because in our family, it’s assumed that 1) tea is a benign and holy fluid and 2) you should never trust a person who doesn’t drink it. I had my first cup at the age of three and it’s the only liquid I relish including water. In fact, the

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good Prof is of the view that ALL tea (including herbals) is a likely urinary irritant which in susceptible people contributes to prostatic inflammation and hence the ominous urge to urinate.

“Cut the quantity”, he said, “and indulge only in the mornings”. Why: “It’s the same with carbonated fluids. All such drinks produce acidic urine causing systemic inflammation – although the science isn’t completely exact”. I heeded and said: “Why should I travel to London and *not* do what your 30 years of clinical experience recommend?” to which he wearily responded: “You’d be surprised”. He laments the rise of the half-pint mug in place of the quarter-pint cup as a piece of modern idiocy leading remorselessly to increased peeing frequency.

Cycling home, it occurred to me – as if pierced by a catheter – that I had never been taught how to urinate. Potty-training we’ve all endured but why did my parents never worry about what and how much we consumed? I hold more than one university degree but on this subject have never connected inputs with outputs. I’ve even watched my own children monitor THEIR children’s urine colour to ensure all is healthy without thinking – mm – maybe the tea is taking its toll on mine? Warnings about caffeine are legion – but not “Lay off the Chamomile, Peppermint, Echinacea and Red Zinger!”

Since every man who lives long enough will possess a big prostate we’ve naturally focused on size at the price of sense. And yet if your organ is horribly irritated too, like mine, the symptoms only worsen. So for the present, I am following doctor’s orders and getting acquainted with the spa qualities of what the Wessex Water Company apparently supplies to my house through a tube. I now own a dozen redundant teapots.

If you’ve read this far, you may like to know that once my organ is more quiescent, I intend to embrace “Urodynamics”. No it’s not the EU’s future football team. A woman doctor is to insert a camera into my urethra to make a map – and give me a thumbs up or down for project Urolift. I hope to remain dignified, but you never know...

### PART THREE

Medically speaking, until you’ve found yourself strapped to a vertical bench in the hospital gown of your nightmares while female nurses insert a two-way catheter plus video attachment into your manhood, I’d suggest you haven’t lived. Especially when the procedure culminates in a perverse form of pelvic waterboarding by one of London’s leading radiologists, Dr Clare Allen... My method of coping was to revert to good old fashioned bravado and journalism: “Tell me, Dr Allen, when you went up to medical school did you imagine you’d spend the rest of your days infibulating naked men?”

Dr Allen, an expert in “Urodynamics”, or the computer-mapping of bladder capacity, responds crisply: “You’re my fifth this morning – I also specialise in all forms of urologic cancer, and I see both women and children. Now then, I am going to auto-inflate your bladder with liquid and I want you to tell me when it becomes uncomfortable. You can watch on that screen across the room”. And so saying, she did.



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Of course, true crispness runs deep: “Okay, now I’m going to continue filling and want you to let me know when you’re becoming desperate but at the same time do hold your water!”

Always patient, ever-obedient, I perform as required and am hopping from one foot to another near the end of my tether when Dr Clare pronounces that I am doing rather well. I think of course that she’s confusing my bladder with a well – but she replies that she is the doctor and she’ll make the jokes.

“Now before you empty – and don’t worry the system’s perfectly self-contained – I’m going to test your mental control by repeatedly pouring water from this tumbler into another before your eyes to see whether psychological suggestion produces a difference in outcome”.

“Ah”, I said, “that’s conceivably a mistake. You have now entered the realm of my entire family psychopathology. Having survived an older sibling plus two bossy parents, whole geologic ages could expire before I’d yield. So saying, I held my ground and liquid until her arms grew tired with pouring. Not a flicker; not a drop. Then she conceded I could pee and I watched my bladder empty on television like an office water cooler.

The result was more than a victory: Dr Allen’s research established two facts and confirmed another: 1) I possessed a strong bladder which 2) I could empty completely but 3) it was obstructed by an over-large and irritable prostate.

One week later, my consultant, Prof McNicholas, scanning these returns, concluded that a brief ‘Urolift’ operation to pin the prostate away from the urethra giving it room to ‘breathe’ using five titanium staples was not only possible it was desirable. We had the green light. I packed a small valise.

Never a hospital fan, I negotiated my way to an intensive but limited, three-hour visit at the Hertfordshire centre of medical excellence where the good Professor practises. Once I was checked in, Mr McNicholas enumerated the pre-op checks with such scrupulousness he began to sound like my financial adviser: “As you must be aware”, he said, “results can go down as well as up. Procedures like this always contain elements of unpredictability. Over the next week, the symptoms are probably going to get worse before they get better”. He was particularly emphatic on the subject of “post-surgical urinary urgency”. (And all too accurate – on the drive home, I had to emergency-stop in order to avoid one of those spillages on the M25 the traffic report is always announcing).

For anaesthesia, Prof McNic had promised some “really good stuff that would let him do anything he liked during the operation”. Reader, that sounded both encouraging and a tad Sixties. It may not have been my cleverest rejoinder but just before this sweet sedation, I asked the two anaesthetists why some surgeons and all anaesthetists were hippies. They just grinned. A clear case of pre-operative hysteria on my part which they were very good about, I hope.

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An hour later I was awake, refreshed by my legal high. A sympathetic nurse called Lindsay came to my side to teach me how to self-catheterise in case the wounds became obstructive. “You need to grasp your chap in your dominant hand and make him stand up”, she said knowingly. “No, more firmly, like this”, matching actions to words and sounding increasingly like my Satnav: – “Then insert the tube until it’s obvious you’ve reached your destination”. (Much is made of male squeamishness at the very notion of such practices. Let me say I’d rather self-catheterise than visit the dental hygienist. It is actually a doddle).

A cup of tea, a consultant’s debrief and the verdict “all’s good” was illustrated in two easy-to-gather analogies. My prostate, he said, was like Billy Bunter: – “enlarged, obstructive and rather oedematous” – whereas the bladder “rather resembled a gnarled gym instructor: muscular and trabeculated in keeping with years of over-activity”. A humbling business, this.

**NOTE: The Urolift procedure meets all current NHS and NICE treatment criteria. However, because it is a relatively new procedure in Britain, it’s my experience there may be bureaucratic delays to do with ‘coding’ in your health area. Should you find your symptoms qualify for a Urolift (and you especially wish to preserve sexual function if a benign prostate enlargement is to be surgically managed) it’s sensible to ask the GP to press your case when negotiating with the hospital authorities.**

From a pain perspective, a week of recovery on strong antibiotics plus a few paracetamol was the worst of it. Leaving the clinic, my head felt clear enough to drive but it was obviously prudent to use the tolerant chauffeuse in my life who generously offered. Next day, I felt like what I was – a man held together by five staples walking cautiously with no wish to ride a bike. I’ve possessed neither fallopian tubes nor womb but started to think this is probably what you sense when they quarrel. There were also a few moments of pseudo-cystitis but this was just my apparatus adjusting to its new reality. After three days, all discomfort eased. Even the urgency retreated. And boy did I begin to perk up.

How good is it? Well, a stream now flows where previously a brook meandered. I notice my entire torso is free from tension which was obviously triggered by the plumbing conflict. I no longer think twice about car journeys. The tedious but unavoidable and universal process of penny-spending has again returned to a wider world of choice, as though I can be re-trusted with the charge of my own waste-management company. It’s as if Tony Soprano has been demanding protection money since 2011 but finally the pressure is off: he’s been eliminated by a killer urologist in the series finale. As for sex, it is once again in working order with orgasms that DON’T vanish en route. What more could an older man wish for?

PS, the staples do NOT set off airport security alarms, and only heat up by 1.3 degrees centigrade in an MRI scanner, in case you were wondering.

*Psychotherapist, author and broadcaster Phillip Hodson is a Fellow of the British Association for Counselling and Psychotherapy*

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### Appendix 5: Full text of comment 31

Before undergoing the UroLift procedure I had been suffering BPH for many years and had put off having the traditional procedures (HoLeP and TURPS) because of the associated risks (incontinence and impotence). My enlarged prostate made my life intolerable and I therefore paid approximately £7K to have the UroLift procedure done privately in September 2014 and it has transformed my life.

When I was suffering with BPH I had all the classic symptoms; frequent visits to the loo, sometimes every 20 minutes or so, poor flow rate, very low volume of urine, and hesitancy in getting started. I monitored and recorded my fluid intake, and frequency and volume of urine. Volume was usually around 50–100mL and frequency was up to 20 times a day. When I had the urge to urinate I had to go straight away or risk losing control.

My work life had become very difficult. In meetings, I was always last in and first out and sometimes I had to leave in the middle of meetings to urinate. This was, at best, embarrassing. In the end, I simply had to tell people that I had a problem. Travelling was also a nightmare. I frequently had to drive to contractors' premises on business and most of the time the journeys were extremely uncomfortable with a constant feeling of needing to urinate, frequent stops, and at times severe urgency and stress. My BPH symptoms were one of the factors in my decision to take an offer of early retirement.

I tried several drug therapies prescribed by a urology consultant but these provided no improvement in my symptoms. I also used a herbal remedy called Saw Palmetto for a couple of years without improvement. I researched all the available surgical treatments thoroughly; Transurethral Resection of the Prostate TURPS, Greenlight laser and Holmium Laser Enucleation of the Prostate (HoLEP) but all carried the risks of incontinence and impotence.

I am a young at heart, fit and very active 66 year old and I am in a relationship. I go to the gym regularly, cycle and run. The possibility of incontinence or impotence was just too high a risk for me to take. Either of those conditions would have been disastrous to my lifestyle and wellbeing.

But I was desperate too. Despite the risks I had seriously been considering HoLEP. I had seen a consultant urologist at Addenbrookes NHS hospital and had actually set a date for a HoLEP procedure to be carried out when a friend gave me an article that had appeared in the Daily Mail in March 2014 about a new treatment called the UroLift System.

I researched the UroLift procedure and found that it didn't carry the risks of impotence or incontinence. I was also surprised to find that, although NICE had judged the UroLift procedure as safe for use in the UK, it was not available to me on the NHS. In my view UroLift is so much better for men suffering with BPH than the available NHS treatments and their associated risks. After further research I referred myself to the private Spire Cambridge Lea Hospital and had an initial consultation with a consultant urologist Mr Nikesh Thiruchelvam.

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Investigations demonstrated that I had a severely restricted urethra and I elected to have the UroLift procedure. After the procedure, initially I had some blood in my urine but this cleared within a few days. I had been advised to drink lots of water, which I did, and this helped flush out my bladder and urethra. I felt really well but unfortunately I developed a urinary tract infection after a few days. I understand that this is common following any kind of surgery on this part of the anatomy and it was cleared up very quickly with a course of antibiotics and some painkillers from my GP.

Initially, I was a bit disappointed with my urine flow rate but this improved within days, to the point now where I would say UroLift has made a remarkable difference to my life. My life is no longer dominated by being concerned about where the nearest toilet is and becoming stressed when I am unable to find a toilet. My volume has trebled, frequency has halved and the hesitation has gone completely. The urgency, which caused me so much stress, is a thing of the past. I can now leave the house and travel without any concern or stress.

I have absolutely no hesitation in recommending the UroLift procedure to every man that is suffering with the symptoms of BPH. Fortunately, I had the resources to pay for the UroLift procedure privately. Many men will not be able to do this and I feel very strongly that the UroLift procedure should be available to all men on the NHS irrespective of the resources at their disposal.