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UROLIFT FOR THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS IN A PATIENT WITH AMS 700 PENILE PROSTHESIS: THE FIRST REPORTED CASE

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ABSTRACT

The UroLift system (Teleflex Inc.) is a minimally invasive and non-ablative technique used for the treatment of male lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia. It has been introduced as an alternative to transurethral resection of the prostate (TURP) to avoid any unwanted side effects such as erectile dysfunction, hospital stay and catheterization. A 68-year old patient with bothersome LUTS and significant co-morbidities presented for consideration of UroLift to avoid the risks associated with more invasive TURP surgery. The patient had previously had an AMS 700 MS implanted penile prosthesis (IPP) inserted for erectile dysfunction refractory to medical therapy. To the authors best knowledge, there have been no reports or published literature on the use of the UroLift device to treat male LUTS in the presence of an IPP. This case report aims to present this unique case and discuss operative technique for use of the UroLift device in the presence of an IPP.

The UroLift system (Teleflex Inc.) is a minimally invasive technology developed to treat bothersome lower urinary tract symptoms (LUTS) as a result of benign prostatic hyperplasia (BPH). The National Institute for Health and Care Excellence (NICE) recommends use of the UroLift system (Figure 1) for treating LUTS in BPH.

There are many advantages of the UroLift system as opposed to transurethral resection of prostate (TURP) for BPH refractory to medical therapy. The advantages of this non-ablative and minimally invasive procedure include documented improvement in functional outcomes and avoiding common complications such as bleeding, TUR syndrome, ejaculatory and erectile dysfunction (ED) associated with TURP (1).

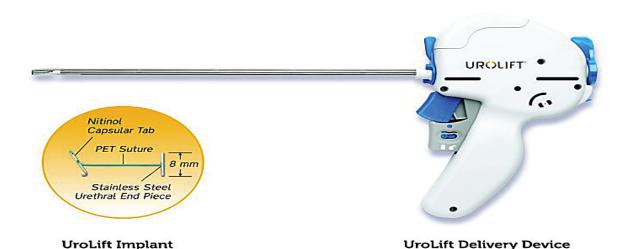
Here, we report our unique experience of UroLift for the treatment of LUTS in a patient with an inflatable penile prosthesis (IPP). To our best knowledge, there is no reported literature on the use of the UroLift device in a patient with an IPP.

BACKGROUND

A 68-year old gentleman presented to the urology outpatients department with an 18-month history of bothersome LUTS. His main complaints were poor flow, hesitancy, and nocturia of up to 4 episodes each night. There was no history of urge or incontinence, and the patient denied any recurrent urinary tract infection and visible hematuria. Examination revealed a benign feeling prostate gland. International Prostate Symptom Score (IPSS) while taking tamsulosin confirmed mild LUTS with a total of 4, his Quality-of-Life (QoL) was 3. International Index of Erectile Function (IIEF) score was 13 but interpreted with caution, as an inflatable penile prosthesis (IPP) was in situ.

Although on IPSS he did not appear to be greatly symptomatic, the patient had stopped taking his tamsulosin as he considered this to be negatively affecting his cardiac function. As a result, his LUTS deteriorated rapidly and he restarted his tamsulosin

FIG. 1 UroLift device and UroLift Implant. Images provided courtesy of Teleflex Inc.. All rights reserved.



and was keen to pursue a surgical intervention in a bid to improve his symptoms without the need to take medication. He was also reluctant to pursue TURP due to the risks of bleeding, sexual dysfunction including risk to prosthesis, and catheter. He therefore wished to explore the option for UroLift.

His past medical history was for significant cardiac disease, with ST-elevated myocardial infarct in 1998 and a cardiac arrest in 2012. The patient had an implanted cardiac device for ventricular tachycardia and severe left-ventricular systolic dysfunction. His other co-morbidities included chronic obstructive pulmonary disease, hypertension, hypercholesterolemia, non-insulin dependent diabetes and chronic kidney disease stage 3. His drug history is for amiodarone, apixaban, and ramipril.

His past surgical history is for an IPP for ED following failed conservative and medical treatments. This operation was performed in February 2008; the device used is the AMS 700 MS IPP (Figure 2).

The initial urology consultation was at his local unit that did not offer UroLift. The patient was subsequently referred to Hereford County Hospital for consideration of surgery.

ASSESSMENT AND INVESTIGATIONS FOR UROLIFT

The patient was investigated with a transrectal ultrasound revealing 45-cc prostate. A flow study

was performed that found a Qmax of 6.8 mL/s and a post-void residual of 69 mLs. A flexible cystoscopy was also performed for completeness to assess for suitability for UroLift. Cystoscopy demonstrated no urethral strictures, a long prostatic urethra with bilateral obstructive prostatic lobes, no middle lobe, and normal bladder urothelium.

Following these investigations, the patient was considered suitable for UroLift. It was considered pertinent for anesthetic assessment given his extensive cardiac history. He was deemed suitable for general anesthesia with advice to stop apixaban for 48 hours prior to the procedure. The patient was extensively counselled in accordance with the new British Association of Urological Surgeons (BAUS) guidelines for UroLift3 to include documented risks and complications. It was difficult to counsel the patient with regards to risk of damage to the prosthesis as no data was found despite extensive literature searches. The UK and US representatives were also unaware of any data or similar cases. After extensive patient counselling, the patient was happy to proceed fully aware of the unknown risk to the prosthesis.

OPERATIVE TECHNIQUE

UroLift was performed as day case at Hereford County Hospital. A 160-mg dose of gentamicin was

FIG. 2 AMS 700 Penile Prosthesis. Material provided courtesy of Boston Scientific. Copyright 2018 © Boston Scientific Corporation or its affiliates. All rights reserved.

AMS 700™

Inflatable Penile Prosthesis



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administered at induction of general anesthesia. The intra-operative findings were occlusive lateral lobes of the prostate, with the left lobe being the more occlusive. There were 3 implants to the left lobe and one implant to the right. The left-sided implants were placed at 2 cm below the bladder neck, the level of the mid prostate, and the verumontanum. The right-sided implant was placed at the mid prostate. It is important to note that no special surgical adjustments were made in consideration of the prosthesis and a "standard" UroLift technique was used. A large prostatic urethra was achieved after applying the implants (Figure 3). There were no immediate complications to the IPP.

The total theatre time (including anesthetic) was 37 minutes, the operative time was 12 minutes and the total hospital stay was 6 hours.

Post-operatively, there were no immediate concerns and the patient was discharged on the same day voiding well. Telephone consultation one week after the operation confirmed no complications to the IPP that remained fully functioning. The patient awaits follow up at 4 months post-procedure with a repeat flow study.

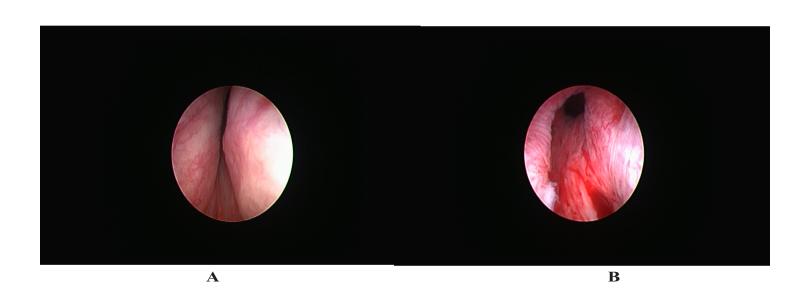
DISCUSSION

Male LUTS are defined by NICE as storage, voiding, and post-micturition symptoms.² The incidence increases with age and the most common cause is BPH. This can affect up to 30% of men over the age of 65, with Kirby et al. reporting that BPH affects 3.2 million men in the UK.⁴

The treatment for male LUTS consists of medical therapy as a first-line, this includes alpha-blockers or 5-alpha reductase inhibitors. Surgical intervention is offered when medical therapy fails, and the current gold standard is TURP surgery.

The success of TURP surgery is suggested by significant improvement in patient symptoms scores, improved flow rate studies, and reduction in post-void

FIG. 3 (A) Pre UroLift implant deployment image of the prostate demonstrating a prominent left lobe. (B) Post UroLift channel created.



residual volumes.⁶ There are however, well-documented risks associated with TURP surgery that include ED (2–10%) and incontinence (2–10%).⁷

The UroLift device (Teleflex Inc.) is a non-ablative, minimally invasive option for managing male LUTS as a result of BPH.¹ The UroLift procedure is undertaken transurethrally with either general or local anesthesia.⁸ The UroLift device works by introducing a single-use, pre-loaded delivery device through a rigid sheath under cystoscopic visualization. The delivery device then deploys permanent, trans-prostatic, Nitinol implants to retract the lobes of the prostate towards the capsule.⁸ Typically, multiple implants are used to retract the obstructing lateral lobes and create an open, continuous voiding channel¹ (Figure 4).

There are multiple advantages for use of the UroLift device over TURP surgery for LUTS resulting from BPH. UroLift is considerably less invasive and can be performed under local anesthesia, it has reduced sexual dysfunction, and has shorter operative times. As a result, the UroLift procedure can be performed as a day case procedure, which in turn alleviates bed pressures in NHS trusts.

Outcomes following UroLift are favourable and there have been multiple studies confirming that it is an effective method for managing LUTS due to BPH. Bardolli et al. Preported 11 cases of UroLift in a single-centre cohort study demonstrating a reduction in IPSS at 4 months post-operatively of -9.1 (mean pre-operative IPSS = 25.4, mean post-operative = 16.3, p = 0.02). There was also reduction in PVR volume at 4 months with a pre-operative mean of 300.1 mL to 193.8 mL post-operatively (difference = -106.3 mL, p = 0.04). Bardoli et al. also reported significant improvement in QoL scores (5.1 vs. 3.5, difference -1.6).

Further, Roehrborn et al. conducted a prospective, multi-centre, randomized, blinded sham control trial of the use of PUL for LUTS in BPH (L.I.F.T study). This study reported that use of PUL techniques offer rapid improvement in symptoms, QoL and flow rates, and that these were durable for 5 years post-operatively. There was also preservation of both erectile and ejaculatory function and that this was stable over the 5-year period. 11

BPH is also associated with sexual dysfunction that can include ED. ED is defined as the inability to achieve and maintain a penile erection adequate for satisfactory sexual intercourse. ¹² Demir et al. reported that patients with severe LUTS had significantly lower IIEF erectile function scores than those with moderate LUTS. ¹³

ED is a very common disorder, and the incidence and prevalence is high worldwide. The Massachusetts Male Aging Study reported an overall prevalence of 52% of ED in those between 40–70 years. ¹⁴ It is predicted that 322 million men will be affected by the year 2025. ¹⁵ Increasing age correlates most strongly with rates of ED. The incidence of moderate ED doubles from 17% to 34% between the ages of 40 and 70, and those with severe ED tripling from 5% to 15%. ¹⁶

This condition can severely impact a patient's QoL, and there are many medical and surgical interventions to try to manage ED. According to the EAU male sexual dysfunction guidelines,¹⁷ the use of a penile prosthesis is considered as third-line treatment option for ED, with 2 types of prosthesis available; these include malleable type or inflatable type.¹⁸

Scott et al. designed and developed the first IPP¹⁹ in 1973. Since its development, advances in materials and surgical technique have allowed for product enhancements and improved patient satisfaction.²⁰

FIG. 4 UroLift procedure and deployment of implants to increase the diameter of the prostatic urethra. Images provided courtesy of Teleflex Inc.. All rights reserved.



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There is also greater mechanical reliability of more modern implants, with Wilson et al. reporting 79.4% of implants having a reported rate of freedom of mechanical breakage at 10 years.²¹

Despite these advances, it remains well documented that reduction in penile length remains an issue post-insertion. This continues to negatively affect the IIEF satisfaction scores.²² As a result, the American Medical Service (AMS) designed and produced the AMS 700 IPP in 2006, its introduction aimed to minimize penile shortening associated with IPP surgery.²³

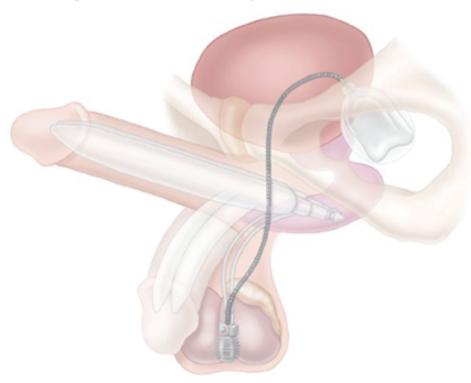
The AMS 700 MS IPP is an implantable, closed fluid-filled system used for ED.²⁴ It consists of 2 cylinders, 1 pump, and a fluid reservoir that stores fluid to expand the penile cylinders. The patient operates the pump to inflate the cylinders by squeezing the pump; this transfers fluid from the reservoir to the cylinders, in turn making the penis erect. Detumescence is achieved by deflating the cylinders by pressing a deflation button for 2-4 seconds. In doing so, fluid is transferred back into the reservoir and makes the penis flaccid²⁴ (Figure 5).

The reservoir is traditionally placed in the prevesical or retroperitoneal space. The initial steps for introduction of the reservoir are the same. This involves a transverse infra umbilical incision and the pubic tubercle is used as a landmark for gaining entry into the superficial inguinal ring. Commonly, in men who have had no prior pelvic surgery, the reservoir is placed posterior to the transversalis fascia. As the images suggest, there is close proximity of the working elements of the IPP to the operative fields for UroLift (see Figure 2). This may result in damage to the IPP when using the UroLift device.

CONCLUSION

We report our experience of using the UroLift device in the presence of an inflatable penile prosthesis to manage LUTS caused by BPH. To our best knowledge, there is no published literature on surgical technique for this unique case. By using the standard UroLift technique, we surmise that it is safe to perform the UroLift procedure in such cases following appropriate patient counselling on the risks to the prosthesis.

FIG. 5 AMS 700 MS penile implant. Material provided courtesy of Boston Scientific Copyright 2018 © Boston Scientific Corporation or its affiliates. All rights reserved.



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FUNDING AND CONFLICT OF INTEREST

There was no funding received for the production of this manuscript. There was no conflict of interest from the authors involved.

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