

# An adjustable continence therapy device for treating incontinence after prostatectomy: a minimum 2-year follow-up

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## OBJECTIVE

To evaluate the efficacy and safety of the ProACT™ (Uromedica, Inc., MN, USA) balloon device, an alternative for the surgical management of incontinence after prostatectomy.

## PATIENTS AND METHODS

The initial patients who received this device at our institution were evaluated, using urodynamics at baseline and at 6 months.

Perioperative variables were recorded and pad usage, volume adjustments, an estimate of Incontinence Quality of Life (I-QoL) and adverse events were recorded at baseline, and 1, 3, 6, 12 and 24 months after surgery.

## RESULTS

In all, 37 patients were treated on this protocol between November 2001 and March 2005. Of these, 30 had had radical prostatectomy and seven holmium laser enucleation of the prostate. The mean (range) pad usage decreased from 2.81 (1–12) at baseline to 0.7 (0–4) pads at 24 months, and the I-QoL increased from 49.7 (4.5–77) to 81.3 (13.6–100) over the

same period. At 24 months, 62% of 34 men were pad-free and 81% required one pad or less. Bilateral explantation was required in three patients (11%) for infection (one) and balloon migration (two). All other adverse events were mild and transient.

## CONCLUSIONS

The ProACT balloon device is an acceptable therapy for the surgical management of incontinence after prostatectomy.

## KEYWORDS

male urinary incontinence, prostatectomy, continence device, ProACT™

## INTRODUCTION

Incontinence after prostatectomy due to sphincteric weakness can significantly compromise the quality of life (QoL) of affected patients [1–4]. The current standard for the surgical treatment of this condition is placing an artificial urinary sphincter (AUS) which, despite confirmed efficacy, still has ongoing concerns about cost, device infection, durability, mechanical failure and urethral erosion [5–7]. Other less invasive procedures, including slings and injectable agents, have been, or are currently being investigated [8–12]. Suboptimal efficacy and the lack of a durable effect with injectable peri-urethral bulking agents is well documented [13,14].

The ProACT™ device (Uromedica, Inc., MN, USA) consists of two silicone balloons placed at either side of the bladder neck. Each balloon is attached to a titanium port placed

in the scrotum, aiming to achieve continence through static extrinsic compression and support of the urethra. The device has several potential advantages over both the AUS and the male sling. First, circumferential compression (as occurs with the AUS) is avoided, thus reducing the risk of urethral atrophy and device erosion. Second, the adjustable nature of the balloons means that volumes can be titrated in an outpatient setting to achieve optimum efficacy (continence) and minimize complications (urinary retention). Whilst it is possible to adjust certain sling techniques, this requires surgical re-intervention. Third, mechanical failure (apart from balloon deflation) cannot occur. Fourth, placing the device is relatively straight-forward, as is removal.

Here we report the initial prospective experience with the ProACT device using a standardized protocol at our institution.

## PATIENTS AND METHODS

After obtaining Regional Ethics Committee approval, patients who had had a prostatectomy >1 year previously and who in whom conservative therapy had failed were assessed for their eligibility for the study. All patients must have had stress urinary incontinence confirmed by urodynamics and to require regular pads. Patients who had had radiotherapy within the last 6 months were excluded, as were patients with an overactive or atonic bladder at urodynamics, untreated urethral stricture disease, previous anti-incontinence surgery, active UTI, abnormal bladder pathology or bleeding disorder. Baseline evaluations included a detailed history, including medication and daily pad usage, physical examination, video-urodynamic measurement including cystometry, abdominal leak-point pressure (ALPP) and an estimate of postvoid residual urine volume (PVR), cysto-urethroscopy, an

Incontinence QoL (I-QoL) questionnaire, and urine analysis. Key variables were re-assessed at 1, 3 and 6 month intervals after surgery, and then annually. Perioperative data and adverse events were recorded.

The ProACT device consists of two adjustable silicone balloons positioned on each side of the urethra at the level of the anastomosis in radical prostatectomy, or adjacent to the prostatic apex after TURP [15–19]. The tip of each balloon has a radio-opaque marker that can be easily visualized under fluoroscopy to confirm the correct position. Each balloon is connected via a conduit to a titanium injection port sited in subcutaneously in the scrotum, which enables percutaneous adjustment after surgery in an outpatient setting. The balloons must be filled with an isotonic solution to minimize osmotic volumetric fluctuations. It is recommended to use an isotonic contrast medium and water solution, which enhances fluoroscopic viewing. Each balloon can be inflated to a maximum of 8 mL. The ProACT device is available in two lengths, 12 and 14 cm; the choice of length is predicated on patient anatomy (i.e. the distance from bladder neck or membranous urethra to perineal edge), but should take into account the scrotal volume and perineal thickness.

The patient is prepared and placed in the lithotomy position under general or spinal anaesthesia. After cystoscopy, the rigid cystoscope sheath is retained to provide tactile feedback during percutaneous dissection and to clearly demarcate the urethra. The bladder is filled with radiographic contrast medium and fluoroscopy used to visualize the bladder and bladder neck. A 2-cm transverse incision is made in the perineum and a haemostat is used to puncture the pelvic floor to create a para-urethral tract. To dilate the space at the level of the sphincter, a specially designed blunt trocar and cannula is passed carefully using a rotating action. Fluoroscopic imaging assists in determining a para-urethral tract 0.5–1 cm lateral to the urethra, and enabling the tip to reach the urethral anastomosis at the bladder neck after prostatectomy, or the membranous urethra in those patients with a prostatic remnant. A purpose-built dilating forceps (tissue-expanding forceps; Fig. 1) and fluoroscopy are then used to correctly position the device and to avoid bladder or urethral perforation. The correct anterior-posterior plane at the bladder neck or the level

of the membranous urethra can be further ascertained by gentle manipulation of the cystoscope, showing simultaneous movement of the trocar and cannula. The ProACT devices (Fig. 2) are 'primed' to remove any air and the lubricated device delivered via the U-shaped channel. Once the balloon is in the correct position, the balloon is inflated using a non-coring needle, injecting 0.5–1 mL into the port. Each balloon is only inflated to 0.5–1 mL during surgery to reduce the risk of migration during or soon after surgery. The position is verified by fluoroscopy and the procedure repeated on the contralateral side (Fig. 3). A urethrogram can be taken to further identify the correct position of the balloons relative to the urethra. The ports are buried superficially in the sub-dartos fascia in the posterolateral wall of the scrotum, which enables percutaneous adjustment after surgery. A 16 F urethral catheter is inserted overnight and patients are discharged the following day, after a trial of voiding. One week of antibiotic cover is used. A pseudo-capsule forms around the balloons and 4–6 weeks later further adjustments can be made if total continence has not been achieved. It is generally recommended to allow 4 weeks between adjustments to fully allow expansion of the tissue space and the subsequent clinical effect. Adjustments should be limited to 1 mL per balloon per visit, to minimize pain and the risk of migration. The balloons can be deflated earlier if the patient develops voiding difficulties. Some patients might be initially continent because of postoperative swelling but usually become incontinent after the oedema has subsided.

## RESULTS

In all, 37 eligible patients (November 2001 to March 2005) treated at one institution were evaluated on this protocol. All treatments were administered by one surgeon (P.J.G.). The patient demographics are detailed in Table 1. The mean (range) time since the patients' original prostate surgery was 30.8 (12–105) months. All patients had undertaken pelvic floor muscle training before enrolment, with no success. The mean (range) follow-up since placing the device was 51.5 (24–60) months. Four patients withdrew from the study, two within 6 months due to migration (one) and infection (one); both of these patients had successful implantation of an AUS. One patient elected to discontinue the follow-up after 6 months due to recurrent prostatic carcinoma. At his last review his

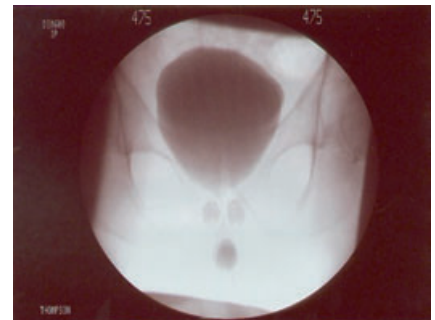
FIG. 1. The sharp-tip trocar sheathed in the U-shaped cannula; blunt trocar and tissue-expanding forceps.



FIG. 2. The inflated and deflated ProACT devices, showing the titanium port for adjustment, and the removable push wire.



FIG. 3. Fluoroscopic image showing the devices in place.



continence was better than at baseline. One patient moved out of the area and was unable to return for follow-up, although was continent at his last visit. All patients were operated under general anaesthesia; the mean operative duration was 26 (13–48) min, with minimal blood loss (<50 mL) in all. The mean fluoroscopic imaging time was 2.2 min. Most (31) patients had 14-cm devices placed, with the remaining six receiving 12-cm devices. A mean of 1.98 (0.5–3) mL of isotonic fluid (radiographic contrast medium mixed with water) was placed into each balloon at surgery. After surgery, oral analgesia alone, as necessary, was available, with no patients requiring medication after discharge. Two patients failed a trial of catheter removal on

Characteristic	Mean (range) or <i>n</i>	<b>TABLE 1</b> <i>Baseline patient demographics</i>
Age, years	69.9 (59–79)	
Time from initial prostate surgery, months	30 (12–105)	
Original surgery		
Radical retropubic prostatectomy	21	
Radical perineal prostatectomy	9	
Holmium laser enucleation prostate	7	
Previous treatments (salvage radiation)	4	

Time	No. of patients	Mean (SD, range) or (SD)		<b>TABLE 2</b> <i>Pad usage and I-QoL after surgery, compared to baseline; all differences were significant at <math>P &lt; 0.05</math></i>
		No. of pads	I-QoL	
Baseline	37	2.81 (2.06, 1–12)	49.7 (19.3)	
Months after surgery				
3	37	1.63 (1.53, 0–5)	70.1 (21.4)	
6	34	0.96 (1.27, 0–4)	75.4 (20.7)	
12	34	0.80 (0.94, 0–4)	81.4 (15.3)	
24	33	0.75 (0.86, 0–4)	80.2 (18.1)	

Months	Mean (range) volume/implant, mL	Number of adjustments, <i>n/N</i>	<b>TABLE 3</b> <i>The ProACT adjustment schedule</i>
At implantation	1.98 (0.5–3)		
Months after			
1	2.7 (1–4)	33/37	
3	3.5 (1.5–5.5)	30/34	
6	4 (1.5–6)	23/34	
12	4.5 (1.5–7.5)	13/34	
24	4.6 (1.5–7.5)	11/33	

**TABLE 4** Video-urodynamic data at baseline and 6 months, and voiding uroflowmetry results at baseline and 12 months

Variable	Baseline	6 or 12 months
<b>Urodynamic</b>		
No. of men	37	32
No leakage, <i>n</i>	0	11
Mild (ALPP >100 cmH <sub>2</sub> O)	9	15
Moderate (ALPP 60–100 cmH <sub>2</sub> O)	21	6
Severe (ALPP <60 cmH <sub>2</sub> O)	7	0
<b>Voiding uroflowmetry, mean (range):</b>		
Maximum flow rate, mL/s	16.8 (4–21)	18.4 (6–36)
Voided volume, mL	178.4 (30–455)	303.7 (79–538)
PVR, mL	6.7 (0–70)	12 (0–120)

the first day after surgery and required delayed removal at 5 days, which was successful.

Pad usage and the I-QoL score are described in Table 2; the pad-free rate at 2 years was 62%, with 81% of men using one pad or less at that time. The pad use and I-QoL scores were significantly better than at baseline at all

sample times after surgery ( $P < 0.05$ , paired *t*-tests).

Details of balloon adjustments are listed in Table 3; 89% (33 men) required one or more adjustment with a mean of 3.3 (0–7) adjustments being required at 2 years. Most adjustments were made within the first

6 months. Only one patient required removal of 1 mL from each balloon for urinary retention, and no patient had >1 mL added at any one office visit.

The video-urodynamic and voiding uroflowmetry data are detailed in Table 4; there was one intraoperative bladder injury (3%) which was successfully treated conservatively with an indwelling catheter placed for 7 days. Wound infections occurred in three patients (8%), requiring unilateral removal in two and bilateral removal in one. The patient who required bilateral removal went on to have an AUS implanted; one of the other patients had a successful single balloon re-implantation, and the other remains continent with a single balloon. Device migration and subsequent bilateral removal occurred in two patients (5%). Overall there were two patients (5%) requiring unilateral removal and three requiring bilateral removal (8%). Self-limiting minor complications included transient pain (six), urinary retention (two), UTI (two) and de-novo urgency (two).

## DISCUSSION

The AUS is effective and durable, but a recent review of 270 cases described an infection rate of 5.5%, urethral erosion in 6%, urethral atrophy in 9.6%, mechanical failure in 6% and a revision or removal rate of 27.1%. Overall, only 35% of patients become pad-free in the long term [20]. The idea of a pump in the scrotum is aesthetically unacceptable in some patients, as is the need to manipulate a device to void; the AUS is also expensive. While success rates of the AUS have been quoted at >80%, most of the reports on the AUS come from centres of excellence with large volumes of cases; these results might not be applicable to those achieved in centres with a smaller caseload.

Various alternatives are currently being investigated as possible alternatives to the AUS. The lack of efficacy and durability of injectable treatments is well documented [21,22]. The bone-anchored male bulbar-urethral sling has recently been promoted as a potentially effective device for the treating incontinence after prostatectomy, by increasing static compression of the urethra. However, a significant proportion of reports on the male sling comprises studies with few patients, and with an inadequate duration of follow-up. For example, a recent study by Fassi-Fehri *et al.* [23] investigating the

InVance bulbourethral sling, described an overall success rate of 74.5%, but a median follow-up of only 6 months. Studies with a longer follow-up describe a pad-free rate of 37–67% [24,25]. It is possible that in the long term, erosions, failure and other complications might approximate those with the synthetic female slings. Although purported to be less invasive than inserting an AUS, the male sling still risks urethral erosion, osteitis pubis, refractory urinary retention requiring re-operation and chronic perineal pain.

The ProACT device has potential advantages over both the AUS and its alternatives; it is a simpler device than the AUS and therefore less likely to fail mechanically, while being adjustable means that it is less likely to cause refractory obstruction to voiding and urinary retention than placing a male bulbar-urethral sling.

The present study, which essentially documents the early experience from one of the initial institutions involved with the male device, shows that the ProACT is an effective treatment for incontinence after prostatectomy. Of men with devices remaining at 2 years, 82% were using one pad or less, 61% were pad-free, and there were statistically significant reductions in overall pad use and improvements in I-QoL scores in the remainder. The adjustable nature of the balloons means that a simple replenishment of the balloon volume can overcome any minor deterioration in the patient's level of continence, as might be seen with tissue compression or atrophy, which is not possible with other treatments.

In the present study, two patients had device migration (these were the first treated and it was probably due to an over-inflation at the time of implantation) and three had infection (due possibly to poor adjustment technique after surgery) necessitating device removal. Intraoperative balloon inflation is now limited to 1.5 mL and particular care is taken with asepsis during implantation and adjustment after surgery. Importantly, removing the ProACT is straightforward compared to removing an AUS or male sling, and can be done under local anaesthesia in the office if necessary. Although only four of the present patients received radiotherapy, with no adverse events at 2 years, it appears likely that there will be a higher incidence of complications in this subgroup. However,

more recent experience suggests that ProACT is an acceptable option in this subgroup, with success in many. Compared with other reports of the ProACT, the incidence of significant complications (infection, migration, perforation) in the present study compares favourably. The series of Hubner and Schlarp [15,17], which also involved their early experience, described a revision rate of nearly 30%, intraoperative perforation rates of 4.7%, postoperative erosion rates of 6.4% and device removal due to lack of response in 26%. The incidence of these complications reduced with increased surgical experience, as we also noted. Whilst the early overall morbidity is not insignificant, the device can be removed easily in the office, and reimplantation was simple and not impaired by previous device placement.

In our practice, there are significant cost advantages for the ProACT over both the AUS and prosthetic male sling. The ProACT device is less than half the cost of the AUS, and operative costs are less because the surgery is quicker and minimally invasive.

In conclusion, placing the ProACT device(s) is a minimally invasive procedure and can be considered a viable alternative to the AUS or male sling for treating incontinence after prostatectomy.

#### CONFLICT OF INTEREST

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**Abbreviations:** (I-)QoL, (Incontinence) quality of life; AUS, artificial urinary sphincter; PVR, postvoid residual urine volume; ALPP, abdominal leak-point pressure.

## EDITORIAL COMMENTS

The authors report the 2-year follow-up of a relatively recent, minimally invasive method of treating men with incontinence after prostatectomy. The ProACT is a device introduced through a perineal mini-incision, under radiographic and cystoscopic guidance. The authors are to be praised for their honourable reporting of the morbidity of the technique. The frontier of surgical treatment of incontinence after prostatectomy is safeguarded by the time-honoured AUS. Cost, mechanical malfunction and urethral erosion (3.5–23%), and urethral atrophy (6.6–19%) are the major shortcomings. The development of the male sling, whether placed totally via the perineal or combined perineal/retropubic route, yielded a multiplicity of techniques with a wide range of morbidity and cost. Many reports have an increasingly longer follow-up. The present study is intended to confirm the safety and efficacy of the ProACT. My concerns are primarily morbidity and cost effectiveness compared with its peers. In this report, one patient had bladder perforation, five (15% of 33 who completed the follow-up) required device removal because of infection or migration (two migration, three infections; one needed bilateral and two unilateral removal). Moreover, two patients had erosions and one had device failure after 2 years of follow-up (the endpoint of this report). So the morbidity of a presumably minimally invasive ProACT is notable.

A 62% pad-free rate at 2 years would be considered acceptable by most clinicians treating incontinence after prostatectomy, but simple techniques of the male sling would yield a similar outcome at a similar follow-up. However, for cost combined with efficacy, the authors considered the ProACT to have a significant cost advantage over the AUS and prosthetic male sling ('less than half the cost of an AUS'). This might hold true for the AUS but certainly is not so for male slings, as some of them would cost less than a 10th of an AUS.

Time and more cases will decide the place of the ProACT in the management of incontinence after prostatectomy, because to date it is not so good.

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This is a prospective, single-institution cohort study of 37 men with incontinence after prostatectomy who were treated with the ProACT balloon device, a modification and improvement of the original Kaufman procedure described 30 years ago. Most men (81%) were incontinent after prostatectomy, and in the remainder, after HoLEP. At 2 years of follow-up, 81% of the men required one pad per day or less. We applaud the authors for their pursuit of other options for treating this condition in an era when the AUS is considered the reference standard, and the male sling is often being used as the default option, as periurethral injectables such as collagen are falling from favour for male stress incontinence. The AUS has long been considered the standard treatment for incontinence after prostatectomy, with variable cure rates (one pad per day or less) of 69–90%. Based on two recent studies [1,2], limitations of this procedure include its invasiveness, potential for mechanical failure (6–25.2%), infections (5.5%) and urethral erosion (6–17.6%) [1,2]. In part, because of these limitations, the male sling was re-introduced as a minimally invasive alternative for treating incontinence after prostatectomy earlier this decade. Initial descriptions of the revised male sling involved the use of a polypropylene mesh affixed to the ischiopubic rami using bone anchors (in 21 men) [3]. The cure rate for this procedure was 90% (one pad per day or less) at a mean follow-up of 12 months, with no infection, pain or de novo voiding symptoms after surgery. With a longer follow-up ( $\geq 1$  year), there were continued favourable results [4], but more recently infection, erosion and chronic perineal pain were reported [5]. The modified 'out-in' transobturator approach (Advance, AMS) was subsequently introduced, and although no prospective series have yet been reported, it might have a lower complication rate in our experience.

The ProACT device is minimally invasive and, although it was placed under general anaesthesia in this series, the authors claim it can be placed or revised in the office. This represents a clear advantage over existing techniques. Without circumferential compression, there might be less urethral erosion or atrophy than with the AUS, leading to lower explant or revision rates. In addition, the balloons can be deflated if there is urinary retention, or inflated if there is continued activity or stress-related leakage. Therefore,

placing the ProACT device and revision (13.5% in this series) of the device is fairly straightforward, with minimal patient morbidity. The wound infection rate was higher (8.1%) than that described for the AUS or sling, and might be related to differences in preoperative preparation. Achieving a cure might be comparable to the AUS and male sling, based on this contemporary series. However, some important questions remain. How will patients react to the possibility of multiple adjustments over time? Also, does this need for adjustments represent a disadvantage of balloon therapy when compared with other treatments for incontinence after prostatectomy? As we continue to develop and refine the treatment options for this condition, we would encourage researchers to routinely include

pad weights before and after surgery, validated quality-of-life assessment and patient-determined estimates of their outcome, such as the Patient Global Impression of Improvement (PGI-I). We look forward to a longer follow-up of this procedure in the future.

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