

# Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy

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## OBJECTIVE

To evaluate the safety and efficacy of a new minimally invasive urological implant for incontinence after prostatectomy.

## PATIENTS AND METHODS

The adjustable continence therapy device (ProACT™, Uromedica, Plymouth, MN, USA) consists of two balloons placed via a perineal approach bilaterally at the bladder neck in patients after prostatectomy. Titanium ports, attached via discrete tubing to each balloon, are placed in the scrotum, allowing for separate volume adjustments of the balloons at any time during and after surgery. Changes in a quality-of-life questionnaire (I-QoL), pad usage and a subjective continence grading score were assessed in 117 consecutive men after implanting the Pro-ACT, at baseline and at 1, 3, 6, 12 and 24 months.

## RESULTS

After a mean (range) follow-up of 13 (3–54) months and with a mean of 3 (0–15) adjustments, 67% of men were dry, using at most one 'security' pad daily; 92% were significantly improved, and 8% showed no improvement. The I-QoL score improved from a median of 34.7 to 66.3 after 2 years (42 men;  $P < 0.001$ ), the daily pad count decreased from a mean of 6 (1–24)/day to 1 (0–6)/day at 2 years ( $P < 0.001$ ). Continence achieved at  $\leq 6$  months after implantation through incremental adjustment remained durable at  $\geq 2$  years in most patients. There were complications during and after surgery in 54 patients, mostly minor and decreasing with increasing expertise, primarily reflecting the development and refinement of the new surgical technique and its instrumentation. Re-implantation for complications was required in 32 patients, with a 75% success rate.

## CONCLUSIONS

The ProACT peri-urethral prosthesis produces durable outcomes equivalent or better than other minimally invasive treatments for incontinence after prostatectomy. Its unique design allows for easy adjustment after surgery to achieve the desired urethral resistance, with no further surgical intervention, thus allowing for an optimum balance between voiding pressures and continence. The promising results reported here suggest that this may be an appropriate, effective and durable first-line treatment to offer men with stress urinary incontinence after prostatectomy.

## KEYWORDS

prostatectomy, stress urinary incontinence, genitourinary sphincter artificial, quality of life

## INTRODUCTION

Incontinence after radical prostatectomy (RP) is a very distressing complication for both the patient and the treating urologist [1]. Reports of the rate of such incontinence vary considerably, occurring in  $\approx 21\%$  of patients at 3 months after RP [2]. Studies based on questionnaires completed by the patient at home reveal high rates of emotional distress related to incontinence [3]. It is important to distinguish among these reported values, which might reflect the total percentage of men who report varying degrees of stress urinary incontinence after RP, many of whom will recover over time with numerous rehabilitation methods, and those men who proceed to have total, intractable incontinence that does not respond to any noninvasive rehabilitation programme. The

values reported for the latter, more seriously affected group of patients who at 1 year after RP report being moderate to severely incontinent, also ranges widely, at 0–8% [2,4]. Nevertheless, these values are markedly lower than the numbers of men reporting some degree of stress incontinence within the same summarized study cohorts. The reasons for the onset of incontinence after RP have been examined by numerous authors [5–8], with the most frequent cited causes being either a combination of urethral sphincter damage and detrusor instability, or urethral sphincter damage alone [4]. While detrusor instability can be managed medically, urethral sphincter damage usually requires a surgical approach to adequately address the problem.

Many efforts have been made to treat this condition surgically, including the use of

minimally invasive techniques such as the injection of various bulking agents [9], e.g. glutaraldehyde cross-linked (GAX-) collagen, 'free' silicone particles (Macroplastique™), carbon beads (Durasphere™) and non-animal stabilised hyaluronic acid, detachable, fixed volume peri- or transurethrally inserted microballoons, and more elaborate surgery like implanting an artificial urinary sphincter (AUS), which is still considered to be the 'gold standard' [10]. In recent years, various male bulbar-urethral sling procedures using various fixation techniques, including bone anchors, have also been introduced, with varying rates of success [11,12]

Except for the AUS, which attempts to mimic the physiological function of the external sphincter, all current approaches to solving intractable male incontinence are directed at

increasing outlet resistance or resistance to increases in abdominal pressure, either by attempting to enhance residual sphincteric function through 'bulking', or by attempting to compress the urethra more proximally, usually at the level of the bulbar urethra, as is the case with the recently reported bone-anchored male bulbar urethral sling (InVance™, American Medical Systems, Minnetonka, MI). Adjusting the outlet resistance to establish continence in the individual without overly challenging the underlying detrusor function is desirable, as this function might alter in the long term with ageing, detrusor activity or other factors, in response to increased outlet resistance.

In this report we describe our initial experience with an entirely new technique that is designed to produce continence through increased outlet resistance, but which also allows for incremental postoperative adjustment via percutaneous volume changes in the implant, so as to accommodate any individual responses to this altered outlet dynamic.

## PATIENTS AND METHODS

The ProACT™ (Uromedica, Plymouth, MN, USA) implant is constructed from silicone elastomer, similar to the materials used in the manufacture of the AMS AUS. Each Pro-ACT implant consists of a silicone balloon attached to a titanium port (re-injectable) via a short length of tubing (Fig. 1). Two implants are supplied in a kit and are required for each patient. With peri-urethral placement, each balloon is directed to either side of the bladder neck, just distal to the area of anastomosis of the remnants of the bladder neck and of the external sphincter, via a perineal approach. The re-injectable titanium ports are sited in the scrotum, under the dartos fascia, allowing for future percutaneous access to the implanted injection ports, using a fine-gauge needle. This allows the surgeon or physician to adjust the volume of the balloon after implantation, thus making it possible to adjust the level of obstruction needed to keep the patient dry but still free from developing retention. During this prospective study, the manner in which the 'generation I' balloons were bonded to the tubing that connects to the injection port was called into question after several balloon leakages were discovered. The 'generation II' balloons, introduced after the

first 50 patients had been implanted, were re-engineered to strengthen the way in which they are attached to the tubing during manufacture. Similarly, design modifications to the dedicated instruments used for insertion were made, to facilitate placing the implantable balloons during the first 50 patients.

Between September 1999 and July 2004, the ProACT system was implanted in 117 prospectively enrolled men. Of these, 110 reported incontinence after RP, six were incontinent after TURP and one was incontinent after radical cystectomy and an orthotopic neobladder. Table 1 details the numbers and percentages of men implanted with the ProACT device after the various approaches to RP, TURP and cystectomy. Of the 117 men implanted with this device, 78 had previously been treated for incontinence using other forms of management, including pelvic floor training and electrostimulation, and the use of injectable bulking agents including Macroplastique, Durasphere and GAX-collagen. All 117 patients were evaluated before surgery by medical history, physical examination, daily pad count and urodynamic investigation to assess bladder capacity, compliance, voiding pressure and Valsalva leak-point pressure. A validated quality-of-life questionnaire (I-QoL) [13] was used to evaluate all patients. Flexible cystoscopy was used to assess the presence of any urethral or anastomotic strictures. The evaluation after the implant included a medical history, physical examination, pad counts, I-QoL and overall assessment using the continence grading score described by Stamey [14] at 3, 6, 12 and 24 months. Cystoscopy was also used at time of implant and afterwards if clinically indicated.

The statistical evaluation followed the intention-to-treat strategy based on the observed-cases technique. The statistical analysis was exploratory in the context of the pivotal and early nature of this research, with a two-sided 5% level of statistical significance. Significant differences between baseline and follow-up for the continuous variables (I-QoL and pad use) were assessed by paired, two-sided, continuity-corrected, Wilcoxon signed-rank tests. In the absence of a validated incontinence score specifically for men the Stamey score results were used as contingency tables for 'cure' (a score of 0) vs some stress urinary incontinence symptoms (scores of 1, 2 or 3) between baseline and the

FIG. 1. The ProACT™ periurethral prosthesis, inflated and deflated, consisting of balloon, tube, titanium port and introducer.

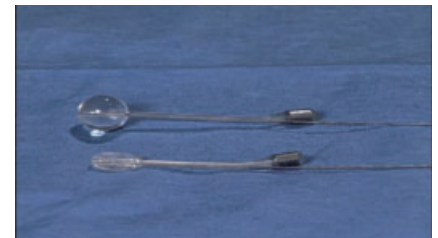


TABLE 1 The primary cause and period of incontinence before surgery, and the previous treatments, in the 117 men

Group	n (%)
<b>Primary cause</b>	
Retropubic RP	88 (75)
Perineal RP	16 (14)
Laparoscopic RP	6 (5)
TURP	6 (5)
Cystectomy	1 (1)
<b>Period</b>	
<1 year	15 (13)
1–2 years	41 (35)
>2 years	61 (52)
<b>Treatment</b>	
Physical exercise	78 (67)
Macroplastique	28 (24)
Collagen	1 (1)
Durasphere®	1 (1)
Urovive®	1 (1)
Urethrotomy	19 (16)

relevant follow-up. McNemar's chi-squared test was used to determine the significance of these contingency tables.

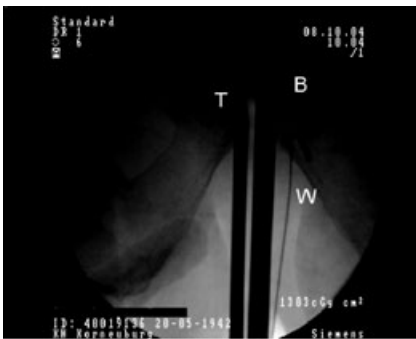
## OPERATIVE TECHNIQUE

Under general anaesthesia the patient was placed in a lithotomy position and prepared and draped in sterile fashion. A rigid cystoscope was inserted under direct vision, and 50 mL of contrast medium instilled to visualize the bladder neck. Leaving the cystoscope sheath in place with the obturator, a 1.5-cm horizontal skin incision was made at the perineum; using a Kelly clamp, the urethra and the descending pubic ramus were palpated and bluntly dissected under fluoroscopic control. The pelvic floor was then perforated next to the urethra in the cephalad

FIG. 2. Penetration of the pelvic floor with a Kelly clamp under fluoroscopic control; K, Kelly clamp perforating the pelvic floor; C, cystoscope sheath, the arrow indicating the level of the pelvic floor.



FIG. 3. Applying the balloon (B) using the trocar (T) at the level of the bladder neck (W, wire of the introducer).



and lateral direction (Fig. 2). Using a specially-designed insertion instrument combining a trocar and a 'U-shaped' cannula to create a suitable tract under fluoroscopic guidance, the two balloons were then positioned peri-urethrally above the pelvic floor, with the cystoscope sheath functioning as a parallel guide for correct placement (Fig. 3). The balloons were then filled with 1–5 mL of contrast medium and sterile water mixed to an isotonic medium, and a urethrogram was taken to confirm the correct position of the device (Fig. 4). Finally, the two ports were brought into a subcutaneous scrotal position to allow future percutaneous needle puncture and volume adjustment after surgery (Fig. 5). The incision was closed with a 4/0 resorbable suture and a 12–14 F Foley catheter inserted overnight.

## RESULTS

In all, 117 patients had the ProACT implanted secondary to stress incontinence after

FIG. 4. A retrograde urethrogram showing the resistance caused by the balloons.



FIG. 5. Percutaneous adjustment of the balloon volume.



prostate surgery (median age at implantation 70 years, range 50–89). The median (range) period of incontinence was 33 (3–180) months, and 87% had been incontinent for >1 year before implantation. Details of the patients' preoperative status, time to implant and previous unsuccessful treatments are shown in Table 1. Preoperative urodynamics showed a normal bladder capacity (>200 mL) and compliance in 107 (91%) of the 117 patients, while 10 (9%) had reduced bladder capacity and compliance. Twenty-seven men had had previous surgical treatment for anastomotic stricture, while eight had a relative stricture of the bladder neck with no previous treatment. The ProACT implantation took 14–56 min, and the last 20 operations all took <25 min as experienced increased. The surgery was uneventful in 96 men but there were 15 urethral or bladder perforations during surgery (five in the last 37 cases). In

these men the implantation was abandoned on the ipsilateral side and only one balloon was placed contralaterally. Patients who had a perforation during surgery were implanted on the affected side 1–4 months later. There were no bleeding complications. On the first day after surgery only five patients were fully continent and needed no further percutaneous adjustment of the balloon volume; 112 (96%) needed a median (range) of 3 (1–15) adjustments to achieve a satisfactory result. The median balloon volume at implantation was 2 (0.5–7.5) mL, and the final mean volume after percutaneous adjustments of all successful cases was 3.5 (1–10) mL. In seven of the 117 patients (6%) urinary retention developed 1 day after surgery, but was resolved immediately by withdrawing a small amount of the balloon-filling volume via the injection ports. The mean follow-up was 13 (3–54) months. The number of pads decreased from a mean (range) of 6 (1–24)/day before surgery to 2 (0–15)/day at 3 months (117 men), 2 (0–7)/day (92 men) at 6 months, 1 (0–6)/day (63 men) at 1 year and 1 (0–6)/day (40 men) at 2 years after surgery (all  $P < 0.001$ ). Specific changes in pad use are shown in Table 2. For changes in the I-QoL score (maximum points 100), all 117 patients were formally assessed at baseline and were followed, the median score improved significantly from 34.7 at baseline (117 men) to 64.8 at 6 months (92 men), 64.9 at 12 months (63 men) and 66.3 at 24 months (42 men, all  $P < 0.001$ ; Table 2). Based on each patient's history of symptomatic stress incontinence, the baseline Stamey incontinence scoring system classified 37 cases as grade I, 33 as grade II, and 47 as grade III. This subjective assessment, repeated at each follow-up visit, showed a decreasing incidence of moderate-to-severe incontinence (Stamey 2 or 3), from 68% at baseline to 13% at 1 year, and a greater incidence of continence or mild incontinence (Stamey 1), from 32% at baseline to 88% at 1 year ( $P < 0.001$ ; Table 2). At 1 year; there was less pad use than at baseline for 92% of the patients; 5% had no change from baseline, and 3% increased their pad use by one or two pads/day; pad use was  $\geq 50\%$  below baseline in 80% of patients and 80–100% below baseline in 50% of patients (Fig 6).

The complications during and after implantation and the outcome are reported in Table 3, including all patients treated during

TABLE 2 The analysis of pad use, the I-QoL scores and changes in Stamey score grading of incontinence

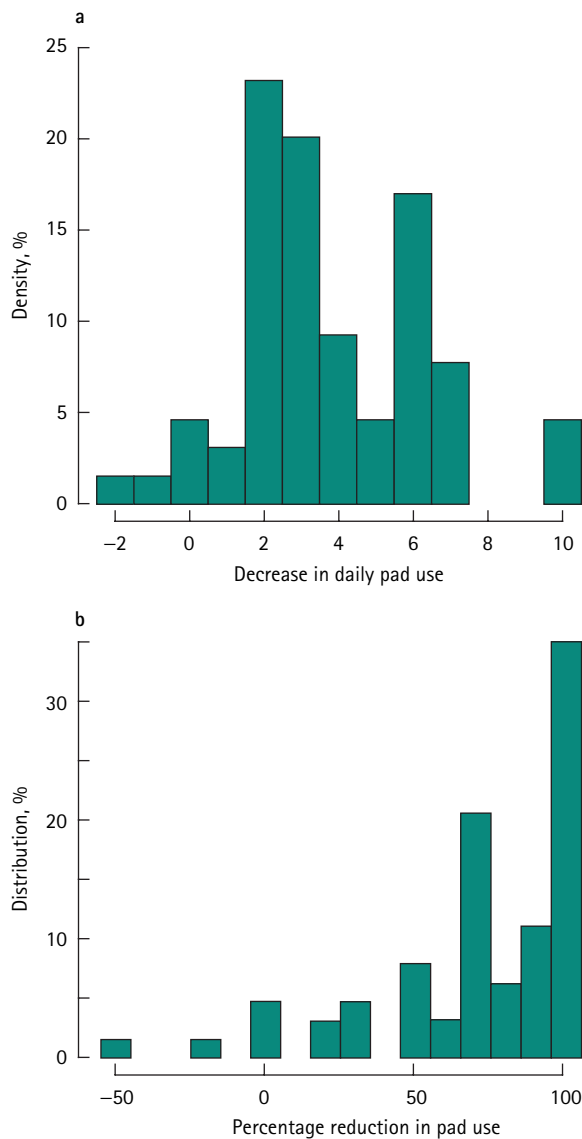
Variable	Assessment at months				
	Baseline	3	6	12	24
N	117	116	92	63	40
n (%) using:					
No pads	0 (0)	26 (22)	29 (31)	22 (35)	14 (35)
1	4 (4)	25 (22)	19 (21)	20 (32)	18 (45)
2–3	33 (28)	33 (28)	24 (26)	13 (20)	4 (10)
4–5	33 (28)	17 (15)	12 (13)	6 (10)	2 (5)
>5	47 (40)	15 (13)	8 (9)	2 (3)	2 (5)
Mean (sd)	5.6 (3.8)	2.5 (2.5)	1.9(2.0)	1.4 (1.5)	1.2 (1.5)
Range	1–24	0–15	0–7	0–6	0–6
P (Wilcoxon)	–	<0.001	<0.001	<0.001	<0.001
≥50% reduction, n (%)	–	71 (61)	66 (72)	53 (84)	35 (88)
I-QoL					
N	117	101	90	63	42
Mean (sd)	34.7 (22.6)	60.3 (23.2)	64.8 (23.9)	64.9 (25.9)	66.3 (27.3)
P (Wilcoxon)	–	<0.001	<0.001	<0.001	<0.001
Stamey score, n (%) of total cohort assessed at each time					
N	117	116	92	63	40
0	0 (0)	51 (44)	48 (52)	42 (67)	32 (80)
1	37 (32)	33 (28)	24 (26)	13 (20)	4 (10)
2	33 (28)	17 (15)	12 (13)	6 (10)	2 (5)
3	47 (40)	15 (13)	8 (9)	2 (3)	2 (5)
P (McNemar's test)	–	<0.001	<0.001	<0.001	<0.001
Improved, n (%)	–	84 (72)	77 (84)	57 (90)	36 (90)

TABLE 3 All complications: 234 devices in 117 patients, with outcome

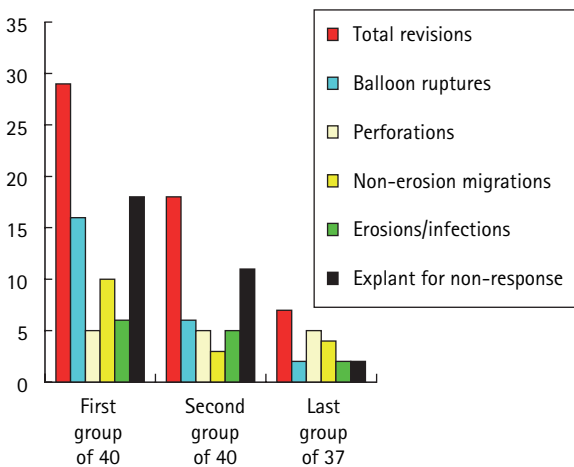
Event	During surgery	After surgery	Management	Outcome
Perforation, n/N (%)				
bladder	11/234 (4.7)	0	Ipsilateral implant completed in 4 7 reimplanted 1–4 months later	5 dry, 2 improved, 4 not improved (1 proceeded to AUS)
Bladder unilateral				
Urethra unilateral	4/231 (1.7)	0	Ipsilateral implant completed 4/4	4 not improved (2/4 proceeded to AUS)
Retention	0	7/117 (6)	Removal of 0.5–1 mL on day after surgery	3/7 dry, 4 not improved (4/7 proceeded to AUS)
Balloon:				
Ruptures	–	24 in 21 (10) 20 GI (9) 4 GII (1.7)	Balloons replaced after 1–2 months	13/19 dry, 1 improved, 7/19 not improved (5/7 proceeded to AUS)
Migration with no erosion	0	17 in 16 (7) 16 unilateral 1 bilateral	Balloons re-positioned	7/13 dry, 3 improved, 6 not improved (2 proceeded to AUS implant)
Urethral/bladder erosion	0	13 (6.4) 11 unilateral 2 bilateral	Balloon(s) removed Reimplanted 6 weeks later	1/13 dry, 2 improved, 10 not improved (8 proceeded to AUS, 1 to Reemix sling)
Explanted, no response	0	31 (26)	Balloons removed AUS 800 implanted at same surgery (23/28)	23 proceeded to AUS 800, 3 had InVance Sling but then AUS 800, 2 had Reemix sling, but then AUS 800 (total 28/31 implanted with AUS 800)

Some patients (14/117) had more than one complication; GI, prototype balloons used until August 2002; GII, current balloon design from August 2002; Percentages are based on total number of devices implanted (231 ProACT in 117 patients). Most complications were unilateral, allowing contralateral implantation to proceed.

**FIG. 6.**  
The distribution of **a**, pad use and **b**, percentage reduction in pad use, at 1 year after implanting the ProACT device in 63 patients.



**FIG. 7.**  
Changes in the incidence and rates of complications by type, analysis for the first and second groups of 40 patients compared with the most recent group of 37.



the development and refinement of the new system. In all, 79 revisional procedures were required in 54 of the 117 patients. The rate of revision decreased dramatically between the first 40 patients, the second 40 and the most recent 37, reflecting the development of the device, better insertion instruments, and the experience gained while developing the procedure with no benefit from other colleagues' previous experience (Fig. 7). Overall, 36 of 117 (31%) patients did not have a satisfactory result. As the ProACT device is easily removable with no adverse clinical impact, alternative but more invasive procedures were offered. Of these 36 men, 28 (21% of 117) finally received an AUS (three of this group had AMS InVance slings and two had Reemex slings with no success, before an AUS was implanted), three declined further treatment after removal and five were lost to follow-up. In the first 40 patients, 18 (40%) failed to respond satisfactorily. With improved implants, instruments and surgical technique, only five patients in the last 37 (14%) have not responded favourably.

To summarize, 231 ProACT devices were implanted into 117 patients, with 114 receiving the typical two balloons and three implanted with just one. At the time of writing, 81/117 (69%) patients have 162 effective devices *in situ*.

**DISCUSSION**

Stress urinary incontinence, secondary to injury of the urinary sphincter, affects many patients undergoing RP and occasionally TURP. Although most men with stress urinary incontinence after RP report resolution with time, up to 8% remain intractably incontinent [4]. Incontinence after RP may be related to sphincteric insufficiency, detrusor instability and a low-compliance urethra secondary to anastomotic strictures [15]. However, sphincteric insufficiency is the most common urodynamic finding in such patients [16]. The action of the intrinsic, smooth-muscle sphincter component seems to be primarily compromised after RP, if the neurovascular bundle supporting the intrinsic sphincter system is damaged during such surgery [17]. However, pelvic floor striated muscles, supported by the pudendal nerve, are usually unaffected and urologists may confirm the intact striated muscle reaction when the patient is told to 'pull-up' or contract his pelvic floor muscles during cystoscopy.

However, scar tissue at the level of the anastomosis may further impair both smooth and striated sphincter function [18].

Currently available treatments may be structured into adynamic 'passive' methods that aim to increase urethral resistance, e.g. periurethral bulking agents [19,20], or interventions supporting the bulbar urethra, commonly known as male slings [11,12,21], vs the dynamic 'active' hydraulic AMS 800 AUS, capable of opening and closing the urethra on demand. The superiority of the AMS AUS is unquestioned, with reported success rates of up to 92% in mimicking the normal sphincter function, thereby allowing the maintenance of low voiding pressures [22]. Nevertheless, urologists and patients have often been reluctant to accept this comparatively elaborate procedure because of the complexity of the surgery, or its cost. Also, some patients lack the necessary fine finger control or the overall ability to successfully use the implanted hydraulic pump of the AMS AUS, and so might be better suited to a passive method of 'controlled resistance' through a peri-urethral prosthesis.

In terms of minimally-invasive procedures, several bulking agents have been examined over the last decade. Some, such as PTFE, have been abandoned because of concerns with distal particle migration and granuloma formation [23], while others such as GAX-collagen have required repeated procedures for recurrence, while reporting only modest success rates beyond the 1-year follow-up, independently of the materials used for injection [9].

In general, reported results of various injectable materials in men have been over comparatively short periods and in relatively few patients, and many studies have reported the need to repeat the injection of considerable amounts of material to maintain continence. As a result, the use of the currently available injectable materials for incontinence after prostatectomy is regarded as being of equivocal value [10].

With the introduction of male slings supporting the bulbar urethra, effective adynamic urethral resistance was achieved, resulting in reasonable continence rates, but reports of up to 52% of patients having persistent perineal numbness or pain at a median follow-up of 9.6 months after such interventions [24], plus a possible aversion to

the use of bone anchors in the pelvic region by many clinicians, may have limited the use of this technique to date. In addition, these procedures recommend that the leak-point be measured during surgery, to avoid postoperative retention or leakage [11], although this recommendation from the manufacturer might not be routinely adhered to. Clemens *et al.* [25] reported that, by 22 months after bulbar urethral sling insertion, 27% of the study group had undergone further 'tightening' procedures; adjustments cannot be done after surgery without a further procedure. Although the male bladder can generate higher pressures than the female bladder, and therefore can overcome some obstruction with no retention, it seems to be desirable to be able to adjust the degree of urethral resistance to the needs of each patient, thus resulting in the lowest voiding pressures possible whilst preserving continence.

As with male sling procedures, the ProACT implant also causes a relative increase in outlet resistance, with the balloons mimicking the presence of a prostate. However, the ProACT implant leaves the possibility of adjusting the level of this outlet resistance with no further surgery, making it possible to react to any change in bladder function or the pelvic floor over time. Indeed, we had to reduce the balloon volume in four men after a year, due to increasing voiding pressures. The adjustment of the volumes to suit each man might require patience from both the physician and the patient, as this should be approached conservatively, adding small amounts (1–2 mL) once every  $\approx 4$  weeks. This allows for gradual tissue expansion of the dense scar tissue often encountered at the point of anastomosis after RP, without dislocating the balloons. Overly rapid adjustment can precipitate a loss of effect through balloon migration, requiring re-operation to reposition the device. Interestingly, the outcomes in terms of decreasing pad use and increasing I-QoL scores continued to improve after 6 months in men in the present series who reached the 2-year or longer follow-up.

Although this series reports high complication rates, most were during the first 40 cases (29 required subsequent revision), possibly reflecting the accumulation of experience as we developed and refined the operation with prototype insertion instruments and the limited quality of the 'Generation I' balloons,

which were re-engineered after the first 50 cases. Recent balloon failures, although now rare, might be related to the presence of staples at the level of the anastomosis of the bladder neck, which possibly erode the silicone elastomer surface if in direct contact with the device. As the relatively high complication rates should be viewed in the context of developing a new procedure, it has been re-assuring to see the decline in the incidence of complications with increasing experience. Of the next 40 patients, 18, and of the last 37, only seven, required some form of revisional surgery, reflecting both improved technique and equipment.

Almost all patients who had the device removed for leakage or migration with no erosion demanded early replacement with another ProACT device, which was then successful in 24 of 32 (75%). Dense scarring of the peri-urethral tissue usually caused perioperative bladder perforations, which although relatively minor, resulted in a delayed implant on the affected side. We acknowledge that it might be possible to continue implanting on an affected side after an unintended perforation of the bladder, but chose a more conservative option to return later. Further research and development of new instruments (a round tip of the obturator sheath, specially designed dilator) might reduce the occurrence of such complications.

If the ProACT failed because there was no response, placing a hydraulic bulbar sphincter is not difficult, with the ProACT device being removed during the same procedure before placing the AUS. Indeed, the ease with which this device can be removed, if necessary under local anaesthetic only, is reassuring for both patient and surgeon. From the present series of 117 men, 28 have now had an AMS 800 AUS implanted; five of these opted for male sling surgery but this also proved insufficient to control their incontinence, leading them to eventually accept an AUS.

Among all patients in whom the ProACT failed we sought predisposing risk factors. One patient, who was implanted after a radical cystectomy, had in hindsight an inappropriate indication for this implant. Postoperative intraurethral or bladder migration of the balloons, considered the worst complication (in 13), was associated with patients after irradiation (two), iatrogenic traumatic rigid cystoscopy (two) and with a previous history of repeated releasing incisions for stricture

(eight) as well as implanting in the presence of an untreated anastomotic stricture (one). Ten of these 13 patients subsequently failed to improve. Patients who have had one anastomotic stricture incision do not necessarily have to be excluded from this treatment option, but, such potential patients should be counselled before embarking on this option, to address the lower success rate and possible side-effects. In our experience, patients after external beam radiation or seed-implantation should not have the ProACT implanted, as there is a greater risk of urethral erosion.

The adjustability of the ProACT device, achieved without recourse to further surgery, is an entirely new approach to male incontinence therapy. We have not reported the method previously, as this surgery and the implant have developed throughout this series, and sufficient time for follow-up in a reasonably sized cohort was deemed necessary before initial conclusions could be made. Although this series produced several undesired complications, most were minor and can be justified in terms of developing both the best approach to this procedure and the ongoing development of the device and the instruments for its insertion. Despite this experience, 117 prospective patients with a median follow-up of >1 year now allow some conclusions.

The procedure can be categorized as minimally invasive, as it is conducted via small perineal incisions and can be undertaken as day surgery, with just one night of urethral catheterization generally advised. Adjustments are best started after 4–6 weeks, to allow tissue healing to be completed and stabilization of the device through the development of surrounding fibrotic tissue that may further secure the implant peri-urethrally. Adjustments can normally be made with minimal local anaesthesia (freezing spray) as the ports in the scrotum are easily accessed with a fine needle. Small adjustments of 1–2 mL per adjustment 'session' allow for the gradual expansion of the local tissue to accommodate the increasing volumes of the Pro ACT peri-urethral prostheses.

Although the present series includes the initial surgical developmental experience, and changes to both the device and instruments used for its insertion, the results and complication rates compare reasonably with

pre-existing methods [26–29]. In the worst case where explantation is required for no response, an AUS may be substituted in the same procedure. The overall level of patient satisfaction in 69% of patients with a median follow-up of 13 months was excellent. Follow-up continues with this group to assess the long-term results for future publication.

In conclusion, the ProACT compares favourably with existing treatments for incontinence after prostatectomy; its unique design allows for postoperative adjustment of the desired urethral resistance with no need for further surgical intervention. This ensures an optimum balance between voiding pressures and continence. The relationship between the minimal invasiveness of this procedure and the promising results suggest that this might be an appropriate and effective first-line option for treating men with stress urinary incontinence after prostatectomy.

#### CONFLICT OF INTEREST

This study was supported by Uromedica Inc.

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**Abbreviations:** AUS, artificial urinary sphincter; RP, radical prostatectomy; I-QoL, quality-of-life questionnaire; GAX, glutaraldehyde cross-linked (collagen).