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Adjustable Continence Therapy (ProACT™): Evolution of the Surgical Technique and Comparison of the Original 50 Patients with the Most Recent 50 Patients at a Single Centre

Wilhelm A. Hübner *, *Oliver M. Schlarp*

Department of Urology, Humanis Clinic, Korneuburg, Lower Austria, Austria

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Abstract

Objectives: The desire for an adjustable surgery for male stress urinary incontinence that avoids further surgery has produced a percutaneous adjustable device. The adjustable continence therapy (ProACT™) consists of two balloons, placed bilaterally at the bladder neck after prostatectomy. Titanium ports, attached via tubing to each balloon are placed in the scrotum allowing for volume adjustments of the balloons at any time perioperatively and postoperatively. This paper examines the evolution of the technique and the impact of this progression on patient outcomes.

Methods: Two groups, one representing the first 50 patients, the second consisting of the last 50 patients are compared for changes in pad use and incontinence quality of life (I-QOL) with a mean follow-up of 23 mo (range: 1–46 mo) in group 1 and 20 mo (range: 18–24) in group 2. A comparison of complications and retreatment is summarised.

Results: Pad usage was reduced significantly in both groups ($p < 0.001$). Overall, group 2 patients obtained more consistent outcomes compared to group 1 (80% vs. 60% dry or >50% improved). I-QOL improved in both groups although more significantly in group 2 ($p = 0.005$). Operative time was reduced in group 2. The rate and range of complications experienced in group 1 as the technique evolved decreased dramatically in group 2.

Conclusions: The evolution of technique and expertise has facilitated an efficient surgical implantation procedure with reproducible and effective objective and subjective outcomes. The implantation of this device is now conducted in >100 centres across Europe.

* Corresponding author. Urology Department, Humanis Clinic, Wiener Ring 3-5, 2100 Korneuburg, Lower Austria, Austria. Tel. +43(0)2262 7806992; Fax: +43(0)2262 780 2850.
E-mail address: wilhelm_huebner@compuserve.com (W.A. Hübner).

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1. Introduction

The rate of incontinence following radical prostatectomy remains contentious with the reported incidence varying between 2% and 57% but with a median value of approximately 10–15% [1]. This discrepancy arises from fundamental differences in the definition of incontinence and differences in study, population, and investigative site characteristics. Nevertheless, stress urinary incontinence (SUI) after prostatectomy remains a recognised complication that severely affects the quality of life (QOL).

Male SUI may be addressed by numerous established methods. These vary from relatively noninvasive methods of pelvic floor stimulation or biofeedback to progressively more invasive methods involving the use of various injectable bulking materials, bulbar-urethral sling surgeries, and the use of the artificial urinary sphincter (AUS).

A common feature of all of these generic surgical methods has been the inability to postoperatively adjust the implanted component, without further surgical intervention should the patient's incontinence worsen. Conversely, should the degree of ''obstruction'' caused by the continence surgery result in undesired voiding changes, subtle adjustments to alleviate the obstructing device are difficult without additional surgery. The advent of such ''two-way'' adjustability, via a nonsurgical method (in this case, percutaneous injectable volume adjustment) was believed to be warranted and advantageous to both patient and surgeon in terms of cost, invasiveness, infection rate, and maintenance of long-term efficacy.

To address this perceived deficiency, the principle of using ''adjustable balloons'' as a method of augmenting titration for optimal urethral coaptation had originally been conceived and developed as a treatment for female SUI in 1998 [2,3]. In late 1999, we adapted this technique and balloons were developed for use in postprostatectomy incontinence. The ProACT™ (adjustable continence therapy for the prostate) was first presented internationally in 2000 and showed encouraging short-term results in an initial cohort of 13 men [4]. Its use has gradually been adopted in numerous European, South American, Asian, and Australasian countries, being first presented as a multicentre international study in 2003 [5].

This paper examines the changes in the operative technique and the device since inception and compares our most recent results in the last 50 men given the implants compared to the original 50 patients treated with the ProACT to illustrate the evolution of the use of this device.

2. Patients and methods

2.1. Patients

The first 50 patients represent the original ''learning curve'' of two surgeons, as they adapted the procedure for men. The same two surgeons (both with >40 such surgeries) conducted the majority of surgeries in the second series of 50 patients analysed. A third surgeon, who completed 5 of 50 surgeries in group 2, did so under the direction of the two experienced surgeons. All patients were available for follow-up.

The ProACT device was implanted in the initial 50 patients (group 1) between September 1999 and July 2002. The most recent 50 patients (group 2) with sufficient follow-up to facilitate medium-term analysis of the outcomes at 12–8 mo underwent implantation surgery between January 2004 and August 2004. The average age of group 1 men was 72 yr (range: 62–80 yr) and that for group 2 men was 69 yr (range: 51–83 yr). All patients in both groups had undergone a radical prostatectomy as their primary operation for prostatic cancer. The median period of incontinence was 35 mo (range: 4–140 mo) for group 1 and 36.5 mo (range: 6–131 mo) for group 2. In group 1, 18 of 50 had failed one or more transurethral bulking injectables, whereas in group 2 only 3 of 50 had similar histories, reflecting the decline in the use of this as a first-line therapy in this region.

All patients in group 1 underwent preoperative evaluation including medical history, pad count, urodynamics, cystoscopy, and a quality of life (QOL) evaluation. In group 2, medical history, pad count, cystoscopy, and a QOL evaluation was included into the evaluation; however, due to our initial experience, urodynamic evaluation was not routinely undertaken preoperatively.

Postoperatively, both groups were assessed according to changes in pad count and QOL questionnaire. Within each group patients were graded as ''dry'' (i.e., no pads, or a single ''security pad'' per day), significantly improved against baseline (a >50% reduction in pad usage; usually representing 2–5 pads/d, depending on preoperative pad use), and little/no improvement (>5 pads/d and <50% improvement against baseline).

2.2. The device and operative technique

The ProACT device is constructed from silicone elastomer, similar to the materials used in the AMS800™ AUS. Each ProACT balloon is attached to a reinjectable titanium port via a short length of tubing (Fig. 1). The two balloons are implanted periurethrally, on either side of the bladder neck, just proximal to the remnant external sphincter. The ports are sited subcutaneously under the Dartos fascia of the scrotum to allow for future percutaneous adjustments of the balloon volume under local anaesthesia by fine-needle puncture of the port.

Since 2004, a new instrument called a tissue expansion device (TED) has enhanced the implantation technique by improving the preparation of a periurethral space, especially in difficult conditions such as the presence of dense scar tissue around the anastomosis of the bladder neck and external sphincter. The TED has a tip that resembles a rongeur, which

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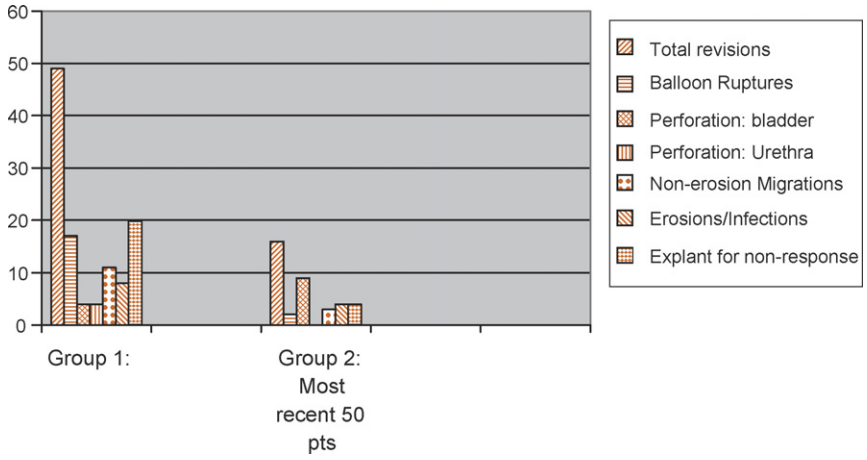

Fig. 1 – Comparison of complications.

when opened laterally from the urethra, creates a space for the balloon without the danger of damaging the urethral wall. Following creation of a tract using the trocar and U-shaped cannula, the TED is inserted prior to placement of the ProACT balloon. The use of a Kelly clamp to perforate the pelvic floor as was previously described in the first published report of this device has now been abandoned [6]. The development of the TED instrument allowed a more discrete device insertion channel to be created, thereby inhibiting a tendency of the device to migrate down the overly wide tract usually created by the use of the Kelly clamp.

The operative procedure has been previously described [6,7] and can be clearly viewed on the DVD available through the journal.

In our early experience, adjustments were commenced 24–48 h after initial implantation; however, we have since modified this approach so that first outpatient adjustments, if necessary, are now performed 3–4 wk after surgery.

Statistical analysis was done using a single factor analysis variance (ANOVA) to test for differences between group 1 and group 2 at each time point observed as well as within groups at each time point observed.

3. Results

The surgery took between 14 and 56 min during the first 50 surgeries and between 12 and 24 min during the last 50 cases, reflecting operative refinement and practice. The mean follow-up was 23 mo (range, including revisions: 1–46 mo) in group 1 and 20 mo (range: 18–24 mo) in group 2.

After an average of five postoperative adjustments, group 1 had 26 patients (52%) dry or using $\leq$1 pad/d, 4 (8%) had >50% improvement against baseline (but requiring 2–5 pads/d), and 20 (40%) had failed to respond. An improved overall response was seen in group 2, where after an average of four outpatient adjustments, 30 patients (60%) were continent (0–1 security pad/d), 11 (22%) were significantly improved with a >50% reduction in daily pad usage compared to baseline, and 8 (16%) had <50% pad reduction. The reduction in average pad usage in both groups decreased significantly compared to baseline ($p < 0.0001$), with no difference detected between the two groups in terms of average pad reduction ($p = 0.848$). The changes in pad use are compared between the two groups in Table 1. The average daily pad usage decreased in group 1 from 6.3 (±4.2) pads daily at baseline to an average of 2.1 (±2.1, $p < 0$ .0001) pads daily at 12 mo ($n = 39$). In group 2, the average daily pad usage dropped from 5.0 (±4.3) pads daily at baseline to 1.8 (±2.4; $p < 0.0001$) pad at 12 mo ($n = 50$).

Incontinence QOL (I-QOL) assessment (maximum of 100 points) [8] was conducted for all patients at baseline and at 3-, 6-, and 12-mo intervals. Overall both groups improved significantly as compared to baseline at all time points ($p < 0.0001$). The clinically significant improvement in I-QOL score in group 2 was greater than that reported in group 1 ($p = 0.004$). These results are also detailed in Table 1. Group 1 improved from a baseline average of 33 (±19.8) to 64 (±24.7; $p < 0.0001$) at 12 mo. Group 2 improved from a baseline median of 32 (±22.7) to 80 at 12 mo (±18.2; $p < 0.0001$).

In group 1 implantation was uneventful in 38 of 50 of the first surgeries. Intraoperative complications occurred in 24% (12 of 50) with four (8%) urethral perforations, four (8%) bladder-neck perforations, two (4%) immediate balloon ruptures, and two (4%) balloon migrations. In the most recent surgeries, 42 of 50 (84%) were uneventful cases, with no urethral perforations, balloon ruptures, or migrations seen intraoperatively. However, nine (18%) bladder-neck perforations were seen, all in patients with densely

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Table 1 – Incontinence quality of life and pad use

	I-QoL (/100) Average score (SD) Group 1	I-QoL (/100) Average score (SD) Group 2	*p* (among groups 1 and 2)
Before treatment	(*n* = 50) 33 (±19.8)	(*n* = 31) 32 (±22.7)	*p* = 0.817
1 mo postoperatively	(*n* = 50) 51 (±25.7) *p* = 0.0001 (baseline vs. 1 mo)	(*n* = 31) 66 (±23.7) *p* < 0.0001 (baseline vs. 1 mo)	*p* = 0.010
3 mo postoperatively	(*n* = 44) 58 (±21.9) *p* < 0.0001 (baseline vs. 3 mo)	(*n* = 31) 73 (±21.5) *p* < 0.0001 (baseline vs. 3 mo)	*p* = 0.006
6 mo postoperatively	(*n* = 41) 66 (±23.2) *p* < 0.0001 (baseline vs. 6 mo)	(*n* = 31) 76 (±20.4) *p* < 0.0001 (baseline vs. 6 mo)	*p* = 0.048
12 mo postoperatively	(*n* = 38) 64 (±24.7) *p* < 0.0001 (baseline vs. 12 mo)	(*n* = 31) 80 (±18.2) *p* < 0.0001 (baseline vs. 12 mo)	*p* = 0.005
	Average pad use Group 1	**Average pad use Group 2**	
Baseline	(*n* = 50) 6.34 (±4.26)	(*n* = 50) 5.04 (±4.37)	*p* = 0.135
3 mo	(*n* = 49) 3.08 (±3.25) *p* < 0.0001 (baseline vs. 3 mo)	(*n* = 50) 1.9 (±2.44) *p* < 0.0001 (baseline vs. 3 mo)	*p* = 0.043
12 mo	(*n* = 43) 2.1 (±2.1) *p* < 0.0001 (baseline vs. 12 mo)	(*n* = 50) 1.8 (±2.4) *p* < 0.0001 (baseline vs. 12 mo)	*p* = 0.176

I-QOL = incontinence quality of life; SD = standard deviation.

scarred bladder necks. The management of intraoperative perforations evolved between the two groups. During the first 50 cases, any perforation resulted in delayed implantation on the affected side. In the most recent 50 cases, where a minor perforation was seen either a placement of the balloon more distally was done (7 of 9), or the ipsilateral implantation was delayed for 4 wk (2 of 9). In all such cases the Foley catheter was left in place for 3 d rather than the standard 12 h for uncomplicated surgery. No bleeding complications were noted in either group. All complications, including their management, across both groups are summarised in Table 2, and a comparative graph (Fig. 1) shows the decrease in incidence of all complications between these two groups.

Complications requiring revision surgery occurred in 29 of 50 patients (58%; total 49 revision surgeries) of group 1 and in 12 patients (24%; total 16 revision surgeries) of group 2. There was a high rate of primary non-response in the first 50 patients (20 of 50, 40%) as the operation and implants evolved. All of these patients proceeded to using an AUS. In group 2 there were four cases (8%) of primary non-response requiring explantation, with two of these proceeding to bulbar urethral slings and two proceeding to implantation with the AUS800. Subsequently, four other responsive patients deteriorated, through device erosion (2 cases; 1 urethral, the other bladder), infection (1 case), and device migration (1 case), and one other patient did not improve but did not request reoperation for a total non-response rate of 18% (9 of 50). The ProACT balloons were easily and quickly removed when required without affecting subsequent surgery.

Overall, group 2 patients had more consistent outcomes in pad use reduction compared to group 1 (80% vs. 60% dry or >50% improved) and the number of non-responding patients was also dramatically reduced in group 2 compared to group 1 (16% vs. 40%).

4. Discussion

SUI is a recognised complication after prostate surgery, mostly associated with radical prostatectomy. Even with use of continence-improving techniques such as preservation of the puboprostatic ligaments, regaining continence after radical

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Table 2 – Complications in groups 1 and 2 with management strategies and outcomes

Event	During surgery		After surgery		Management	Outcome
	Group 1	Group 2	Group 1	Group 2		
Total revisions			49 in 29 patients	16 in 12 patients		
Balloon rupture	2	0	15 in 13 patients	2 in 2 patients	Reimplant	G1 Intraoperatively: 2 patients dry; Postoperatively: 13 patients (×2 multiruptures). 10 dry after revision; 3 failed at 18 mo (7–39 mo) after implant → AUS800. G2 Postoperatively: 2 patients. Both significantly improved.
Bladder perforation	4 (8%)	9 (18%)			Minor perforation: placement more distally, late adjustment	G1 Intraoperatively: 8 patients; 3 dry after revision, 5 failed at average 15 mo (5–39 mo) after implant → AUS800.
Urethral perforation	4 (8%)	0			Major perforation: abandoned implant and reimplant 4 wk later	G2: Intraoperatively: 9 patients. 4 placements more distally 5 reimplant after 4 wk 4 dry without revision 5 revisions (4 successful, 1 failed → successful AUS) Total = Successful 8; failed 1.
Retention	0	0	3 in 3 patients	0	Remove 0.5–1.0 ml	G1 Only: 1 dry; 2 failed to respond (poor patient selection? → AUS800)
Dislocation	2	0	9	3 (6%)	Repositioning	G1 Postoperative: 9 patients. 5 dry; 2 without revision; 3 with revision; 4 failed at average 12.75 mo (range 7–20 mo) → AUS800 G2: 3 revisions (2 successful, 1 failed)
Erosion (urethral bladder)			5 1	4 0	Explant and reimplant 6 wk later	G1: 4 revisions (0 successful → 1 AUS) G2: 4 revisions (3 successful, 1 failed)
Wound infection	0	0	2	0	Remove balloon on infected side	G1 Only: 2 revisions (1 successful, 1 failed)
Explant for primary non-response			20	4	Change to sling procedure or AUS	G1: 3 had an InVance sling but then proceeded to an AUS800; 2 had a Reemix sling but then proceeded to an AUS800 (+15 AUS implants, total = 20 AUS) G2: 2 sling (2 success); 2 AUS (2 success)

G1 = group 1; G2 = group 2; AUS = artificial urinary sphincter.
Some patients had multiple complications of the same type and of different types.

surgical treatment for prostate cancer is a tedious process for many, with up to 24% of men reporting involuntary urine loss 3 mo after surgery [9]. Pelvic floor exercises may help to regain early sphincteric control, especially when started soon after catheter removal following radical prostatectomy [10]. However, persistent severe incontinence beyond 6 mo after surgery should guide the patient towards a surgical therapy. Treatment using transurethral injectable bulking agents may improve the continence, but only in low-grade or mildly incontinent patients [11]. Moreover, repeated injections are usually necessary to establish and then to maintain continence, with the overall long-term results of such an injection therapy being disappointing [12,13]. Most patients having committed to treating their SUI and having disappointing outcomes from injectable therapy request additional more invasive therapy [14]. This was also the case in our population, where 36% (18 of 50) of the patients in group 1 had previously undergone injectable bulking therapy. The failure of bulking agents may be caused by a rapid degradation of material implants and the lack of tissue regeneration/integration properties [15]. It is not known whether the prior use of injected materials in group 1 compared to group 2 (18 vs. 3 of each group, respectively), may have contributed to the higher rate of complications seen in group 1 compared with group 2 as changes to the method of adjustment (i.e., delaying the initial adjustment in group 2 and adjusting using smaller volumes) may also have helped reduce the rate of balloon dislocation and erosion as was seen in group 2 versus group 1.

Although the ''reference standard'' for the treatment of severe incontinence remains the AUS (AUS800) [16], a place exists for a minimally invasive alternative, especially for men who may not have sufficient fine-motor control or the motivation to operate the implanted pump used with the AUS800. The AUS evolved slowly before being accepted into routine clinical use with clearly defined surgical principles and indications. Reported continence rates following AUS implantation, defined as zero to one pad per day range between 59% and 87% [13]. Although the secondary surgery rate is low (19%), some patients (36%) require more than one intervention [17]. Although secondary surgery in the case of a failed AUS affects every fifth man having the implant, almost three fourths (73.9%) result from a nonmechanical cause [18]. In such instances the surgical addition of a second (or ''tandem'') cuff or exchanging the pressure-regulating balloon (PRB) are two options used to ''adjust'' the AUS in most instances of recurrent incontinence [19]. The ProACT device offers the possibility of adjustment without recourse to further surgery.

5. Conclusion

Following assessment of other obsolete and evolving bulking therapies and as a result of the gradual improvements made in both the device and the surgical technique, this adjustable form of urethral bulking appears to present a better and more durable alternative to free-material injectable bulking therapy. For those, with a compliant bladder neck, the ProACT is a simple minimally invasive therapy, providing a high rate of patient satisfaction and the ability to adjust the degree of outlet resistance without recourse to further surgery.

Conflicts of Interest

Uromedica, Inc provided some financial support for the conduct of this study. Dr Hübner acts as a clinical consultant for Uromedica Inc.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.eururo.2006.10.054 and via www.europeanurology.com. Subscribers to the printed journal will find the supplementary data attached (DVD).

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