

Transrectal ultrasound-guided implantation of the Proact™ system in patients with post-radical prostatectomy stress urinary incontinence: 5 years experience

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Introduction & Objectives

The ProACT™ system (male Adjustable Contenance Therapy, Uromedica, Plymouth, MN, USA) is an adjustable, permanent device for post-radical prostatectomy stress urinary incontinence. Initially, as first described by Huebner and Schlap, system implantation was performed under fluoroscopic guidance. More recently, the safety and feasibility of Trans Rectal UltraSound (TRUS) guided ProACT system implantation has been demonstrated in order to improve placement and ensure reproducible results.

We evaluated our 5 years experience with Transrectal UltraSound (TRUS)-guided ProACT™ (Adjustable Contenance Therapy, Uromedica, Plymouth, MN, USA) system implantation in male patients with stress urinary incontinence after radical prostatectomy. To our knowledge this is the largest series with the longest follow up on TRUS-guided ProACT system implantation.

Materials and methods

Between June 2005 and June 2010 we operated on 117 consecutive patients (mean age 68.6 years, range 51-82) with post-radical prostatectomy urodynamic intrinsic sphincter deficiency without detrusor overactivity. At baseline, all patients underwent urodynamic testing including measurement of Valsalva Leak Point Pressure (VLPP) and Maximal Urethral Closure Pressure (MUCP). A pre operative 24 hour pad test was repeated periodically at post operative periods as were the daily pads per day used (PPD). Patients were asked to complete a validated quality of life questionnaire (Incontinence Quality of Life – IQoL). Table 1 lists patient characteristics at baseline.

The ProACT™ system implantation was performed using TRUS-guidance with a 7.5 MHz linear and small convex probe (Figures 1-6).

Safety was assessed by the incidence and severity of adverse events. Continence recovery was evaluated when balloon adjustments were completed with efficacy determined by a change in the 24h pad test (< 8 gr = dry), number of PPD used (0 or 1 safety PPD = dry; >50% PPD reduction = improved; <50% PPD reduction = failure). In addition the number of adjustments required to achieve continence was recorded.

TABLE 1

Number of patients	117
Mean age (range)	68.6 yr (51-82)
Mean months interval RP-ProACT implantation (range)	37 (7-122)
Patients with previous adjuvant radiotherapy	26
Degree of incontinence	n
Mild	39
Moderate	55
Severe	23
Mean 24 h pad test (range)	423.6 g (20-1300)
Mean VLPP (range)	56 cmH2O (25-110)
Mean MUCP (range)	44.2 cmH2O (9-100)
Mean PPD (range)	4.1 (1-10 or condom use)
Mean I-QoL score ± SD	47 ± 18.7

TABLE 2

Number of patients	102
Mean age (range)	68.2 yr (51-82)
Mean months interval RP-ProACT implantation (range)	39 (7-122)
Patients with previous adjuvant radiotherapy	18
Degree of incontinence	n
Mild	34
Moderate	48
Severe	20
Mean 24 h pad test (range)	420.7 g (20-1300)
Mean VLPP (range)	53 cmH2O (25-110)
Mean MUCP (range)	46 cmH2O (9-100)
Mean PPD (range)	3.9 (1-10 or condom use)
Mean I-QoL score ± SD	45.8 ± 18.7



Fig. 1 - With the patient in the lithotomy position, a Foley catheter is inserted and the bladder is inflated with 40-50 ml of saline solution. Two horizontal 8-10 cm skin incisions are made on the perineum about 1 cm lateral to the median line and about 1.5 cm above the coccyx.

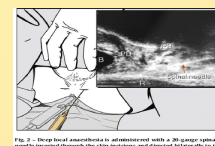


Fig. 2 - Deep local anaesthesia is administered with a 20 gauge spinal needle inserted through the skin incision and directed laterally to the urethral sphincter. The needle is inserted at a depth of 2-3 cm and the urethral sphincter is infiltrated with 10-15 ml of 0.5% bupivacaine. The urethral sphincter is then palpated and the needle is inserted at the level of the urethral sphincter. The urethral sphincter is then palpated and the needle is inserted at the level of the urethral sphincter.

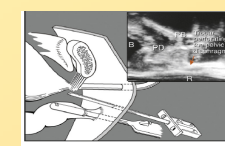


Fig. 3 - Under transrectal ultrasound (TRUS) guidance (as shown in the box), the specially designed, sharp-tipped, separable, tissue contained within a 10-angled sheath is inserted through the skin incision. A constant action (constant pressure) is required to perform the procedure. The sheath is then inserted into the urethra. The urethral sphincter is then palpated and the needle is inserted at the level of the urethral sphincter. The urethral sphincter is then palpated and the needle is inserted at the level of the urethral sphincter.

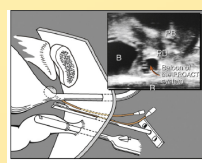


Fig. 4 - The incision is removed, leaving the 10-shaped sheath in place. The internal channel of the sheath is inflated using sterile gel and with the help of the push wire, the Proact device is passed along the sheath into position in the bladder neck. The balloon is inflated with 1 ml 0.9% saline solution via the titanium part. Transrectal ultrasound is used to confirm correct balloon placement, as shown in the box. B = bladder; P = pelvic floor; P = pelvic diaphragm; R = rectum.

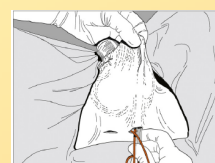


Fig. 5 - Using a suture or a trolley clamp, a subcutaneous paramedian tunnel is fashioned to allow placement of the continence side and titanium part.

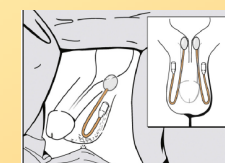


Fig. 6 - The procedure is repeated on the contralateral side, and the final position of the Proact system is shown.

Results

The 102 patients, where the balloon adjustment process was completed (Table 2), are the object of the continence outcome data analysis. In this group of patients the mean follow-up is 30 months (range 2-62). The mean number of adjustments required to obtain continence recovery was 3.9 (range 0-14). According to the 24h pad test and the mean number of PPD used 67 patients are dry (65.7%), 24 patients improved (23.5%) and 11 patients failed treatment (10.8%). The majority of failures (7) occurred in previously irradiated patients. The overall dry rate in non irradiated patients was 72.6%. Figure 7 summarizes clinical results in non irradiated and previously irradiated patients. Major complications (5 unilateral balloon migrations and 3 urethral erosions) occurred exclusively in the irradiated group (Table 3). When migration or erosion occurred the balloon was deflated and simply removed using local anaesthesia with a small skin incision in the area where the titanium port for postoperative adjustments is located.

FIGURE 7. CLINICAL OUTCOME

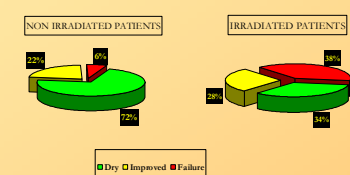


TABLE 3. COMPLICATIONS

Intraoperative (/117 patients)	n.	%
Bleeding	-	-
Bladder perforations	3	2.5
Urethral or rectal perforations	-	-
Early postoperative (/117 patients)		
Urinary retention	1	0.8
Port site infection	1	0.8
Long term (/102 patients)		
Infections	1	0.9
Device migrations	5	4.9
Erosions	3	2.9

Conclusions

The ProACT system using the TRUS guided implantation technique provides significant improvement in continence with an acceptable risk of major complications. The ProACT system appears to have a number of advantages. It is implanted via a minimally invasive procedure under local anaesthesia with modest patient discomfort. Furthermore, it is easily adjustable at any time post operatively, so that the optimal level of urethral resistance may be determined based on patient response. Moreover, if the system must be removed, there are no limitations to further surgical treatments for stress urinary incontinence. Finally, the cost of the system is relatively low compared to alternative modalities. Continence recovery is reduced in previously irradiated patients which are at higher risk of perioperative complications. Therefore, adjuvant radiotherapy seems to be relative contraindication to ProACT system implantation.

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