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Surgery in Motion

Transrectal Ultrasound–Guided Implantation of Adjustable Continence Therapy (ProACT): Surgical Technique and Clinical Results After a Mean Follow-Up of 2 Years

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Abstract

Background: Treatment for stress urinary incontinence (SUI) after radical prostatectomy (RP) with the male Adjustable Continence Therapy (ProACT) system, implanted using fluoroscopy for guidance, has been described with promising clinical results.
Objective: This retrospective study aims to describe the surgical technique in detail and to evaluate the continence recovery and complication rate of a cohort of male patients with SUI after RP. All patients were treated with a modified technique that uses transrectal ultrasound (TRUS) for guidance and that may be performed under local anaesthesia.
Design, setting, and participants: Between June 2005 and March 2009, we operated on 79 consecutive patients with post-RP urodynamic intrinsic sphincter deficiency.
Surgical procedure: ProACT system implantation was performed with TRUS guidance under general or local anaesthesia.
Measurements: Perioperative data and adverse events were recorded in all patients. Outcome data (24-h pad test, number of pads per day (PPD) used by patients, a validated incontinence quality of life questionnaire) were analysed in the 62 of 79 patients who completed the postoperative system adjustments. In this group of patients, the mean follow-up is 25 mo.
Results and limitations: According to the 24-h pad test and the mean number of PPD used, 41 patients were dry (66.1%), 16 patients improved (25.8%), and 5 patients failed treatment (8%). The dry rate in previously irradiated patients was 35.7%. Complications included intraoperative bladder perforations (2 of 79; 2.5%), transient urinary retention (1 of 79; 1.2%), migrations (3 of 79; 3.8%), and erosions (2 of 79; 2.5%). According to the degree of incontinence, the dry rate in patients with mild, moderate, and severe incontinence was, respectively, 85%, 63.6%, and 33.3%.
Conclusions: TRUS guidance for ProACT implantation results in success and complication rates that compare favourably with published data using fluoroscopy for guidance. Previous radiotherapy and severe incontinence seem to be a relative contraindication. Larger series and longer follow-up are progressing to establish long-term efficacy.

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1. Introduction

The male Adjustable Continence Therapy (ProACT) system (Uromedica, Plymouth, MN, USA) is a postoperatively adjustable, permanently implantable device for the treatment of stress urinary incontinence (SUI) after prostate surgery. Initially, as first described by Hübner and Schlarp, the system implantation was performed under two-dimensional fluoroscopic guidance [1–5]. More recently, the safety and feasibility of transrectal ultrasound (TRUS) guided ProACT system implantation has been described to achieve a more accurate placement by the use of multiplanar ultrasound imaging and to avoid radiation exposure [6].

This study aims to evaluate the continence recovery and complication rate of a cohort of male patients with SUI after radical prostatectomy (RP), all treated with the TRUS-guided ProACT system implantation. We describe the surgical technique in detail and retrospectively report our findings at a mean follow-up of 2 yr. To our knowledge this is the largest series with the longest follow-up on TRUS-guided ProACT system implantation.

2. Methods and patients

2.1. The ProACT system

The system is an adjustable permanent implant designed to achieve continence through increased outlet resistance in male patients with SUI. It is composed of an expandable silicone balloon attached with a 2-lumen conduit to a reinjectable titanium port. One lumen contains a 15-cm by 0.8-mm push wire, while the other acts as a channel for balloon inflation. The device is manufactured in two lengths: 12 cm and 14 cm. In general, the 12-cm device is employed for patients with residual prostate following benign surgery (ProACT balloons are placed more distally, on either side of the prostatic apex), and the 14-cm device is required for post-RP patients. Post-RP patients require two balloons, which are placed on either side of the vesicourethral anastomosis just above the pelvic diaphragm. A specially designed, sharp-tip, removable trocar contained in a 4.6-mm diameter U-shaped sheath is used to insert the balloons through a transperineal route. The two titanium ports are placed into a subcutaneous parascrotal position to allow easy percutaneous access for adjusting the balloons postoperatively (maximum: 8 ml) using a 23-gauge noncoring needle. This allows the device to be adjusted by modifying the level of coaptation needed to achieve continence.

2.2. System implantation: the original technique

As described by Hübner and Schlarp [1], system implantation is performed under fluoroscopic guidance with a cystoscope sheath inserted in the bladder functioning as a guide for correct placement. The balloons are then filled with contrast medium and sterile water mixed to an isotonic medium.

2.3. Patient population

After obtaining institutional review board approval, between June 2005 and March 2009 we operated on 79 consecutive patients (mean age: 67.9 yr; range: 51–82) with post-RP, urodynamic, intrinsic sphincter deficiency. Twelve patients had had a RP at our department while 67 patients were referred to our institution after a RP performed at different hospitals. All patients were free from distant metastasis. Flexible cystoscopy and TRUS were used to evaluate the bladder neck, anastomosis, and urethra in order to exclude local recurrences and strictures. At baseline, all patients underwent urodynamic examination according to the methodology and definitions of the International Continence Society guidelines [7]. Urodynamic investigations were performed to exclude detrusor overactivity or compliance abnormalities; Valsalva leak point pressure and maximal urethral closure pressure were measured.

Incontinence was evaluated as the number of pads per day (PPD) used by patients, and categorised as mild (one or two PPD), moderate (three to five PPD), and severe (more than five PPD or condom use). All patients were also assessed with a 24-h pad test and with the incontinence quality of life questionnaire (I-QoL) validated by Wagner et al [8]. Table 1 lists patient characteristics at baseline.

Table 1 – Patient characteristics

No. patients	79
Mean age, yr (range)	67.9 (51–82)
Mean interval between RP and ProACT implantation, mo (range)	35 (7–122)
No. patients with previous adjuvant radiotherapy	16
Degree of incontinence, No. patients	
Mild	25
Moderate	39
Severe	15
Mean 24-h pad test (range)	389.7 g (20–1300)
Mean VLPP (range)	58 cm H_2O (30–110)
Mean MUCP (range)	44.9 cm H_2O (9–100)
Mean PPD (range)	3.7 (1–10 or condom use)
Mean I-QoL score ± SD	49 ± 19.3

I-QoL = incontinence quality of life questionnaire; MUCP = maximal urethral closure pressure; PPD = pads per day; ProACT = male Adjustable Continence Therapy system; RP = radical prostatectomy; SD = standard deviation; VLPP = Valsalva leak point pressure.

2.4. Patient preparation

Patients are advised to take an antiseptic shower and a cleansing enema the night before surgery. A prophylactic antibiotic regime consisting of a single 2-g dose of ceftriaxone is administered intravenously prior to entering the operating room. Hair removal from the surgical field area is performed in the operating room just before surgery. Antibiotic solution is used to immerse the elements of the system prior to implantation and is used to liberally irrigate throughout the procedure.

2.5. Surgical technique

The patient is placed in the lithotomy position and the lower abdomen, genitalia, perineum, and the perianal area are disinfected. A 14- or 16-Ch Foley catheter is inserted in the bladder, which is filled with 40–50 ml of saline solution to clearly visualise the urethra and the bladder neck with TRUS. The scrotum is held above the perineum with tape. The anal ring is isolated from the perineum with a drape and TRUS is performed using a 7.5-MHz linear probe and a small convex probe.

When local anaesthesia only is used, 10 ml of ropivacaine 7.5 mg/ml is administered with a regular 20-gauge needle in skin and subcutaneous tissue at 1–2-cm intervals bilaterally around the intended perineal incisions.

Two horizontal 0.5–1-cm skin incisions are made in the perineum about 1 cm lateral to the median line and about 1.5 cm above the rectum (Fig. 1).

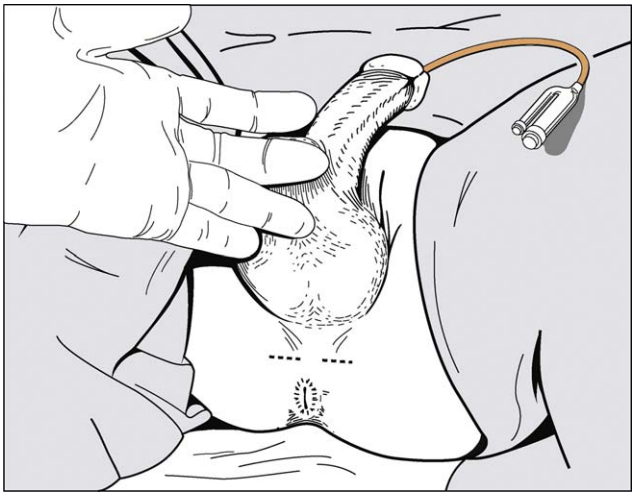

Fig. 1 – With the patient in the lithotomy position, a Foley catheter is inserted and the bladder is filled with 40–50 ml of saline solution. Two horizontal 0.5- to 1-cm skin incisions are made in the perineum about 1 cm lateral to the median line and about 1.5 cm above the rectum.

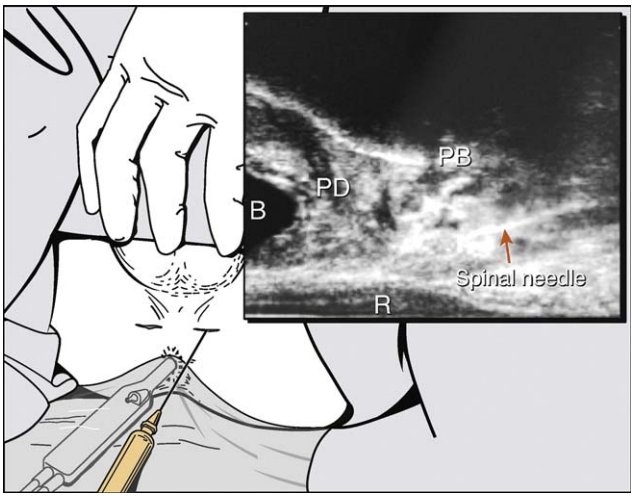

Fig. 2 – Deep local anaesthesia is administered with a 20-gauge spinal needle inserted through the skin incisions and directed bilaterally to the vesicourethral anastomosis under multiplanar transrectal ultrasound guidance (as shown in the box). The linear probe monitors advancement of the 20-gauge spinal needle towards the bladder neck, while the convex probe is used to monitor the distance from the urethra. The anaesthetic is released along the needle path in the subcutaneous tissue, in the pelvic diaphragm, and laterally to the anastomosis, creating the space for the ProACT balloon by a mechanism of hydrodissection. B = bladder; PB = pubic bone; PD = pelvic diaphragm; R = rectum.

Deep local anaesthesia is then administered with 20 ml of ropivacaine 7.5 mg/ml. A 20-gauge spinal needle is inserted through the skin incisions and directed bilaterally to the vesicourethral anastomosis under multiplanar TRUS guidance (Fig. 2). The linear probe monitors advancement of the 20-gauge spinal needle towards the bladder neck, while the convex probe is used to monitor the distance from the urethra. The anaesthetic is released along the needle path in the subcutaneous tissue, in the pelvic diaphragm, and laterally to the anastomosis, creating the space for the ProACT balloon by a mechanism of hydrodissection. Anaesthesia requires 1–15 min before becoming effective. If the patient is under general anaesthesia or spinal block, the hydrodissection is obtained using saline solution administered under TRUS guidance with a 20-gauge spinal needle as described above.

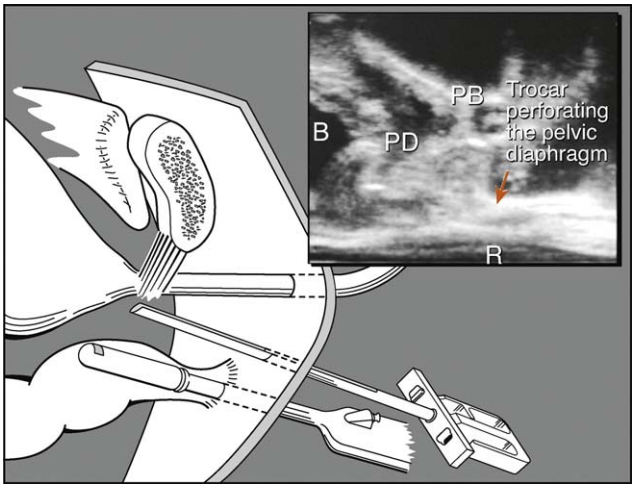

Fig. 3 – Under transrectal ultrasound (TRUS) guidance (as shown in the box), the specially designed, sharp-tipped, removable trocar contained within a U-shaped sheath is inserted through the skin incision. A rotating action (twisting motion) is employed to perforate the pelvic diaphragm and advance the trocar towards the hydrodissected scar tissue at the level of anastomosis on one side of the bladder neck. Position of the trocar and cannula is confirmed by TRUS. B = bladder; PB = pubic bone; PD = pelvic diaphragm; R = rectum.

Under TRUS guidance, the specially designed implantation instrument, consisting of a sharp tipped, removable trocar contained within a U-shaped sheath, is inserted through the skin incision. A twisting motion is employed to perforate the pelvic diaphragm and advance the trocar towards the hydrodissected scar tissue at the level of anastomosis on one side of the bladder neck. Position of the trocar and cannula is confirmed by TRUS (Fig. 3). The trocar is removed, leaving the U-shaped sheath in place. During this manoeuvre the sheath is gently advanced about 0.5 mm to occupy the space created by the trocar tip.

The internal channel of the sheath is then lubricated using sterile gel. With the help of the push wire, the ProACT device is passed along the sheath into position at the bladder neck. The sheath is withdrawn approximately 2 cm to permit balloon expansion as it is inflated with 1 ml 0.9% saline solution via the titanium port (Fig. 4). TRUS is used to confirm correct balloon placement in all planes (linear probe to establish proximity to the bladder neck and convex probe to assess balloon position laterally in relation to the urethra). Optimal balloon placement is considered as being 5–10 mm distal to the bladder neck and 2–5 mm lateral from the urethra. Ideally the balloons should be at 9 o'clock and 3 o'clock in relation to the urethra to create a triangular coaptation of the urethra between the two balloons and the symphysis pubis. The push wire is removed. Using scissors or a Kelly clamp, a subcutaneous parascrotal tunnel is fashioned to allow placement of the conduit tube and titanium port (Fig. 5). The tunnel should be sufficiently sized to ensure that the balloon tubing is not looped or kinked and the port can lie in a supine position. The procedure is repeated on the contralateral side. The incisions are closed in two layers with 4-0 resorbable sutures. Fig. 6 shows the final position of the ProACT system. The Foley catheter is removed if local anaesthesia is used or it is maintained overnight if the procedure is performed under general anaesthesia or spinal block. A 5-d course of antibacterial prophylaxis is given with oral fluoroquinolone.

2.6. Follow-up and postoperative adjustment of the ProACT system

On postoperative day 30, the patient is evaluated according to the number of PPD and the 24-h pad test. If complete continence has not

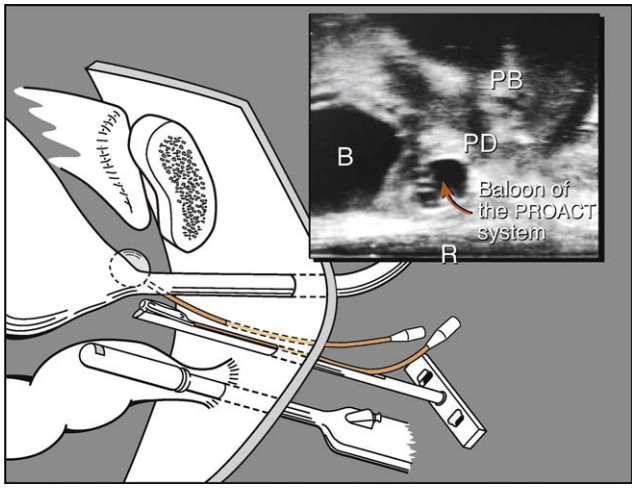

Fig. 4 – The trocar is removed, leaving the U-shaped sheath in place. The internal channel of the sheath is lubricated using sterile gel and with the help of the push wire, the ProACT device is passed along the sheath into position at the bladder neck. The balloon is inflated with 1 ml 0.9% saline solution via the titanium port. Transrectal ultrasound is used to confirm correct balloon placement, as shown in the box. B = bladder; PB = pubic bone; PD = pelvic diaphragm; R = rectum.

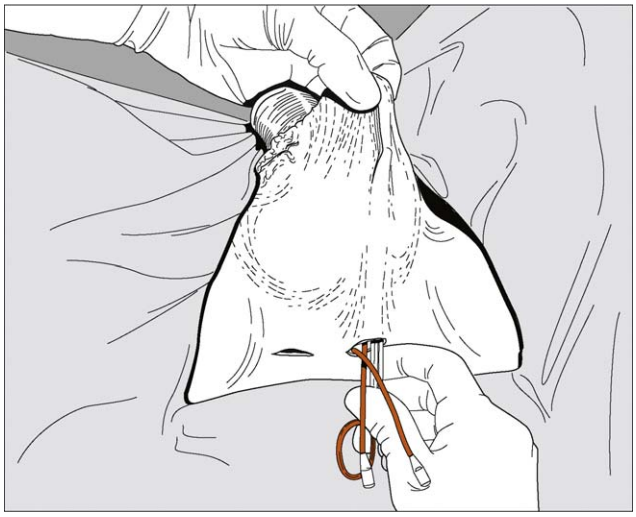

Fig. 5 – Using scissors or a Kelly clamp, a subcutaneous parascrotal tunnel is fashioned to allow placement of the conduit tube and titanium port.

been achieved, each balloon is filled with a further 1 ml 0.9% saline (0.5 ml 0.9% saline in previously irradiated patients). The procedure is performed through percutaneous access to the two titanium ports with a 23-gauge noncoring needle without the need for anaesthesia. The same patient evaluation and balloon adjustment are done every 30 d until continence or a maximum filling volume of 8 ml is reached. If the system fails to achieve continence or a complication occurs, each balloon may be deflated and simply removed using local anaesthesia with a small skin incision in the area where the titanium port is located.

After balloon adjustments were completed, patients were assessed with the 24-h pad test (<8 g was considered dry [9]), with the number of PPD used (no or one safety PPD was considered dry; >50% PPD reduction was considered improved; <50% PPD reduction was considered failure), and with the I-QoL questionnaire. Perioperative data and adverse events were recorded for all patients.

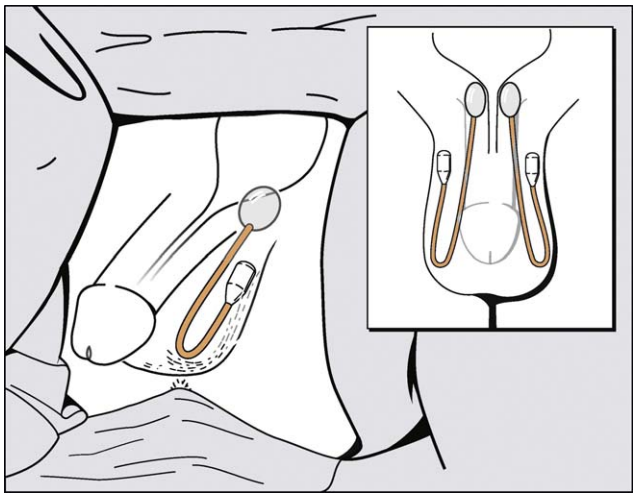

Fig. 6 – The procedure is repeated on the contralateral side, and the final position of the ProACT system is shown.

As part of this clinical evaluation, we instructed patients to refer to our institution any clinical changes or adverse events likely to be linked with the surgical procedure.

We did not perform postoperative urodynamics evaluations, so as to avoid any kind of postoperative urethral instrumentation, minimising the risk of infections or erosions.

3. Results

3.1. Operative results

All patients were judged to be free of cancer at the time of ProACT system implantation.

The ProACT systems were successfully implanted in all cases by a single surgeon (AG) in a mean time of 23 min (range: 14–60) using general anaesthesia in 18 patients and local anaesthesia only in the remaining 61 patients. All patients had 14-cm long devices placed. Blood loss was unremarkable in all cases. No patients required post-operative analgesia. All patients were discharged from the hospital within 24 h after surgery.

3.2. Continence outcome data

In the last 17 patients, balloon adjustments are still ongoing. Balloon adjustments were completed in 62 of 79 patients, and this population is the subject of the continence outcome data analysis (previously irradiated patients were 14 of 62). In this group of patients, the mean follow-up is 25 mo (range: 3–45). Table 2 lists patient characteristics at baseline.

The mean number of postoperative adjustments required to obtain continence recovery was 3.6 (range: 0–14). The mean final-fill volume was 4.2 ml (range: 1–8). According to the 24-h pad test and the mean number of PPD used, 41 patients were dry (66.1%), 16 patients improved (25.8%), and 5 patients failed treatment (8%). All failures occurred in previously irradiated patients. The overall dry

Table 2 – Characteristics of patients who have completed adjustment process

No. patients	62
Mean age, yr (range)	68 (51–82)
Mean interval between RP and ProACT implantation, mo (range)	31 (7–84)
Patients with previous adjuvant radiotherapy	14
Degree of incontinence, No. patients	
Mild	20
Moderate	33
Severe	9
Mean 24-h pad test (range)	407.5 g (40–1300)
Mean VLPP (range)	56 cm H_2O (30–110)
Mean MUCP (range)	43.2 cm H_2O (9–100)
Mean PPD (range)	3.5 (1–10 or condom use)
Mean I-QOL score ± SD	46.5 ± 13.5

I-QoL = incontinence quality of life questionnaire; MUCP = maximal urethral closure pressure; PPD = pads per day; ProACT = male Adjustable Continence Therapy system; RP = radical prostatectomy; SD = standard deviation; VLPP = Valsalva leak point pressure.

Table 3 – Outcome data

	Nonirradiated patients	Previously irradiated patients
No. patients	48	14
Dry, *n* (%)	36 (75)	5 (35.7)
Improved, *n* (%)	12 (25)	4 (28.6)
Failure, *n* (%)	0 (0)	5 (35.7)

Table 4 – Complications

	n	%
Intraoperative (79 patients total)		
Bleeding	–	–
Bladder perforations	2	2.5
Urethral or rectal perforations	–	–
Early postoperative (79 patients total)		
Urinary retention	1	1.2
Long term (62 patients total)		
Infections	–	–
Device migrations	3	4.8
Erosions	2	3.2

rate in nonirradiated patients was 75%. According to the degree of incontinence, the dry rate in patients with mild, moderate, and severe incontinence was, respectively, 85% (17 of 20 patients), 63.6% (21 of 33 patients), and 33.3% (3 of 9 patients). Mean I-QoL score improved from 46.5 to 84.3 (±17.3 standard deviation; $p < 0.0002$, paired *t* test). Table 3 summarises clinical results in nonirradiated and previously irradiated patients.

3.3. *Perioperative complications*

Two intraoperative bladder perforations occurred in previously irradiated patients. This was immediately identified by the presence of saline in the U-shaped sheath. We continued implanting on the affected side by repositioning the trocar via a more lateral access. These patients were conservatively managed with 5 d of indwelling catheter with no further complications. We did not observe any bleeding complications or rectal or urethral injuries in any patient.

One patient had urinary retention after catheter removal and so required an additional 48 h of catheterisation.

No device infections were observed during the follow-up period. We observed three unilateral balloon migrations and two urethral erosions (all within 3 mo of surgery and all in previously irradiated patients). When migration or erosion occurred, the balloons were simply removed on an outpatient basis using local anaesthesia. After an erosion, patients were conservatively managed with 21 d of indwelling catheter, which was removed after checking the complete urethral healing with flexible urethroscopy. One month after complete urethral healing had been confirmed, unilateral reimplantation was performed without further complications. Table 4 summarises the perioperative complications.

4. Discussion

Male SUI is a challenging problem for men following RP. Persistent post-RP SUI (after 1 yr) affects 2–45% of patients [10–12], and when rehabilitation methods fail, surgery may be considered.

Implantation of an artificial urinary sphincter is associated with continence and patient satisfaction rates in approximately 90% of refractory post-RP SUI cases and currently remains the reference treatment [13]. However, the artificial urinary sphincter is expensive and requires a complex surgical procedure that may be associated with significant complication and revision rates. In fact, surgical revision or substitution of the device may be required in up to 40% of cases due to mechanical failures, infections, or early and late erosions [14–17].

Male bulbourethral slings have been developed [18,19]. Initial results in patients with mild to moderate incontinence are comparable to those previously published for male sphincters, but long-term results are lacking. Moreover, the slings cannot be adjusted beyond 3 mo, and there would seem to be a high incidence of early postoperative perineal pain [20,21]. To date, there are minimal long-term data in the literature on which to comment.

ProACT was first developed in 2000 and has been reported on extensively since that time [22]. The original technique of implantation using fluoroscopic guidance has been well described over the last 6 yr. Continence rates of 65–70% have demonstrated reproducible results in centres where fluoroscopy is readily available and by surgeons who are familiar with the implantation procedure. The introduction of TRUS may enable more widespread adoption of the procedure in that the ability to visualise the pelvic anatomical landmarks in three dimensions rather than two may theoretically make it possible to place the balloons more accurately and precisely. Furthermore, this improved visibility could reduce the incidence of perioperative urethral or bladder perforations. This feature is especially

important when considering the need for postoperative adjustment to achieve complete continence. Furthermore, the ability to perform this procedure using only local anaesthesia is of particular interest to those urologists treating elderly and frail patients [23].

Considering the limits of the present study (retrospective design, no postoperative urodynamics evaluations), our midterm (2 yr) outcome data appear more than satisfactory with a low complications rate. However, results appear worst in patients with severe incontinence and in previously irradiated patients, who are also at higher risk of perioperative complications. Therefore, we agree with Hübner et al [22] that adjuvant radiotherapy seems to be a relative contraindication to ProACT system implantation.

We compared our results with ProACT outcomes reported in earlier studies [2–5,22]. Our reported dry rate of 66.1% is in line with the majority of studies (62–67% with an outlier at 30%). Our failure rate (<50% improvement) is at the very low end of reported failure rates (8–22%). The more significant difference was found in the intraoperative–early postoperative complications and in long-term postoperative complications, where we saw an incidence of 3.7% (compared with 7.8–12.8% in other studies) and 7.9% (compared with 11.0–27.4%), respectively. The highest complication rates were, as expected, reported in the initial study, which also included development of the devices and surgical technique [22]. However, our complications also compared favourably with those in more recently published studies [2–5], and this may be a result of the more precise device placement with ultrasound guidance. We also compared the average balloon filling in our study (4.2 ml) with that in other studies (3.1–4.6 ml). Our hypothesis is that in some instances, the balloon is placed closer (in some cases, maybe too close) to the urethra or bladder, and so requires less filling to reach continence but also results in a higher incidence of perioperative perforations and postoperative complications leading to explantations.

5. Conclusions

In conclusion, the use of TRUS guidance for ProACT system implantation is safe, avoids radiation exposure, and results in success and complication rates that compare favourably with published data by other investigators of ProACT implantation using the original fluoroscopic-guided technique. Larger series and longer follow-up are progressing to establish long-term safety, efficacy, and durability. It would indeed be desirable to compare this technique with the SUI reference treatment, which is the artificial urinary sphincter. Randomised trials should also be conducted to compare the TRUS and fluoroscopy-guided techniques to establish which kind of procedure is better for ProACT system implantation. Adjuvant radiotherapy and severe incontinence seem to be relative contraindications to ProACT system implantation.

Author contributions: Andrea Gregori had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Gregori, Gaboardi.
Acquisition of data: Romanò, Scieri, Pietrantuono, Salvaggio, Granata.
Analysis and interpretation of data: Gregori, Romanò.
Drafting of the manuscript: Gregori, Romanò.
Critical revision of the manuscript for important intellectual content: Gregori, Romanò, Gaboardi.
Statistical analysis: Incarbone, Romanò.
Obtaining funding: None.
Administrative, technical, or material support: Scieri.
Supervision: Gregori, Gaboardi.
Other (specify): None.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at doi:10.1016/j.eururo.2009.11.031 and via www.europeanurology.com. Subscribers to the printed journal will find the Surgery in Motion DVD enclosed.

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