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# Transrectal Ultrasound Guided Implantation of the ProACT Adjustable Continence Therapy System in Patients With Post-Radical Prostatectomy Stress Urinary Incontinence: A Pilot Study

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**Purpose:** We evaluate the feasibility and potential advantages of ProACT system implantation using transrectal ultrasound rather than fluoroscopy for guidance.

**Materials and Methods:** The transrectal ultrasound guided procedure was done between June and October 2005 in 7 patients with a mean age of 68.4 years (range 53 to 76) with mild to severe stress urinary incontinence after laparoscopic transperitoneal radical prostatectomy.

**Results:** The ProACT system was successfully implanted in all cases without perioperative complications. Time needed to complete the overall procedure was 15 to 30 minutes. All transrectal ultrasound studies performed during the mean followup of 4.2 months (range 2 to 6) confirmed the exact location of the devices.

**Conclusions:** ProACT system implantation is feasible using transrectal ultrasound for guidance. Transrectal ultrasound enables excellent imaging of all anatomical landmarks during the entire procedure and it seems to provide considerable advantages over fluoroscopy in terms of safety and accuracy.

*Key Words:* prostate; prostatectomy; urinary incontinence, stress; ultrasonography; urinary sphincter, artificial

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Male SUI is a challenging problem following RP. Large contemporary series show incontinence rates over a wide range of 8% to 47%<sup>1,2</sup> but persistent post-RP SUI after 1 year affects 2% to 5% of patients.<sup>3</sup> When rehabilitation methods fail, surgery may be considered. The main surgical options are AUS implantation, urethral bulking injections of various substances, eg autologous fat, silicone and bovine collagen, and male urethral slings.<sup>3</sup>

AUS implantation is considered the gold standard in patients with moderate to severe intrinsic sphincteric dysfunction. The AUS achieves a continence rate of around 90% in the short and long term.<sup>4</sup> However, it is costly and has significant complication and revision rates.<sup>4</sup> Urethral bulking injections are mainly used in patients with mild to moderate SUI but the effect on postoperative continence is limited by poor success rates that decrease with time, often requiring multiple injections.<sup>3,5,6</sup> Male urethral slings with different techniques using synthetic mesh or allogenic grafts have been developed, showing potential good results, and their efficacy is currently under evaluation.<sup>7,8</sup>

Treatment for SUI after RP with an entirely new system, that is ProACT, was recently described with promising initial clinical results.<sup>9</sup> As described by Hubner and Schlarp, system implantation is performed under fluoroscopic guidance and contrast medium is used.<sup>9</sup> We evaluated the fea-

sibility and the potential advantages of ProACT system implantation using TRUS for guidance, avoiding the use of fluoroscopy and contrast medium.

## MATERIALS AND METHODS

### 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 to a re-injectable titanium port through a 2 lumen 12 to 14 cm tube. One lumen contains a 15 cm 0.8 mm push wire. Every patient requires 2 balloons, which are placed on either side of the vesicourethral anastomosis just above the pelvic diaphragm. An especially 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 2 titanium ports are placed into a subcutaneous parascrotal position to allow easy percutaneous access for filling the balloons postoperatively with a 23 gauge non coring needle to a maximum of 8 ml. This allows the device to be adjusted by modifying the level of obstruction needed to achieve continence.

### System Implantation

#### According to Hubner and Schlarp

As described by Hubner and Schlarp, system implantation is performed under fluoroscopic guidance with a cystoscope sheath inserted in the bladder functioning as a guide for correct placement.<sup>9</sup> The balloons are then filled with con-

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trast medium and sterile water mixed to an isotonic medium.

### TRUS Guided System Implantation

After placing the system using the technique described by Hubner and Schlarp,<sup>9</sup> we experimented with a modified TRUS guided procedure in 2 male cadavers that had undergone RP in life. Tests showed the practicability and accuracy of this procedure. Subsequently autopsies demonstrated the correct position of the system.

After obtaining institutional review board approval the TRUS guided procedure was used in 7 patients with a mean age of 68.4 years (range 53 to 76) between June and October 2005. All patients reported mild to severe SUI after laparoscopic transperitoneal RP and failure of rehabilitation methods, including pelvic floor training and electrostimulation. Table 1 lists patient demographics.

Before treatment all patients were evaluated with a complete medical history, physical examination, chest x-ray, abdominopelvic computerized tomography, bone scan, prostate specific antigen and liver function tests to rule out distant metastasis. Flexible cystoscopy and TRUS were used to exclude local recurrences and evaluate the bladder neck, anastomosis and urethra.

Continence was evaluated as the number of PPD used by patients. It was categorized as mild—1 or 2, moderate—3 to 5 and severe—greater than 5 PPD. According to the methodology and definitions of International Continence Society guidelines,<sup>10</sup> urodynamic investigations were done to exclude detrusor overactivity or compliance abnormalities.

### Patient Preparation

The patient is advised to take an antiseptic shower and cleansing enema the night before surgery. Hospital admission is on the day of surgery. Antibiotic intravenous prophylaxis with an aminoglycoside (gentamicin sulfate) plus the glycopeptide vancomycin is preoperatively administered while the patient is on call to 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 and it is liberally irrigated throughout the procedure.

### Operative Technique

The patient is placed in the lithotomy position and the lower abdomen, genitals, perineum and the perianal area are disinfected. A 16Fr Foley catheter is inserted in the bladder to fill the bladder with 100 ml sterile water and clearly visualize the urethra and the bladder neck with TRUS. The scrotum is held above the perineum with tape. The anal ring is separated by the perineum with a drape.

Two horizontal 5 to 10 mm 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, A). Under TRUS guidance using a 7.5 MHz linear and small convex probe the specially designed device, consisting of a sharp tip, removable trocar contained in a 4.6 mm diameter U-shaped sheath, is inserted through 1 skin incision and directed to 1 side of the bladder neck, perforating the pelvic diaphragm (fig. 1, B and C).

The Foley catheter, device and anatomical structures are perfectly visualized on TRUS, so that bladder and urethral injuries may be avoided. The passage above the pelvic diaphragm is also clearly visualized to correctly position the system (fig. 2, A). With a twisting motion the space for the balloon is created in the scar tissue around the anastomosis. The trocar is removed, leaving the U-shaped sheath in place. During this maneuver the sheath is gently advanced to occupy the space created by the trocar tip. If bladder perforation occurs, urine and sterile water may be seen coming out of the sheath. The sheath is then lubricated. With the help of the push wire the system balloon is passed through the sheath. The balloon is inflated with 1 ml 0.9% saline solution via the titanium port after the sheath is pulled back approximately 2 cm to permit balloon expansion. TRUS is used to confirm correct balloon placement (fig. 2, B and C). The push wire is removed. Using a Kelly clamp a subcutaneous parascrotal tunnel is bluntly created to allow placement of the tube and titanium port. The procedure is repeated on the contralateral side.

The incisions are closed in 2 layers with 4-zero resorbable sutures. The Foley catheter is maintained overnight. If gross hematuria or urethral bleeding occurs, flexible cystoscopy may be performed to exclude urethral or bladder perforation. When present, postoperative pain is easily controlled with nonsteroidal anti-inflammatory drugs. A 5-day course of antibacterial prophylaxis is given with the oral fluoroquinolone levofloxacin.

### Followup and Postoperative Adjustment of the ProACT System

On postoperative day 30 the patient is evaluated according to the number of PPD and TRUS is performed to confirm correct placement of the balloons. If the devices are in the correct position and complete continence has not been achieved, each balloon is filled with 1 ml 0.9% saline. The procedure is performed through percutaneous access to the 2 titanium ports with a 23 gauge noncoring needle without using anesthesia.

The same patient evaluation and balloon adjustment are done every 30 days until continence is achieved at a maximum filling volume of 8 ml. If the system fails to achieve continence or a complication occurs, each balloon may be deflated and simply removed using local anesthesia with a small skin incision in the area where the titanium port is located.

### RESULTS

All patients were free of cancer at the time of ProACT system implantation. The systems were successfully implanted in all cases. Time needed to complete the overall procedure was 15 to 30 minutes. We noted a little more complexity to creating the space for the balloon in the pa-

TABLE 1. Patient demographics

No. pts	7
Mean age (range)	68.4 (53–76)
Mean mos from RP–ProACT implantation (range)	29.5 (17–49)
No. radiotherapy:	3
Adjuvant	2
Local recurrence	1
No. incontinence:	
Mild	2
Moderate	4
Severe	1



FIG. 1. *a*, perineal skin incisions with patient in lithotomy position and TRUS used for guidance. *USP*, ultrasound probe. *b*, intraoperative image shows insertion of especially designed trocar. *c*, paramedian sagittal diagram demonstrates that under TRUS guidance trocar (*T*) is directed to 1 side of bladder (*B*) neck, perforating pelvic diaphragm (*PD*). *CB*, Foley catheter balloon. *PB*, pubic bone. *R*, rectum.

tients who had previously received radiotherapy as a consequence of extra scar tissue around the anastomosis. All balloons were confirmed to be in the correct position on intraoperative TRUS.

We did not observe bleeding complications, or bladder or urethral injuries. After catheter removal no urinary retention occurred. All TRUS studies performed during the postoperative period confirmed the exact location of the devices.

Table 2 shows preliminary outcome data in this series, although this was not one of the aims of this report. During followup we did not observe complications such as erosion, migration or device failure.

## DISCUSSION

The rate of persistent SUI after RP is less than 5% but when it occurs, it affects the physical, psychological and social well-being of patients, thus, having considerable impact on quality of life. In most patients SUI is due to intrinsic sphincteric deficiency.<sup>11</sup>

Currently the main surgical interventions are AUS implantation and urethral bulking injections. AUS implantation is associated with continence and satisfaction in approximately 90% of refractory post-RP SUI cases and it currently remains the reference treatment.<sup>12</sup> However, the AUS is expensive and it requires a complex surgical procedure, which 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 failure, infection or early and late erosion.<sup>13–16</sup>

Periurethral injection therapy is a minimally invasive option with low morbidity. Different bulking substances have been used with retrograde or antegrade approaches. The most commonly used agents are silicone, autologous fat and collagen. Short-term results are acceptable with continence achieved in 10% to 38.7% of patients.<sup>5,6</sup> However, the

effectiveness of such therapy has the tendency to decrease with time because of biodegradability or migration. Long-term results indicate a significant decrease in efficacy with a continence rate of between 0%<sup>6</sup> and 10%<sup>17</sup> during followup. Moreover, patients who respond to bulking agents usually need yearly or biyearly injections to maintain continence.<sup>18</sup> Other promising nonmigratory materials, such as calcium hydroxylapatite and dextranomer/hyaluronic acid copolymer, are currently under investigation.<sup>19,20</sup>

Male bulbourethral slings with synthetic mesh or allogenic grafts have been developed.<sup>7,8</sup> Initial results are comparable to those previously published for male sphincters. Long-term results are currently under investigation.

Treatment for incontinence after RP with the ProACT system was recently described by Hubner and Schlarp.<sup>9</sup> They implanted the system in 110 patients who underwent RP via different approaches, including retropubic, perineal and laparoscopic, in 6 patients with incontinence after transurethral prostate resection and in 1 who underwent radical cystectomy. In this series at a mean followup of 13 months (range 3 to 54) Hubner and Schlarp reported a statistically significant decrease in mean daily pad use from 6 to 1 pads 1 year after surgery. The effectiveness of the system did not tend to decrease in 40 patients with a followup of 2 years. All patients were also assessed with the validated quality of life questionnaire developed by Wagner et al.<sup>21</sup> Median score improved from 34.7 at baseline to 66.3 at 2 years ( $p < 0.001$ ).

These initial clinical results are promising, considering that Hubner and Schlarp pioneered of the technique and initially in the first 50 cases they applied a so-called first-generation device, which was associated with a high rate of balloon leakage.<sup>9</sup> Subsequently the device was re-engineered with a remarkable decrease in the failure rate, that is only 1.7%.



FIG. 2. *a*, ultrasound paramedian sagittal view shows trocar (*T*) perforating pelvic diaphragm (*PD*). *CB*, Foley catheter balloon. *b*, ultrasound paramedian sagittal view demonstrates system balloon (*B*) inflated with 1 ml 0.9% saline solution. *c*, ultrasound coronal view reveals system balloon just lateral to bladder neck (*BN*). *R*, rectum.

TABLE 2. Preliminary clinical data

Pt No.	Prostate Ca Stage	Radiotherapy	Incontinence	Followup (mos)	Outcome
1	pT2aN0	No	Moderate	6	Dry without adjustments
2	pT3bN1	Adjuvant	Moderate	6	Dry after 1 adjustment
3	pT2bN0	No	Severe	5	Dry after 3 adjustments
4	pT2bN0	For local recurrence	Moderate	5	Dry after 2 adjustments
5	pT3aN0	Adjuvant	Mild	3	Subjective improvement after 3 adjustments, no change in No. PPDs
6	pT2bN0	No	Mild	3	Dry after 2 adjustments
7	pT2aN0	No	Moderate	2	Subjective improvement after 2 adjustments, no change in No. PPDs

The ProACT system has different advantages. It is implanted via a minimally invasive procedure with modest patient discomfort. Furthermore, it is easily adjustable, so that the proper level of urethral resistance may be determined based on patient response. Moreover, if there is no clinical response or a complication occurs, eg infection, migration or erosion, the system simply may be removed using local anesthesia with a small skin incision in the area where the titanium port is located by deflating the balloon. When the system must be removed, there are no limitations to further surgical treatments for SUI. Finally, the cost of the system is relatively low. At our institution the cost of the 2 balloons required in a patient is €2,300.

The first results of this innovative technique were limited by a relatively high complication rate.<sup>9</sup> Intraoperative complications included 15 bladder or urethral perforations, of which the rate decreased with increasing experience to 5 in the last 37 patients. Patients were treated conservatively with contralateral implantation of the system and delayed implantation on the side of perforation. Postoperative bladder or urethral erosion occurred in 13 cases, including 11 unilateral and 2 bilateral cases. In these patients the systems were simply removed and reimplanted 6 weeks later. Finally, device migration occurred in 16 patients and the system required reimplantation. As stated, a possible reason for this high complication rate was that this was an entirely new procedure that was developed with no benefit from the previous experience of other colleagues.

In our opinion another potential source of complications such as perforations or migration could have been the use of fluoroscopic guidance that those investigators adopted.<sup>9</sup> In fact, the pelvic floor and its relationships with the bladder neck, urethra and rectum are not accurately visualized by fluoroscopy, so that trocar insertion is only guided by cystography with the cystoscope sheath functioning as a parallel guide for placement. Moreover, the C arm of the fluoroscope creates only a 2-dimensional view, so that it is not clear whether the tip of the trocar is cephalic or caudal to the bladder neck in the coronal plane. It is possible to rotate the C arm to achieve sagittal visualization of the bladder and urethra but the pelvic bones interfere and the procedure becomes more complex.

TRUS overcomes these drawbacks, allowing excellent imaging of all anatomical landmarks in the coronal and sagittal planes with continuous, real-time visualization of the entire procedure. Therefore, the technique appears to be safe and accurate. In our series no perioperative complications occurred and the devices were always precisely located lateral to the vesicourethral anastomosis just above the pelvic floor. Another advantage of using ultrasound is that there is

obviously no exposition to radiation for operating room staff. Finally, the balloons and bladder are filled with normal saline with no risks to patients with an allergy to contrast mediums.

Followup in our series is short. Only time will show if the accurate device positioning achieved with TRUS for guidance will translate into better long-term outcomes.

## CONCLUSIONS

ProACT system implantation using TRUS for guidance is feasible. TRUS allows excellent imaging of all anatomical landmarks during the entire procedure and it seems to provide considerable advantages over fluoroscopy in terms of safety and accuracy. However, the ProACT system should be still considered a new, experimental tool in the armamentarium for treating patients with post-RP SUI. Larger series and longer followup are mandatory to establish its safety, efficacy and durability.

### Abbreviations and Acronyms

AUS	=	artificial urinary sphincter
PPD	=	pads daily
RP	=	radical prostatectomy
SUI	=	stress urinary incontinence
TRUS	=	transrectal ultrasonography

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## EDITORIAL COMMENT

This is a pilot study assessing placement of the anti-incontinence ProACT system using TRUS for guidance in men

with incontinence after RP. The concept is interesting and well presented.

Although the aim of the authors was not to show a clinical outcome of the procedure, they present clinical results in 7 patients and also compared their results and complications to the results of other series published in the past. To reach a meaningful conclusion regarding the outcome of 2 techniques patients in the 2 groups should be randomized. As the authors admit, followup was short and only time will show if so called correct position translates to a better long-term outcome. This study should only be viewed as a new, feasible technique for placing the ProACT system and not an endorsement of this treatment for post-RP incontinence in men.

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## REPLY BY AUTHORS

Larger series and randomized studies are mandatory to establish the safety, efficacy and durability of the ProACT system which is a new, experimental tool for the treatment of patients with post-RP urinary incontinence. Furthermore, a comparison of outcomes with the artificial urinary sphincter, which is the gold standard for the treatment of male SUI, is needed. The purpose of our pilot study was to test TRUS for guiding the ProACT system implantation, and the results demonstrated the feasibility of this approach.

After submission of our manuscript Trigo-Rocha et al published an article regarding the ProACT system implanted under fluoroscopic guidance.<sup>1</sup> Their findings corroborate the promising initial clinical results obtained by Hubner and Schlarp (reference 9 in article). However, Trigo-Rocha et al reported 2 intraoperative bladder perforations that required delayed implantation of the system and maintenance of an indwelling catheter. The lower quality of anatomical images obtained with fluoroscopy may be a reason for these complications.

Our study suggests that implantation of a ProACT system using TRUS, which provides excellent imaging of the anatomical landmarks during the entire procedure without radiation exposure, may provide advantages over fluoroscopy for the surgeon and patient in terms of safety and accuracy.

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