

Treatment of Postprostatectomy Stress Urinary Incontinence Using a Minimally Invasive Adjustable Continence Balloon Device, ProACT: Results of a Preliminary, Multicenter, Pilot Study

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OBJECTIVES	To evaluate the safety and efficacy of a new minimally invasive device, Adjustable Continence Therapy (ProACT) for patients with postprostatectomy stress urinary incontinence (SUI).
METHODS	Sixty-two patients with urodynamic SUI after prostate surgery were evaluated according to daily pad count and a specific validated evaluation for persons with urinary incontinence.
RESULTS	All patients were successfully implanted in a single procedure using general or spinal anaesthesia. Procedural time was 37 minutes (range, 18 to 80 minutes). Daily pad usage decreased from 4.6 pads per day to 1.06 pads per day at 12 months. Mean quality-of-life index score increased from 48 to 67 at 12 months. Fifty-nine percent of patients without adjuvant radiation were improved (greater than 50% reduction in pad use), and 30% were cured (no pads), whereas 83% of postirradiated patients failed intervention. Fifty-five patients (88%) required percutaneous balloon adjustments. The mean optimal volume after adjustments for all 45 improved patients was 3.8 mL per balloon. Complications necessitating removal occurred in 19 patients and included erosion, infection, migration, and failure to respond. Of these, 4 were successfully reimplanted. All complications occurred in the first postoperative month.
CONCLUSIONS	Implantation of postoperatively adjustable balloons in postprostatectomy men is technically feasible, with an improvement in continence particularly in patients with nonirradiated periurethral tissues. Optimal urethral resistance is achieved, with easy postoperative adjustment. Implantation of ProACT balloons may represent a promising development in the treatment of postprostatectomy SUI. UROLOGY 71: 256–260, 2008. © 2008 Elsevier Inc.

Stress urinary incontinence (SUI) and erectile dysfunction as a consequence of prostate surgery are the two main complications dreaded by patients and urologists. Progress in prostatectomy techniques, including improved hemostatic and anastomotic tools, has led to a decrease in the risk of SUI, and today it is reported that 1 year after radical prostatectomy (RP) for cancer the incidence of incontinence is less than 20%.^{1–3} Adjuvant radiotherapy has not been clearly proved to increase the risk of SUI, but the treatment of this dis-

ressing condition on previously radiated tissue is less successful.^{4,5}

After prostate surgery most reported incontinence consists only of mild urinary leakage primarily due to intrinsic sphincter damage.^{6,7} Nevertheless SUI is a devastating complication that causes considerable impact on quality of life, with a high rate of emotional distress.⁸ First-line treatment is usually noninvasive rehabilitation, including physiotherapy with pelvic floor exercises and electrical stimulation.^{9,10} When surgery and especially RP induces significant urethral sphincter deficiency, physiotherapy may fail and the patient remains intractably incontinent. In these cases, a surgical treatment approach is generally required. Traditionally an artificial urinary sphincter is proposed, and this continues to be the treatment of reference.¹¹ Nevertheless complications and high costs associated with this discourage its widespread use and therefore new approaches have been proposed, including the injection of bulking agents^{12,13} and

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urethral sling techniques.^{14,15} These minimally invasive techniques aim to increase outlet resistance and therefore maintain bladder competence during increased abdominal pressure. The resistance strength varies from one technique to another, and it seems that adjusting perioperatively to achieve the right resistance continues to be a difficult challenge. In both urethral sling tensioning techniques and injection of bulking agents, the goal is to restore continence with minimal complications, in particular by avoiding dysuria and retention. Neither of these techniques, however, is considered suitable for all patients with prostatectomy incontinence.

Recently a new approach has been developed using prosthetic balloons.^{16,17} The ProACT periurethral prosthesis (Uromedica, Plymouth, Minn) is of interest because it is the first postoperatively adjustable device that is easily reversible should this become necessary. It aims to achieve optimal outlet resistance by progressively increasing the volume of the balloons. The objectives of this first multicenter, prospective study were to assess the safety, feasibility, and efficacy of the ProACT system in the treatment of SUI after prostate surgery.

MATERIAL AND METHODS

Study Population

Seven institutions, comprising 5 public universities and 2 private clinics, participated in this open prospective study, recruiting between 6 and 12 patients per site. After receipt of ethical approval, 62 patients were enrolled. Of these, 56 reported incontinence after treatment of their prostate cancer: 55 after RP (among whom 12 had adjuvant radiotherapy) and 1 treated by high-intensity focused ultrasound. For the remaining patients, incontinence followed surgery for benign prostatic hyperplasia (4 transrectal resection and 2 open prostatectomies). Mean age of the whole patient population was 71.1 years (range, 52 to 87.2 years). Mean time since initial prostate surgery was 4.7 years (range, 0.5 to 20.6 years).

All patients had failed previous rehabilitation (including pelvic floor training and electrostimulation) and were evaluated before implantation by medical history, clinical examination, and cystoscopy to elicit any bladder abnormality (ie, bladder carcinoma) or current urethral or bladder neck stricture. To exclude patients with bladder overactivity, standard saline filling cystometry was performed at baseline on all patients. Urodynamics were not repeated postoperatively. Daily pad counts were recorded as a measure of severity of incontinence at baseline and each postoperative visit. Additionally, quality of life was assessed at each visit with a validated quality-of-life questionnaire (I-QoL) for persons with urinary incontinence,¹⁸ as well as a procedurally related postoperative assessment. Ten patients had previously required one or more urethrotomy or bladder neck incision, and 12 patients had previously undergone pelvic radiotherapy. Four patients had undergone unsuccessful previous invasive therapies, including bulbourethral sling (1) and bulking agent injections (3). Seven patients had previously undergone artificial urinary sphincter implantations. Of these, 3 developed infections, 2 had urethral erosions, and 1 had perineal pain necessitating removal. One patient was unable to manipulate his sphincter after a cerebral vascular accident.



Figure 1. The ProACT kit contains two implants with silicone elastomer adjustable balloons attached by a short tubing (length, 12 to 14 cm) to a titanium port, an introducing cannula, and a syringe with a fine-gauge needle.

Operative Technique

The ProACT system was implanted in all patients. It consists of two silicone balloons, each attached to a port by short tubing (Fig. 1). The balloons are opposed at the bladder neck and can be postoperatively adjusted through percutaneous injection of the port with the aim of compressing the urethra. The procedure was performed as described in previous reports.^{16,17} Using a specific introducer through a perineal incision, the pelvic floor is perforated lateral to the urethra. With fluoroscopic control, the balloons are placed at the level of the vesicourethral anastomosis just under the bladder neck in RP patients or at the prostate apex where there is a prostatic remnant (after transurethral resection of the prostate, open prostatectomy, or high-intensity focused ultrasound therapy). An isotonic radio-opaque solution is injected through each port to secure the balloons at the level of the external sphincter. The reinjectable ports are positioned subdermally in the lateral aspect of the scrotum to be easily accessed for percutaneous reinjection if needed. Initially 2 mL is injected into each balloon, with the aim to increase urethral resistance while avoiding dysuria and retention (Fig. 2). Adjustments are limited to 1 mL per balloon per visit to minimize the risk of migration and erosion caused by splitting of the pseudo-capsule surrounding the balloons.

RESULTS

Feasibility

Mean procedural time was 37 minutes (range, 18 to 80 minutes), including the first procedures performed by novice implanters. All patients underwent successful bilateral balloon implantation during a single procedure. Perioperatively, multiple tract creation or repositioning of balloons was required in 34 patients (52%), to achieve optimal placement, or as a result of bladder (4) or urethral (2) perforation necessitating placement of a urethral catheter for 2 days. Blood loss was minimal in all cases. Mean initial balloon volume was 2.2 mL (range, 1.5 to 6 mL). All surgeons graded the ease of implantation during each procedure, with 88% rating placement

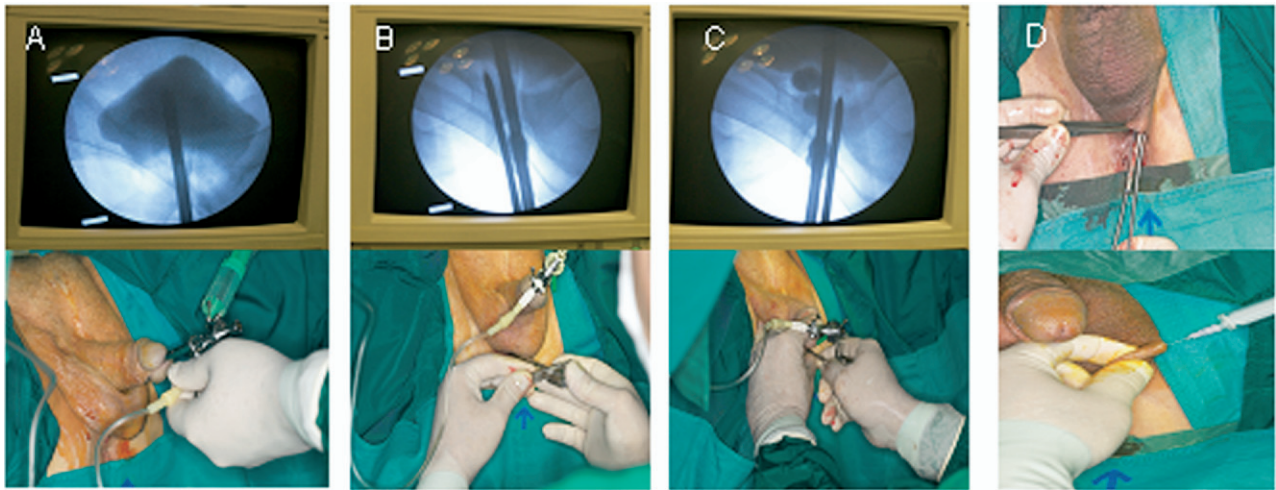


Figure 2. ProACT procedure. **(A)** With fluoroscopic bladder neck localization (contrast agent in the bladder) and direct urethral vision by rigid cystoscopy, the balloon's ideal position is easily localized. **(B)** Through a 2-cm perineal incision parallel to the cystoscope, the distal extremity of the cannula is correctly placed in this area, perforating the pelvic floor laterally next to the urethra. **(C)** Deflated balloon is sited on the "U-shaped" cannula before inflation of the balloon with isotonic solution. **(D)** Port placed in the scrotum just under the skin ready for future percutaneous balloon adjustment.

as "mild," 7% "moderate," and 5% "severe." Interestingly, neither the extra manipulation, the degree of difficulty in placement resulting from previous intervention (eg, radiation, bladder neck contracture), or indeed perioperative bladder or urethral perforation had any effect on patient outcomes.

General and spinal anesthesia was used for 44 and 18 patients, respectively. At the end of the procedure an indwelling Foley catheter was placed overnight. Patients were offered further percutaneous 1-mL injections into each balloon fortnightly as required until optimum continence was restored or no further improvement could be achieved.

Continence Results

Daily pad usage decreased from a mean of 4.6 per day (range, 1 to 10) before surgery to 1.8 per day at 6 months (range, 0 to 10) and 1.06 per day (range 0 to 6) at 1 year after surgery. After 6 months (adjustments completed) 71% of the patients were wearing no pads or 1 pad per day (including security pads).

Among the 44 patients who had RP without adjuvant radiotherapy, 89% improved, including 30% of patients becoming pad free. Conversely, for the 12 patients with adjuvant radiotherapy before ProACT implantation the failure rate was 83%.

These overall positive results are reinforced by a mean increase in quality of life score, from 48 at baseline to 67 at 1 year after surgery. Seven patients were dry immediately after surgery and remained continent without further adjustment. For the remaining 55 patients, percutaneous balloon adjustments were needed of up to 1 mL per balloon per visit. Eight patients required one adjustment, 15 required two adjustments, 8 required three adjustments, and 24 patients required 4 or more. Adjustments

were performed until continence was achieved or there was no further improvement. Of the 45 patients who improved the mean optimal volume after adjustments was 3.8 mL per balloon. Aseptic injection of the port to enable increased or decreased balloon volumes was undertaken without anaesthesia in an outpatient setting.

Complications

Intraoperatively two urethral and four bladder perforations occurred. In the event of a perforation, a new tract was created using the same incision and the device inserted during the same procedure. A total of 19 patients required explantation due to device-related problems (2), infection or erosion (5), migration (1), iatrogenic traumatism (2), or nonresponse (9). Of these patients, 4 were reimplemented with ProACT balloons, and 2 went on to have artificial urinary sphincters implanted. All complications occurred in the first postoperative month. For those patients who did not respond, CT imaging was used to ascertain positioning.

In 3 of 62 patients (5%) urinary retention persisted after catheter removal, but this was resolved by deflating the balloons by 1 mL on each side.

COMMENT

The ProACT system was successfully implanted in all patients across the seven different centers. None of the implanting surgeons were experienced in this specific technique, although first cases were attended by an experienced ProACT surgeon who offered verbal clinical support. Although the implanting surgeons generally reported that the perineal approach and percutaneous insertion of the balloons presented no technical difficulty, there was a definite learning curve in terms of identifying

the most efficacious balloon placement relative to the urethra, a factor that became more apparent after patient outcome review. Furthermore, implanters were able to reduce balloon placement times and with less perforations reported as they gained more experience. Additionally, the technique of implanting ProACT in those patients with a prostatic remnant developed over time, with balloons being placed at the level of the membranous urethra, which is more medial and distal than originally conceived. Initially balloon volume was based on a fluoroscopic interpretation of a bulking effect. After the first 10 patients it was decided to standardize initial filling volume to 2 mL to minimize the risks of erosion and migration.

The 31% of patients requiring explantation was a slightly higher incidence than that reported by Huebner and Schlarp in the single reference center series of 117 patients and Trigo Rocha's series of 25 patients.^{16,17} This may have been because we had numerous implanters, each with their own learning curve.

In our series intraoperative urethral or bladder perforation did not preclude balloon implantation. Conversely, Huebner had previously chosen to reimplant the affected side 1 to 4 months after perforation. Our decision to proceed without delay may have contributed to our higher rate of infection and erosion in the initial learning phase; however, we believe we can safely continue our practice because we are now more experienced in positioning the balloons. Failure of conservative management after RP varies but in large series has been 8% to 47%.^{18,19} These variations are explained by the difficulties in defining objective parameters to evaluate exact continence. Indeed, there is no validated measurement of pad weight for men, and this proves problematic when determining the exact quantity of urine loss according to pad and condom usage only. Surgical treatment remains the principal solution after physiotherapy has failed. Four types of surgery may be discussed: artificial urinary sphincter, bulking agents injection, male slings, and balloons. Implantation of artificial urinary sphincter produces a social continence rate of 90% and patient satisfaction rates of 85% to 95%, despite revisions.²⁰⁻²² Nevertheless the complexity of the device, its cost, its revision rates, and the necessity to manipulate the finger controls lead to highly selected patients. Cure rates with periurethral injections have been reported to be between 5% and 26% and improvement between 31% and 57%.²³⁻²⁵ This technique often requires multiple and nonreversible injections. Male slings supporting the bulbar urethra are reported to have up to 67% success (cured or improved) but a high risk of obstruction leading to dysuria and retention.^{26,27} Moreover, on the basis of a specific questionnaire, Clemens *et al.*²⁸ report up to 52% of patients having persistent perineal numbness or pain after the bulbourethral sling procedure. Many prosthetic devices have been proposed and even the use of bone anchors evaluated in large series. This anchoring has

become questionable for many urologists owing to the potential possibility of osseous complications.²⁹

In terms of implantation of the ProACT balloons, this series confirms previous reports of 69% of patients having effective devices *in situ*.¹⁶ In addition, neither dysuria nor pain was reported at any of the follow-up periods in this study. With 59% of our patients improved at 1 year, the balloon system seems effective. For patients for whom continence was not obtained, the explantation was very simple and did not impact further surgery.

For patients suffering from SUI as a result of sphincteric insufficiency, the treatment result balances delicately between continence and obstruction. In fact, it depends directly on urethral outflow resistance. It would seem desirable to adjust the resistance to the needs of each patient, considering specific bladder pressure, pelvic floor atrophy, and urethral mobility. One of the major interests of the ProACT system is its adjustable resistance. In fact, balloon pressure against the outer urethra mimics the urethral sphincter and therefore the pressure can be adjusted without further surgery in adjusting balloon volume. This adjustment is possible at any time, even after a number of years if necessary (eg, aging bladder, neurologic disease). Optimal continence may be physician or patient driven, and although in some instances further titration was possible, the patient may have deferred further intervention.

In our series only 1 of 12 patients who received adjuvant radiotherapy improved in terms of his continence. Radiation is a highly significant predictive factor of failure when compared with patients who did not have adjuvant radiation. Radiated tissues are probably less compliant to balloon expansion and thus the pressure on the urethra is less efficient. In such cases periurethral tissue fibrosis prevents adequate urethral coaptation. Previous radiation seems to decrease efficacy of most techniques, including bulbourethral sling surgery, as recently reported by the group from the Mayo Clinic.³⁰

This study has demonstrated the technical feasibility in men after prostate surgery, with an achievable learning curve. In terms of continence, results obtained by the ProACT device are comparable to those reported with bulbourethral sling, and moreover these balloon prostheses have been shown to be very well tolerated by the patient. The ideal pressure on the urethra to achieve continence can be easily obtained with this adjustable system without requiring progressive endoscopic or urodynamic explorations. It would be interesting to perform further urodynamic studies to support this supposition. Given the ease of implantation, the improvement in continence, and the ability to reverse if necessary, adjustable balloons may have a role in the treatment of postprostatectomy SUI, particularly in patients with non-irradiated periurethral tissues. Because this study describes our initial experience with an evolving technology, the authors believe further study of this very minimally invasive technique is required to establish

ideal patient selection, durability of the procedure, and whether development in the technique can better predict a reasonably reliable outcome.

References

1. Stanford JL, Freng Z, Hamilton AS, *et al*: Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer: the Prostate Cancer Outcomes Study. *JAMA* **60**: 283–354, 2000.
2. Catalona WJ, Carvalhal GF, Mager DE, *et al*: Potency, continence and complication rates in 18710 consecutive radical retropubic prostatectomies. *J Urol* **162**: 433–436, 1999.
3. Peyromaure M, Ravery V, and Boccon-Gibod: The management of stress urinary incontinence after radical prostatectomy. *BJU Int* **90**: 155–158, 2002.
4. Lee WR, Schultheiss TE, Hanlon AL, *et al*: Urinary incontinence following external-beam radiotherapy for clinically localized prostate cancer. *Urology* **48**: 95–99, 1996.
5. Formenti SC, Lieskovsky G, Skinner D, *et al*: Update on the impact of moderate dose of adjuvant radiation on urinary continence and sexually potency in prostate cancer patients treated with nerve-sparing prostatectomy. *Urology* **56**: 453–458, 2000.
6. Gudziak MR, McGuire EJ, and Cormley EA: Urodynamic assessment of urethral sphincter function in post-prostatectomy incontinence. *J Urol* **56**: 1131–1134, 1996.
7. John H, Sullivan MP, Bangerter U, *et al*: Effect of radical prostatectomy on sensory threshold and pressure transmission. *J Urol* **163**: 1761–1766, 2000.
8. Steineck G, Helgesen F, Adolfsson J, *et al*: Quality of life after radical prostatectomy or watchful waiting. *New Engl J Med* **34**: 790–796, 2002.
9. Floratos DL, Sonke G, Rapidou C, *et al*: Biofeedback vs verbal feedback as learning tools for pelvic muscle exercises in the early management of urinary incontinence after radical prostatectomy. *BJU Int* **89**: 714–719, 2002.
10. Hoffmann W, Liedke S, Dombo O, *et al*: Electrostimulation in therapy of postoperative urinary incontinence. Therapeutic value for quality of life. *Urologe A* **44**: 33–40, 2005.
11. Herschorn S, Bosch R, Bruschini H, *et al*: Surgical treatment of urinary incontinence in men, in Abrams P, Cardozo L, Khoury S, *et al*. (Eds): *Incontinence: Second International Consultation on Incontinence*. 2nd ed. Plymouth, UK, Health Publication, 2002, pp 85–821.
12. Tiguert R, Gheier EL, and Gudziak MR: Collagen injection in the management of post-radical prostatectomy intrinsic sphincteric deficiency. *Neurourol Urodyn* **18**: 653–658, 1999.
13. Klutke JJ, Subir C, Adriole G, *et al*: Long-term results after antegrade collagen injection for stress urinary incontinence following radical retropubic prostatectomy. *Urology* **53**: 974–977, 1999.
14. Migliari R, Pistoiesi D, and De Angelis M: Polypropylene sling of the bulbar urethra for post-radical prostatectomy incontinence. *Eur Urol* **43**: 152–157, 2003.
15. John H: Bulbourethral composite suspension: a new operative technique for post-prostatectomy incontinence. *J Urol* **171**: 1966–1970, 2004.
16. Hubner W, and Schlarp O: Treatment of incontinence after prostatectomy using a new minimally device: adjustable continence therapy. *BJU Int* **96**: 587–594, 2005.
17. Trigo Rocha F, Mendes Gomes C, Lima Pompeo AC, *et al*: Prospective study evaluating efficacy and safety of adjustable continence therapy (ProACT), for post radical prostatectomy urinary incontinence. *Urology* **67**: 965–969, 2006.
18. Wagner TH, Patrick DL, Badevan TG, *et al*: Quality of life of persons with urinary incontinence: development of a new measure. *Urology* **47**: 67–72, 1996.
19. Catalona WJ, Carvalhal GF, Mager DE, *et al*: Potency, continence and complication rates in 1,870 consecutive radical retropubic prostatectomies. *J Urol* **162**: 433–438, 1999.
20. Fowler FJ Jr, Barry MJ, Lu-Yao G, *et al*: Patient-reported complications and follow-up treatment after radical prostatectomy. The National Medicare Experience: 1988–1990 (updated June 1993). *Urology* **42**: 622–629, 1993.
21. Litwiller SE, Kim Kb, Fone PD, *et al*: Post-prostatectomy incontinence and the artificial urinary sphincter: a long-term study of patient satisfaction and criteria for success. *J Urol* **156**: 1975–1980, 1996.
22. Elliot DS, and Barrett DM: Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. *J Urol* **159**: 1206–1208, 1998.
23. Petrou SP, Elliott DS, and Barrett DM: Artificial urethral sphincter for incontinence. *Urology* **56**: 353–359, 2000.
24. Bugel H, Pfister C, Sibert L, *et al*: Intraurethral macroplastic injections in the treatment of urinary incontinence after prostatic surgery. *Prog Urol* **9**: 1068–1076, 1999.
25. Westney OL, Bevan-Thomas R, Palmer JL, *et al*: Transurethral collagen injections for male intrinsic sphincter deficiency: the University of Texas-Houston experience. *J Urol* **174**: 994–997, 2005.
26. Comiter CV: The male perineal sling: immediate-term results. *Neurourol Urodyn* **24**: 648–653, 2005.
27. Schaeffer AJ, Clemens JQ, Ferrari M, *et al*: The male bulbourethral sling procedure for post-radical prostatectomy incontinence. *J Urol* **159**: 1510–1515, 1998.
28. Clemens JQ, Bushman W, and Schaeffer AJ: Questionnaire based results of the bulbourethral sling procedure. *J Urol* **162**: 1972–1976, 1999.
29. Fialkow MF, Lentz GM, Miller EA, *et al*: Complications from transvaginal pubovaginal slings using bone anchor fixation. *Urology* **64**: 1127–1132, 2004.
30. Castle EP, Andrews PE, Itano N, *et al*: The male sling for post-prostatectomy incontinence: mean follow up of 18 months. *J Urol* **173**: 1657–1660, 2005.