# Management of Stress Urinary Incontinence Following Prostate Surgery With Minimally Invasive Adjustable Continence Balloon Implants: Functional Results From a Single Center Prospective Study

Morgan Rouprêt,* Vincent Misraï, Pierre-Nicolas Gosseine, Stéphane Bart, Florence Cour and Emmanuel Chartier-Kastler

*From the Department of Urology, Pitié-Salpétrière Hospital, Assistance Publique-Hôpitaux de Paris (AP-HP), Faculté de Médecine Pierre et Marie Curie, University Paris VI, Paris (MR, VM, PNG, SB, FC, ECK), and Department of Urology, Clinique Pasteur, Toulouse (VM), France*

**Abbreviations and Acronyms**

AUS = artificial urinary sphincter

ISD = intrinsic sphincter deficiency

PPD = pad(s) per day

RP = radical prostatectomy

SUI = stress urinary incontinence

TURP = transurethral resection of the prostate

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* Correspondence: Academic Urology Department, Hospital Pitié-Salpétrière, 47-83 Boulevard de l'Hopital, 75013 Paris, France (e-mail: morgan.roupret@psl.aphp.fr).

**Purpose:** We determined the functional results and morbidity of balloon (ProACT™) implants for the treatment of male stress urinary incontinence after prostate surgery.

**Materials and Methods:** Between 2002 and 2008 a prospective, noncontrolled study was conducted. The ProACT implant consists of 2 adjustable balloons placed on either side of the native striated sphincter. The implants are adjusted by inflation during followup visits. The primary efficacy end point was postoperative continence as defined by the use of 0 to 1 pad daily.

**Results:** A total of 128 consecutive patients underwent implantation. Mean ± SD patient age was 71 ± 42.3 years (range 52 to 87). The severity of incontinence before ProACT was moderate (71), mild (40) and severe (17). Overall 25% of patients previously underwent pelvic radiotherapy. The mean number of daily pads per patient was 1.46 (vs 4.2 at baseline). Mean followup was 56.3 months (range 24 to 95). The functional result was success in 68% of patients with moderate/mild incontinence and the explantation rate was 18%. Among the 30 patients treated with radiotherapy before ProACT the success rate was only 46% and the incidence of urethral erosion was significantly higher ($p = 0.005$).

**Conclusions:** The ProACT implant appears to be an option for the treatment of moderate male stress urinary incontinence, especially given the minimally invasive modalities of insertion, the capacity to adjust the inflation of the balloons to achieve postoperative continence and the relative reversibility.

**Key Words:** biocompatible materials, postoperative complications, urinary incontinence, prostatectomy, transurethral resection of prostate

Stress urinary incontinence is a challenging condition for urologists, occurring in approximately 1% of men after TURP and in up to 87% of men after RP.[1,2] Although most men report resolution of this condition with time and conservative management, some men remain intractably incontinent.[3] Most authors define SUI with intrinsic sphincter deficiency as persistent SUI 1 year after prostatic surgery in the setting of conservative therapy failure.[4]

AUS implantation provides high rates of long-term continence and patient satisfaction, and is currently considered the gold standard for the treatment of postoperative sphincter



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incompetence in men.[5,6] However, an AUS requires a complex intraoperative procedure which may be associated with significant complications.[7] Thus, the development of various minimally invasive alternatives has been considered, including the injection of bulking agents or stem cells, the use of adjustable continence therapy (ProACT system) and the implantation of bulbourethral slings (ie a bone anchored and readjustable system).[1] In 2005 Hübner and Schlarp published the concept of static, progressive and adjustable external noncircumferential urethral compression by 2 balloons placed percutaneously bilaterally at the bladder neck.[8] Only a limited number of series have shown that ProACT implantation is technically feasible or that it is a viable, minimally invasive alternative for the management of mild to moderate SUI after prostate surgery.[8–12] Thus, we assessed continence and morbidity using intermediate followup in a sample of 128 consecutive patients from our center who routinely used the ProACT device.

## MATERIALS AND METHODS

### Patient Population

Between 2002 and 2008 we prospectively recruited consecutive patients who received implantation of the ProACT system for SUI after prostatic surgery at our center. Only patients who presented with SUI due to ISD after prostate surgery were considered. Patients with neurogenic ISD, overactive bladder or distant metastasis were excluded from the current study. Baseline evaluation included medical history, pad count, urodynamics (to exclude detrusor overactivity) and cystoscopy, and was performed on all patients. A quality of life evaluation was only available for the first 30 patients and was not routinely performed for the subsequent following patients. As a result these data were not evaluated in this patient series. Daily pad counts were recorded as a measure of the severity of incontinence at baseline. Incontinence was evaluated as PPD used by patients, and was ranked as mild (1 or 2 PPD), moderate (3 to 5 PPD) and severe (more than 5 PPD or use of condom catheter).

### ProACT Device and Surgical Technique

The ProACT implant is composed of 2 independent balloons connected to a titanium port by fine tubing, allowing for inflation and deflation of the balloon. The insertion kit includes 2 balloons that are positioned percutaneously on both sides of the membranous urethra to exert passive occlusion of the urethra by a bilateral action between the 2 balloons. The volume of each balloon is adjusted by percutaneous puncture of the titanium ports to achieve the maximum continence effect. The ProACT device was implanted as previously described.[12] The procedure was performed with the patient under spinal or general anesthesia in the lithotomy position using intraoperative fluoroscopic and cystoscopic guidance.

### Outcomes and Followup

Patients were reviewed at 4 weeks with routine flexible urethrocystoscopy to check urethral integrity. The ProACT balloons were then adjusted by 1 ml on each side at each visit (the rate was variable based on patient preference without reducing the interval between 2 inflations to less than 2 weeks) if patients continued to report clinically disabling SUI. In cases of persistent incontinence despite consecutive adjustment, placement and integrity of the ProACT device were assessed systematically with abdominal and pelvic x-rays or pelvic computerized tomography with 3-dimensional reconstruction (balloon no longer located at the level of the urethrovesical anastomosis or perforated).

Continence was assessed postoperatively according to changes in pad counts. Success was defined as no pad or 1 security PPD, and failure was defined as more than 1 PPD or change of treatment (patients who died or who were lost to followup also represent treatment failure on intent to treat analysis). Subjective improvement was also assessed with a visual analog scale ranging from 0 (no improvement) to 10 (complete resolution of incontinence).

### Statistical Analysis

Descriptive statistics are presented for the sample as percentages for qualitative variables, and means and standard deviations for quantitative variables. Correlations with failure were tested using Fisher's exact test for qualitative variables and a Mann-Whitney test for quantitative variables. All tests were 2-tailed with a significance level of 5% using SAS® V.8 software.

## RESULTS

### Patient Baseline Characteristics

A total of 128 patients were prospectively included in the study with a mean followup of 56.3 months (range 24 to 95). Mean patient age was 71 years (range 52 to 87). Of these patients 120 experienced post-prostatectomy urinary incontinence and 8 presented with SUI after TURP. Urinary incontinence developed in 9 patients following TURP for cancer, followed by conformal radiotherapy (7), high intensity focused ultrasound (1) and both treatments successively (1). A history of adjuvant radiotherapy after RP was found in 30 patients (25%). Thirteen patients (10%) had undergone prior anti-incontinence surgery with the artificial urinary sphincter AMS 800™ (10), InVance™ Male Sling System (1) and Macroplastique® injections (2). There were 13 patients (10%) who required internal urethrotomy for sclerosis of the urethrovesical anastomosis (10) and urethral stricture below the sphincter (3). Mean preoperative PPD was 4.2 (range 1 to 20). The severity of incontinence was categorized as moderate (71), mild (40) or severe (17).

### Surgical Technique

ProACT balloons were inserted within a mean operating time of 53 minutes (range 25 to 90). Mean