

## TRANSRECTAL ULTRASOUND-GUIDED IMPLANTATION OF THE PROACT™ SYSTEM IN PATIENTS WITH POST-RADICAL PROSTATECTOMY STRESS URINARY INCONTINENCE: CLINICAL RESULTS AFTER A MEAN FOLLOW UP OF 2 YEARS

### Hypothesis / aims of study

The ProACT™ system (male Adjustable Continence Therapy, Uromedica, Plymouth, MN, USA) is an adjustable, permanent device for post-radical prostatectomy stress urinary incontinence. Initially, as first described by Huebner and Schlarp, system implantation was performed under fluoroscopic guidance [1]. 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 [2]. TRUS provides excellent imaging of all anatomical landmarks during the entire procedure without radiation exposure and seems to offer considerable advantages over fluoroscopy in terms of safety and accuracy [2].

This study aims to evaluate the continence recovery of a cohort of male patients with stress urinary incontinence after radical prostatectomy, all treated with the TRUS-guided ProACT™ system implantation. We report our findings at a mean of 2 years. To our knowledge this is the largest series with the longest follow up on TRUS-guided ProACT™ system implantation.

### Study design, materials and methods

Between June 2005 and March 2009 we operated on 79 consecutive patients (mean age 67.9 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) [3]

The ProACT™ system implantation was performed by a single surgeon using TRUS-guidance with a 7.5 MHz linear and small convex probe.

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) and change in the IQoL. In addition the number of adjustments required to achieve continence was recorded.

### Results

At baseline mean VLPP was 58 cm H<sub>2</sub>O (range 30-110) and mean MUCP was 44.9 cm H<sub>2</sub>O (range 9-100). Mean preoperative 24hour pad test was 389.7 grams (range 20-1300), mean number of pads used per day (PPD) was 3.7 (range 1—10 or condom use) and mean (IQoL) score was 49 (±19.3 SD).

Balloon adjustments, completed in 62 patients are the object of the continence outcome data analysis. In this group of patients the mean follow-up is 25 months (range 3-45). The mean number of adjustments required to obtain continence recovery was 3.6 (range 0-14). According to the 24h pad test and the mean number of PPD used 41 patients are dry (66.1%), 16 patients improved (25.8%) and 5 patients failed treatment (8%). All failures occurred in previously irradiated patients. The overall dry rate in non irradiated patients was 72%. Mean quality of life questionnaire score was 82.1 (±19.9 SD; p < 0.0002). Perioperative complications occurred exclusively in the irradiated group and included 2 intraoperative bladder perforations which were conservatively managed with 5 days of indwelling catheter while postoperatively, 3 unilateral balloon migrations and 2 urethral erosions. 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.

### Interpretation of results

Mid term (2 years) outcome data are more than satisfactory. The TRUS-guided technique allows an excellent imaging of the anatomical landmarks during the entire procedure without radiation exposure. Continence recovery is reduced in previously irradiated patients. The overall complications rate is very low. However, previously irradiated patients are at higher risk of perioperative complications.

### Concluding message

After a mid term follow up (2 years), implantation of the ProACT system using the TRUS guided implantation technique provides a significant improvement in continence.

The ProACT system appears to have a number of advantages. It is implanted via a minimally invasive procedure 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.

In conclusion, TRUS guidance for ProACT™ system implantation is accurate, safe, avoids radiation exposure and results in success and complication rates which compare favourably with published data by other investigators with ProACT™ implantation under fluoroscopic guidance [1]. Adjuvant radiotherapy seems to be relative contraindication to ProACT™ system implantation. Larger series and a longer follow-up are mandatory to establish its long term safety, efficacy and durability.

### References

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<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>not required</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
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