

## TRANSRECTAL ULTRASOUND-GUIDED PROACT™ SYSTEM IMPLANTATION UNDER LOCAL ANESTHESIA IN PATIENTS WITH POST-RADICAL PROSTATECTOMY STRESS URINARY INCONTINENCE: SURGICAL TECHNIQUE

### Synopsis of Video

This video demonstrates a new technique for the implantation of the adjustable ProACT™ system (male Adjustable Continence Therapy, Uromedica, Plymouth, MN, USA) under Trans Rectal Ultrasound (TRUS) guidance and using local anesthesia only.

### 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 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]. Implantation of the adjustable ProACT™ using general or regional anesthesia has been well documented. We have incorporated the use of local anesthesia as a less morbid alternative.

### Study design, materials and methods

The ProACT™ system consists of 2 silicone balloons each implanted on either side of the bladder neck. Each balloon is attached via a silicone port to a titanium port buried in the scrotum to facilitate post operative adjustments. Between November 2006 and September 2008 we operated on 37 patients (mean age 67.7 years, range 51-81) with post-radical prostatectomy urodynamic intrinsic sphincter deficiency without detrusor overactivity. Local anesthesia was administered through the perineum in subcutaneous tissue, pelvic diaphragm and laterally to the anastomosis creating the space for the ProACT balloons by hydrodissection with 30 mls ropivacaine 7.5 mg/ml. Patients were asked to report any discomfort throughout the procedure. Immediately after the procedure patients were asked to complete 3 pain intensity scales: a 0-100 mm visual analogue scale (VAS), a 0-10 numeric pain intensity scale (NPIS) and a simple descriptive pain intensity scale (SDPIS).

### Results

Implantation under local anesthesia was successful and without complications in all cases. Operative time ranged from 30 to 50 min. In terms of subjective discomfort, all patients reported "mild burning" during administration of local anesthesia in skin and subcutaneous tissue and "mild discomfort" during administration of local anesthesia in the pelvic diaphragm. One patient (2.7%) reported "mild discomfort" due to time in lithotomy position. Pain scales evaluation: mean VAS was 15.1 mm (range 0-52); mean NPIS was 1.73 (range 0-5); SDPIS: 9 patients (24.3%) reported "No pain", 25 patients (67.5%) reported "Mild pain", 2 patients (5.4%) reported "Moderate pain", 1 patient (2.7%) reported "Severe pain".

### Interpretation of results

This technique combines the advantages of TRUS-guided ProACT implantation (excellent imaging of the anatomical landmarks during the entire procedure without radiation exposure) with those of a surgical procedure performed under local anaesthesia (quick recovery after surgery and decreased use of anaesthesia and operating room resources). Subjective and objective data may be considered more than satisfactory [3].

### Concluding message

TRUS-guided ProACT system implantation under local anaesthesia only, is feasible, safe and very well tolerated

### References

1. Hübner WA, Schlarp OM. Adjustable continence therapy (ProACT): evolution of the surgical technique and comparison of the original 50 patients with the most recent 50 patients at a single centre. *Eur Urol* 2007;52(3):680-6
2. Gregori A, Simonato A, Lissiani A, Scieri F, Rossi R, Gaboardi F. Transrectal ultrasound guided implantation of the ProACT adjustable continence therapy system in patients with post-radical prostatectomy stress urinary incontinence: a pilot study. *J Urol*. 2006;176(5):2109-13
3. Heid F, Jage J: The treatment of pain in urology. *BJU Int* 2002; 90: 481

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