365

Groen J[1], van der Horst A[1], Blok B[1]
1. *Erasmus MC, Rotterdam, The Netherlands*

URODYNAMIC EFFECTS OF ADJUSTABLE CONTINENCE THERAPY FOR MEN WITH STRESS URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY

Hypothesis / aims of study

Implantation of the ProACT™ device is a minimally invasive procedure for the treatment of stress urinary incontinence (SUI) after radical prostatectomy (RP). The system consists of two balloons placed bilaterally to the bladder neck. Each balloon is attached via a conduit to a port placed subcutaneously in the scrotum. The ports allow post-operative balloon volume adjustment. Good clinical results have recently been reported in peer-reviewed articles, but the mechanism of action is as yet unclear. We evaluated the urodynamic effects of ProACT™ placement and paid special attention to the urethral resistance during voiding as it might be hypothesized that the improvement of continence is accompanied by infravesical obstruction.

Study design, materials and methods

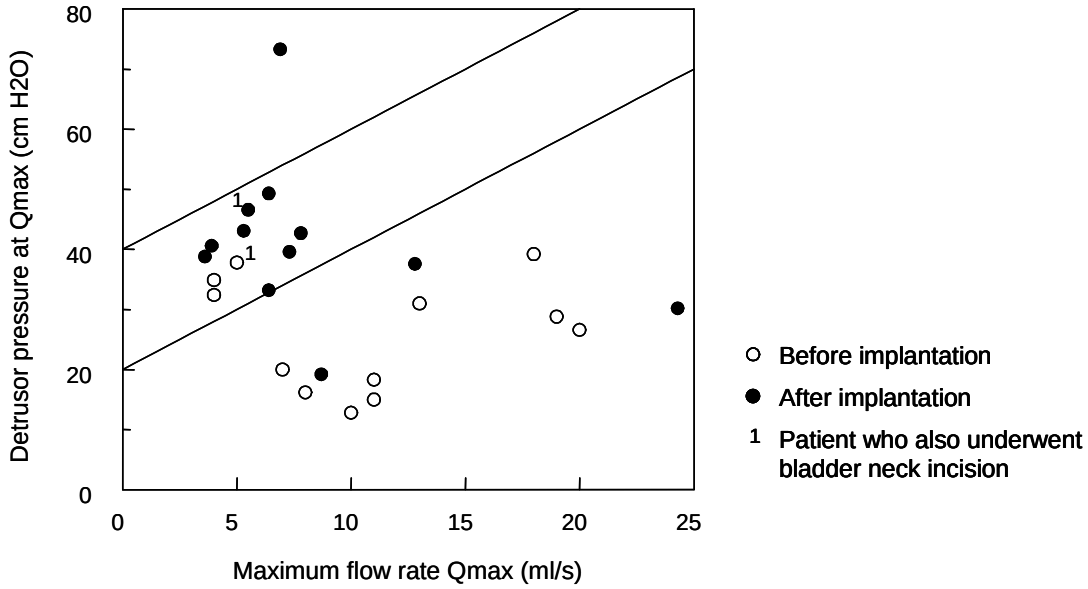
The ProACT™ device is used at our department since May 2007. All procedures are done by the same urologist. Post-operatively, patients are assessed at regular 4-week intervals and the balloon volume is adjusted if required. A multichannel urodynamic examination is part of the evaluation after an optimal clinical result has been obtained.
The results of the post-operative urodynamic studies were compared with those of the pre-operative (diagnostic) ones. The studies included free uroflowmetry, two medium rate (50 ml/min) filling cystometries and two pressure-flow studies. A 7F double lumen transurethral catheter was used. The parameters considered are listed in the table. Results are shown as mean value and standard deviation. The paired t test was used for statistical comparison.

Results

As of March 2009, 25 patients with SUI after RP received the ProACT™ system. The series of balloon volume adjustments to obtain an optimal result was complete in 12 men, one of whom also underwent a bladder neck incision prior to the balloon placement. These men, with Stamey incontinence grade 2 (10 patients) or 3 (2 patients), reported to be cured or significantly improved. Their age at implantation was 66±6 years. They had undergone the RP 64±46 months before implantation. The post-operative urodynamic study was done 40±12 weeks after the implant procedure. The mean balloon volume was 5.0±2.1 ml, resulting from 4.5±2.5 adjustments. The table summarises the results of the pre- and post-operative urodynamic studies.

Parameter	Pre-op	Post-op	p
Maximum cystometric capacity (ml)	459±154	528±120	0.079
Compliance ≤ 20 ml/cm H2O (#Pts)	4	1	
Detrusor overactivity (#Pts)	5	3	
Stress urinary incontinence (#Pts)	6	0	
Voided volume (ml)	430±172	363±159	0.103
Residual volume (ml)	8±20	155±121	0.001
Bladder Voiding Efficiency (%)	96±8	70±25	0.003
Maximum flow rate Qmax (ml/s)	11.2±5.7	8.2±5.6	0.091
Detrusor pressure at Qmax (cm H2O)	26.1±9.3	41.2±12.9	0.003
Bladder Outlet Obstruction Index (BOOI)	3.7±14.6	24.7±19.6	0.005
Bladder Contractility Index (BCI)	82±30	82±27	0.963
Residue after free uroflowmetry (ml)	0±0	38±80	0.125

As might be expected, urethral resistance (BOOI) considerably increased. Voiding of most patients changed from the unobstructed area in the provisional ICS nomogram to the equivocal area (Figure). Although the Bladder Voiding Efficiency decreased significantly in the pressure-flow studies, the post-void residual volume after free uroflowmetry did not considerably increase in most men; there were 3 patients with residues of 50, 180 and 230 ml, respectively. Two of the 5 patients with detrusor overactivity pre-operatively demonstrated this condition after the implant as well. The threshold volume (bladder volume at first involuntary detrusor contraction) in these men increased from 186 and 209 ml to 532 and 405 ml. One of these men used solifenacin during the post-operative examination. There was de novo detrusor overactivity in one man; the threshold volume was 411 ml. The bladder compliance of the 4 patients with a stiff bladder (compliance ≤ 20 ml/cm H2O) changed from 8, 10, 19 and 15 ml/cm H2O to 30, 31, 25 and 11 ml/cm H2O, respectively.



Interpretation of results

Effective treatment with the ProACT™ implant system on average resulted in an increased urethral resistance during voiding. The post-operative pressure-flow study of most men projected on the equivocal area of the provisional ICS nomogram. Infravesical obstruction was found in only one case. Significant residual volumes after free uroflowmetry were found in two cases. The increased urethral resistance had no disadvantageous effects on the bladder storage function. In contrast, detrusor overactivity and bladder compliance seemed to improve, but the numbers of patients involved were too small for a useful comparison.

Concluding message

The ProACT™ implant system cured or significantly improved stress urinary incontinence after radical prostatectomy without causing infravesical obstruction in most patients.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**the study is not a clinical trial.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**