

## CONTINENCE WITHOUT OBSTRUCTION – A LONG-TERM EVALUATION OF THE ADJUSTABLE CONTINENCE THERAPY (PROACT™).

### Hypothesis / aims of study

Most dynamic and passive implantable continence devices carry the potential risk of obstruction. The ProACT device allows for post operative adjustability to minimize this effect. We evaluated a consecutive series of Pro ACT patients with respect to flow parameters and residual urine counts.

### Study design, materials and methods

The ProACT device consists of two balloons placed on either side of the bladder neck. Each balloon is attached via a conduit to a port buried in the scrotum. The port enables percutaneous post operative adjustment of the balloon. This can be by undertaken by the physician at any time in the clinic or outpatient setting to achieve or moderate continence levels.

During 2004, we implanted 55 post prostatectomy incontinent males with the ProACT device in our department. All operations were performed by the most experienced urologist (of more than 120 prior implantations).

Patients were assessed preoperatively and at regular follow up visits by uroflowmetry, quantification of post void residual urine (PVR) and, if required, adjustment of balloon volume.

### Results

Mean follow up was  $24.6 \pm 11.2$  months during which time no retention was observed in any patient. All patients returned for regular assessment other than 3 patients who moved abroad and were unavailable for further follow up. Furthermore, 1 patient required an explantation of both devices due to infection; one underwent implantation of an Artificial Urinary Sphincter and another, Argus Sling for poor response.

Fifteen patients (28.8%) required 1 – 3 adjustments at assessment visits due to residual urine volumes or/ and obstructive voiding patterns.

At last follow up, QMax was  $17.53 \pm 9.19$  ml/sec at a mean voided volume of  $207 \pm 108$  ml.

Forty five of fifty two patients (86.5%) had unobstructed voiding patterns with no significant post void residuals. Seven patients (13.4%) had equivocal flow rates including two (3.8%) with residual volumes of between 60 and 100mls. These patients' balloons were easily adjusted in order to alleviate this.

Overall pad use reduced from  $4.33 \pm 2.35$  pre operatively to  $1.59 \pm 1.2$  at the most recent visit.

### Interpretation of results

Obstructive voiding patterns even in the long term are very rare for patients following ProACT implantation for post prostatectomy incontinence. This is due to the possibility of adjustment at any time of the ProACT system.

### Concluding message

Implantable continence devices which cannot be post operatively adjusted may need revision for relief of obstructive symptoms. The adjustable ProACT device allows for easy titration and therefore does not carry such risks.

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<b><i>Is this a clinical trial?</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>No ethical approval was needed</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>