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INTERNATIONAL MULTI-CENTRE EVALUATION OF THE ADJUSTABLE CONTINENCE THERAPY (PROACT™) FOR MALE POST PROSTATECTOMY STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The Adjustable Continence Therapy (ProACT™) was first used in 2000 as a minimally invasive treatment for male stress urinary incontinence. We evaluated our experience in patients with incontinence arising from multiple aetiologies and examined whether post operative adjustability was beneficial. Efficacy was assessed based on subjective and objective parameters

Study design, materials and methods

Implantation of the ProACT device involves the paraurethral insertion of two silicone balloons on either side of the bladder neck in post radical prostatectomy patients, or at the level of the membraneous urethra in patients with a prostatic remnant. Each balloon is attached via a silicone conduit to a titanium port placed in the lateral aspect of the scrotum facilitating post operative adjustment by percutaneous injection in the clinic.

Patients were selected if they had undergone a prostatectomy at least 6 months previously and had not undergone radiotherapy within 12 months. Detrusor overactivity was considered an exclusion, as was the presence of any bladder abnormality. Baseline assessment included completion of a validated Incontinence Quality of Life score (IQoL) and daily pad usage. These investigations were repeated at 1,3, 6 and 12 months and annually thereafter. Numbers of adjustments were recorded, as were any adverse events.

Results

Between 2000 and 2005, 329 patients have been implanted with the ProACT device in 4 international centres. Mean age at implant was 67.8 yrs (55.2-85.2) with a mean time of 37.1 (5-180) months since their prostatectomy. Operative time was 19 (15- 37) mins with ≤ 50mls blood loss in all cases.

	Baseline	12 Month	24 Month	36 Month	48 Month	60 Month
Pad Use	4.3	1.2	1.0	1.1	1.3	1.2
Quality of Life (/100)	38	72	74	70	78	73

Fifty four percent of patients were dry (<1 pad per day) at 5 years. Balloon adjustments were performed as required in order to achieve and maintain continence. Adjustments were required in 82% of patients with a mean of 4.2 (0-12) adjustments being undertaken with a final balloon volume of 4.15mls at 2 years.

A subgroup of 76 patients were analysed at 12 and 24 months to assess the obstructive effects of balloon placement. Their Qmax at 12 months was 17.52 ml/sec and 17.6 ml/sec at 24 months. In addition, a PVR of less than 20 mls was reported in 71 of those 76 patients. In those 5 patients demonstrating some obstruction, fluid was removed from the balloons to alleviate this non-symptomatic response.

Complications included: infection and erosion (9.8%); migration (9.3%);balloon rupture (8.7%); pain and discomfort (2.5%).

Eighteen percent of patients underwent alternative treatments due to non response or following device removal arising from adverse events (AUS- 29) (Slings- 6). Device removal was easily performed without adverse sequelae allowing for reimplantation or further surgical intervention.

Interpretation of results

The improvement in Quality of Life symptoms and reduction in pad usage was most encouraging and compared favourably to other techniques evaluated at these centers. The ability to post operatively adjust as clearly a very important feature in managing post prostatectomy incontinence. Furthermore, the post operative QMax and low post void residual in those patients so tested indicates that ProACT implantation does not create undue outlet obstruction.

Concluding message

ProACT is a safe, effective and durable treatment for male stress urinary incontinence. The ability to titrate the balloons over time facilitates sustained improvement as demonstrated by the improvement in Quality of Life and reduction in pad usage. Furthermore, implantation of ProACT does not preclude more invasive surgical intervention should that be necessary.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Northern Y Ethics Committee, Bay of Plenty, New Zealand**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**