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THE (PROACT™) FOR THE TREATMENT OF POST-PROSTATECTOMY STRESS URINARY INCONTINENCE: A COMPARISON OF TWO TECHNIQUES WITH A MINIMUM OF SIX MONTHS FOLLOW UP.

Hypothesis / aims of study
Post prostatectomy incontinence following surgery for malignant for benign disease is a debilitating condition, and the choices of surgical management further complicate which
The Adjustable Continence Therapy (ProACT™) consists of two post operatively adjustable balloons placed either at the level of bladder neck in post radical prostatectomy patients or, more recently, at the level of the apex in patients with residual prostate tissue. We compared the efficacy of ProACT in post radical and benign surgery patients.

Study design, materials and methods
Baseline assessment of pad usage; Quality of Life questionnaires and assessment of adverse events were repeated at 6, 12, 24 and 36 months. Perioperative and immediate post operative data was recorded. Additionally, Urodynamics were performed at baseline and 6 months, and pre operative uroflows were repeated following final adjustment.
Balloon placement in post radical patients is at the level of the anastamotic junction distal to the bladder neck. This is easily visible employing image intensification (II) and cystsoscopic manipulation in conjunction with deployment of the specially designed trocar and cannua. Placement of the balloons in post benign surgical patients is technically more challenging as the prostatic remnant is not visible on II.

Results
30 post radical prostatectomy (RP) comprising of 9 perineal and 21 retropubic radicals, and 7 post benign (HOLEP) surgery patients have been evaluated beyond 6 months follow up. Three of the RP and 1 in the benign group had also undergone radiation therapy. Patients in both groups were comparable at baseline. The radical Prostatectomy patients were analysed collectively as there was no difference in parameters between these sub groups.

	Radical Prostatectomy	Benign Surgery
Age	68.6 (59-79)	75.43 (68-81)
Time Since Original Surgery (months)	33.06 (9-105)	21.28 (11-43)
Mean Follow up (months)	18.9	27.8
Operative Time	26.2 mins (13-48)	19.8 (13 – 32)

Three of seven (45%) benign surgery patients and 3 /30 of the radical group (10%) requiring only a 12cm length device with all other patients requiring a 14cm device. No analgesia was required and all patients were able to void within 24 hours of surgery following removal of urethral catheter.

Pad Usage and Quality of Life improved in both groups.

	Pads per day		Dry %		IQOL	
	Radical	Benign	Radical	Benign	Radical	Benign
Baseline	2.6	3.8	0	0	49.6	49.7
6 months	0.7	1.2	51	58	71.7	77.9
12 months	0.5	1	68	75	74.9	78.6
24 months	0.6	1	59	75	70.6	76.1
36 months	0.4	0.7	50	75	88	86.5

Average number of adjustments in the first 12 months was 2.63 in the radical prostatectomy group (range 0-6), and 2.43 in the benign group (range 1-6).
Urodynamic findings demonstrated a decrease in leakage for all patients with no patients deteriorating.

	Baseline		Follow Up	
	Radical (31)	Benign (6)	Radical	Benign
No Leakage	0	0	10	1
Mild >100 cm H_2O	9	0	11	4
Moderate 60 -99 cm H_2O	17	4	5	1
Severe< 60 cm H_2O	5	2	0	0

Fifteen patients in total underwent uroflowmetry at baseline and post operative (mean time 7.3 months). Mean Peak Flow remained stable from 19mls/ sec at baseline to 20mls/sec. Voided Volume increased from 187.7 mls at baseline to 297.8mls at follow up. There were no significant post void residuals in any patient.
Of the four patients who had previously undergone radiotherapy, all patients were significantly improved in terms of pad usage, however were not statistically improved in terms of Quality of Life assessment.

Adverse events including balloon migration (2) and infection (3) were managed by outpatient removal and further re-implantation. All but one event occurred in the radical group.
Two patients remained unchanged in the radical group and underwent successful reimplantation. One patient from each group underwent implantation of an AUS.
Urge incontinence was resolved within 3 months of implantation in 2/3 patients who had reported using anticholinergic medication at baseline. Of these one patient was from each group. A further 2 patients in the radical group reported transient urge at 2 and 3 years respectively.

Interpretation of Results:
There was a significant improvement in all parameters in both groups. Although the operative technique differs for each indication there would seem to be no difference between the two groups in terms of procedural time or outcomes.

Concluding message
Implantation of the Adjustable Continence Therapy provides a significant improvement in continence in post prostatectomy males whether post radical or benign prostatic surgery.

FUNDING: NONE
DISCLOSURES: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the Northern Y Regional Ethics Committee (New Zealand) and followed the Declaration of Helsinki Informed consent was obtained from the patients.