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INTERNATIONAL MULTI-CENTER STUDY ASSESSING THE VALIDATED QUALITY OF LIFE QUESTIONNAIRE AND DIRECT VISUAL STRESS TEST POST ADJUSTABLE CONTINENCE THERAPY (PROACT™) IMPLANTATION FOR STRESS URINARY INCONTINENCE IN MALE POST PROSTATECTOMY PATIENTS

Aims of Study
Whilst post prostatectomy incontinence can often be managed conservatively, persistent leaking may require surgical intervention. There are currently a number of surgical options for management of post prostatectomy incontinence; however the reference standard, Artificial Urinary Sphincter (AUS) is invasive, expensive, has a high re-operation rate for mechanical failure and tissue erosion effects that requires good patient compliance in order to succeed. The development of a more simplistic device called the Adjustable Continence Therapy (ProACT™) provides a viable alternative to the AUS as a minimally invasive technique, involving the periurethral placement of two post operatively adjustable balloons for the treatment of post prostatectomy incontinence. In order to accurately determine its efficacy, we measured objective and subjective parameters at multiple time points after implantation.

Methods
The ProACT consists of bilateral silicone balloons that are inserted and positioned via a small perineal incision either at the bladder neck in post radical patients or at the prostatic apex in post benign prostatectomy patients. Each balloon can be post operatively adjusted percutaneously via a titanium port positioned in the scrotum. Attached to each balloon is a single tubing conduit linked to the port. A total of 68 patients have been enrolled in this international multi-centre study with a follow up from 6 to 24 months. Average age was 66 years (range 52 - 85) with a median time of 43 months (range 3 – 192 months) since their primary procedure. All patients were assessed using Incontinence Quality of Life scores (I-QOL) and also underwent urodynamics to observe visual stress leakage and Abdominal Leak Point Pressure (ALPP). These were repeated at standard post operative periods of 6, 12 and 24 months.

Results
I-QOL consistently improved from 41$\pm$ 25 at baseline (n=62) to 71$\pm$ 19 at 6 months (n=22) and 69$\pm$18 at 12 months (n=14) and 24 months 72$\pm$18 (n= 3). In the 27 patients with direct visual stress test results at 6 month follow-up, 52% reported no leakage (n=14) and 22% reported mild leakage (n=6). This was maintained at 12 months with 54% reporting no leakage (n=7) and 16% reporting mild leakage (n=2) and at 24 months no leakage for one patient. Abdominal Leak Point Pressure increased from 41$\pm$ 28 (n=48) at baseline to 65$\pm$49 at 6 months (n=12) and at 12 months was 51$\pm$ 46 (n=9) and 57$\pm$ 12 (n=2) at 24 months. Initial balloon adjustments were made at 4 - 6 weeks with subsequent titrations administered at successive 4 weekly intervals. Of the patients who were followed for at least six months (n= 28) post implantation, 26 patients (26/28, 93%) required 1 or more adjustments. The number of patients with one adjustment was 6/26 (23%) two adjustments 5/26 (19%) three adjustments 8/26 (31%) four adjustments 1/26 (3%) and greater than four adjustments 6/26 (23%). Adverse Events were reported as being related to balloon failure (10%); migration (5%) and infection (3%) which correlate favourably to other urological implants. An incidence of balloon failure was seen in the first generation balloon only. Subsequent modifications have effectively addressed this issue. Where necessary, these implants have been removed in a few minutes and without negative long term clinical effects.

Conclusions
We conclude there is a marked improvement in both objective and subjective parameters post ProACT implantation. These mid term results demonstrate that there is an improvement for both I-QOL and direct visual stress testing. The ability to post operatively adjust the ProACT

allows for further enhancement of both objective and subjective endpoints. The ProACT implant may provide an alternative first line therapy for men who would otherwise be candidates for the AUS.