

USE OF THE ADJUSTABLE CONTINENCE THERAPY FOR THE TREATMENT OF RECURRENT FEMALE URODYNAMIC STRESS URINARY INCONTINENCE

Hypothesis / aims of study

There are a great number of reported effective minimally invasive treatments for urethral hypermobility yet many do not address the Intrinsic Sphincter Deficiency (ISD) component of Stress Urinary Incontinence. The development and increased adoption of the use of Valsalva leak point pressure (VLPP) as a diagnostic tool has resulted in clearer differentiation between hypermobility and ISD diagnosis, emphasizing the need to specifically manage pure ISD in certain patients. The Adjustable Continence Therapy (ACT®) has been developed with the aim to increasing urethral coaptation. We evaluated the procedure and assessed its mid-long term follow up in our centre.

Study design, materials and methods

The ACT device consists of two silicone elastomer balloons placed para-urethrally in the vesico vaginal space at the level of bladder neck, each being attached to an injectable titanium port placed in the labia majora, enabling postoperative adjustment.

We evaluated this device in a prospective open study. Selection criteria included female adults with a diagnosis of urodynamic stress incontinence and ISD (VLPP < 60cm H₂O and MUCP < 20cm H₂O). Patients were excluded if they presented with detrusor overactivity refractory to medication; reduced bladder compliance; residual volume ≥ 100 mL; (suspected) bladder anomalies; bleeding disorder, diabetes mellitus; active urinary tract infection; uncorrected grade II or more prolapse.

Patients were evaluated using daily pad count; Incontinence Quality of Life (IQOL) questionnaire and Visual Analogue Score (VAS) at baseline and at 1, 3, 6, 12, 24, 36 and 48 months.

Results

49 patients (mean ages 62.59 (range 15-86) years, were implanted with ACT and evaluated with a mean follow up of 40.1 months (range 6-71). All patients had undergone at least one previous pelvic surgery. Operative time was 20.3 mins (range 10-30 mins) with minimal blood loss. No postoperative analgesia was required and all patients were able to void within 24 hours.

	Pre(n=49)	3 month (n=49)	6 month (n=49)	12month (n=38)	24month (n=33)	36month (n=28)	48month (n=23)
IQoL	30	72	74	71	74	86	93
Pads	5.4	1.9	1.4	1.2	1.1	0.7	0.5
VAS		56%	73%	79%	83%	85%	84%

There was a statistically significant increase in Quality of Life and pad usage with 32/49 (65%) patients completely dry, 8/49 (16.3%) significantly improved, and 9/49 (18.3%) remaining unchanged at last observed follow-up.

Eighteen patients (36%) did not require any post operative adjustments. The remainder required singular or multiple adjustments (range 1-11).

Complications were minor and easily remedied. Labial haematomas observed in 3 pre menopausal patients within 24 hours of implantation spontaneously reabsorbed without intervention. None of these patients reported any deterioration in sexual function post operatively.

Device removal resulted from migration seen in 6/49 (12%) patients and urethral erosion in 1/49 (2%) patient. Additionally, 3/98 (3.6%) balloons were explanted due to device failure. Of these, 1 (1%) balloon deflated after one month with 5.5cc. The other two balloons failed at 3 years, one containing 6cc and the other with 2cc. In total, 12 balloons (13%) were removed in 10 (20%) patients with only 2 (4%) patients requiring bilateral removal. Five balloons in 5 patients were reimplanted 6 weeks after removal. 2 out of 5 patients became dry (no pads), 2 were significantly improved (< 1 pad a day) and 1 was unchanged. Five patients did not undergo reimplantation of which 1 patient is continent with 1 balloon, One patient improved and another remained unchanged following prescription of anticholinergic medication. Two patients refused any further treatment.

Two (4%) patients had portal erosions due to poor positioning. The ports were successfully cleaned with antibiotic flush, repositioned and the incision was resutured without any further problem. Pre operative sensory urgency seen in 7 (14.3%) patients was unresolved post operatively. Furthermore 6 (12.2%) patients reported denovo urgency post ACT implantation and appeared to be proportionally related to balloon volume. However, in all 6 patients this was transient and resolved within 3 months without the need for anticholinergic medication.

Interpretation of results

These results demonstrate that implantation of the ACT balloons for the treatment of ISD is both safe and effective. The minimal dissection required for insertion of the balloons makes this an ideal technique for the management of patients who have failed previous incontinence surgeries and present with existing autologous or heterologous material. We will continue to follow up our patients, and are further examining the benefits of this device in sub sets of patients to better determine optimal patient selection.

Concluding message

The ability to post operatively adjust according to the individual patients needs seems to be beneficial in managing patients continence needs long term.

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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 200D 9131 German Ethics Review Board and followed the Declaration of Helsinki Informed consent was obtained from the patients.