

Adjustable Continence Therapy for Severe Intrinsic Sphincter Deficiency and Recurrent Female Stress Urinary Incontinence: Long-Term Experience

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Purpose: ACT[®] was developed to treat female stress urinary incontinence resulting from intrinsic sphincter deficiency by increasing urethral resistance. We evaluated the implantation procedure and assessed patient outcomes at our center.

Materials and Methods: The adjustable continence device consists of 2 silicone balloons on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia to allow postoperative titration. Urodynamic assessment was done in 57 female patients in whom previous pelvic surgery had failed. Pad use and an incontinence quality of life questionnaire were evaluated before ACT implantation, postoperatively at 1, 3, 6 and 12 months, and annually thereafter. Patients recorded the overall impression and percent of improvement postoperatively based on the Patient Global Impression Index and a visual analog scale.

Results: Mean followup was 72 months (range 12 to 84). At 6-year followup in 29 patients mean pad use improved from 5.6 daily at baseline to 0.41 and intrinsic sphincter deficiency improved from 27.2 to 78.6 ($p < 0.001$). As measured on the visual analog scale, 68% of patients considered themselves dry. On the Patient Global Impression Index questionnaire 64% were very much improved, 23% were much improved and 13% were only minimally improved or unchanged. No patients considered themselves worse after the procedure. Complications necessitating device removal developed in 21.1% of patients.

Conclusions: Relative ease of insertion and the ability to tailor this therapy to individual needs makes this an attractive option for the challenging treatment for recurrent stress urinary incontinence due to intrinsic sphincter deficiency.

Key Words: urethra; female; urinary incontinence, stress; prostheses and implants; questionnaires

INTRINSIC sphincter deficiency represents a challenge in treatment for urodynamic stress urinary incontinence.¹ The ISD diagnosis should address urethral elements, including pudendal innervation, striated sphincter mass and

function, and urethral smooth muscle, mucosa and submucosal cushions.² Treatment should focus on increasing urethral resistance. In patients with severe ISD creating adequate intrinsic urethral resistance may be more

Abbreviations and Acronyms

ISD = intrinsic sphincter deficiency

MUCP = mean urethral closure pressure

VLPP = Valsalva leak point pressure

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beneficial than correcting urethral hypermobility, which alone may not result in stress urinary incontinence.³ Even after corrective surgery provides initial improvement, when factors affecting continence change, eg weight fluctuation and estrogen changes, there may be a need for secondary or even tertiary surgical intervention with time. When no benefit is first achieved, a further alternative surgical option should ideally be considered. Thus, we assessed the safety and efficacy of the implantable ACT device, which can be titrated with time as required, in women with recurrent stress urinary incontinence.

MATERIALS AND METHODS

The ACT Device

ACT consists of 2 silicone elastomer balloons on each side of the proximal urethra, each connected via a conduit to a titanium port buried superficially in the fatty tissue of the labia majora.⁴⁻⁶ The balloons are placed at either side of the bladder neck by 2 specially designed reusable blunt and sharp trocars and a U-shaped cannula. The device is available in 4 lengths of 6, 7, 8 and 9 cm, each with a recommended maximum volume of 8 cc. Device length is determined by urethral measurement using the trocar and cannula (part A of figure). At any time postoperatively each balloon can be volumetrically increased or decreased by percutaneous injection through the port using a 23 gauge Huber noncoring needle to achieve optimum continence.⁷⁻¹⁰

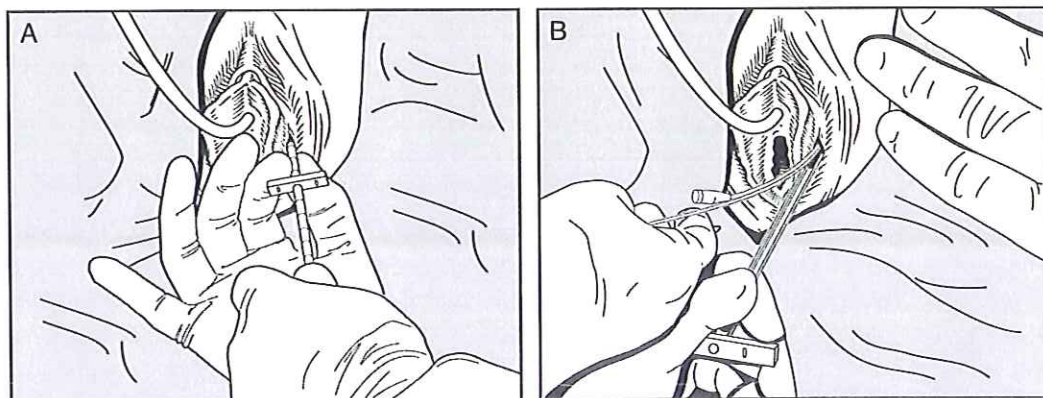
Study Design

After receiving ethical approval we performed a prospective open study to assess the potential merits of this postoperatively adjustable device in women who underwent prior pelvic surgery and had a urodynamically proven severe degree of ISD with a fixed urethra. Selection criteria included female gender, age 18 years or greater and low VLPP, defined as 60 cm H₂O or less, and/or MUCP less than 30 cm H₂O, reflecting more severe stress urinary incontinence and suggesting a relevant ISD component.^{11,12}

Patients underwent physical examination, ultrasound of the lower urinary tract to assess urethral mobility, and urodynamics to measure baseline VLPP and MUCP. An extensive relevant continence and obstetric history was recorded, including body mass index. Patient subjective outcome measures were evaluated using daily pad count, an incontinence quality of life questionnaire¹³ and the visual analog scale score at baseline, and at 1, 3, 6, 12, 24, 36, 48, 60 and 72 months. Patients were also asked to complete the Patient Global Impression Index at each postoperative visit. Objective outcomes were measured 1 year postoperatively using urodynamics, including measurement of uroflowmetry, VLPP and MUCP in willing patients.

Surgical Procedure

The procedure is done as previously described.^{4,5,14} Briefly, the bladder is filled with dilute contrast material and the balloon of a Foley catheter is filled with pure contrast material to enable fluoroscopic visualization of the bladder neck. Bilateral 1 cm incisions are made between the labia minora and labia majora at the level of the vaginal introitus below the urethral meatus to enable passage of a specially designed trocar and cannula toward the bladder neck under fluoroscopic guidance and digital vaginal palpation. After the correct position at the urethrovesical junction is confirmed the ACT device is inserted and filled with 1 to 1.5 cc isotonic contrast medium to stabilize its position. The process is repeated on the contralateral side (part B of figure). The ports are buried in the labia majora in a superior ventral position and the incision is closed. A 16Fr urethral catheter remains in situ overnight as a precautionary measure. Balloon adjustment begins at 4 to 6 weeks to enable the creation of a pseudo capsule around the balloon. Subsequent increments should be spaced at a minimum of 4-week intervals and continued until optimum continence is achieved. Each balloon should be inflated by a maximum of 1 ml per visit to avoid splitting the pseudo capsule, and possible balloon erosion and migration. Statistical analysis was done using Statistica 7.1 (StatSoft®) and Epi Info™ 3.3.



A, trocar used to determine device length. B, balloon in U-shaped sheath.

RESULTS

From May 2001 to May 2006 we implanted 57 patients with a mean age of 62.59 years (range 18 to 86) with the adjustable continence therapy device and evaluated them postoperatively during a minimum 12-month followup. Mean followup was 72 months (median 58, range 12 to 84). Ten patients treated before the study began were not included in analysis due to use of an earlier generation device and the learning curve required for such an innovative procedure. All patients underwent at least 1 previous pelvic surgery, including 1 or more anti-incontinence surgical procedures in 27 with no prolapse repair and prolapse repair in 23 with a concomitant retropubic or tension-free tape continence procedure. Previous anti-incontinence surgery included Burch colposuspension in 15 cases, injectable bulking agents (collagen, Macroplastique® or Zuidex™) in 16, a pubovaginal sling in 8 and tension-free tape (TVT™ or transobturator tape) in 22. Seven patients underwent various pelvic surgical procedures, including urethral reconstruction for bladder exstrophy. No statistically significant differences were found among the different previous interventions. Coexistent grade I prolapse in 19 patients (33.3%) did not require concomitant surgical intervention. The mean incontinence duration since failed previous surgery was 1.74 years (range 1 to 5). At surgery 29 patients (50.9%) were obese with a body mass index of 35 kg/m² or greater, although this did not correlate with incontinence severity or surgical outcome.

Operative time was 20.3 minutes (range 10 to 30) and blood loss was less than 50 ml in all cases. Implantation was done with 14 patients (24.6%) under local anesthesia, 37 (64.9%) under spinal anesthesia and 6 (10.5%) under general anesthesia. Screening time to verify balloon position by fluoroscopy was 2.03 minutes (range 1 to 3.6). Device size was 6, 7, 8 and 9 cm in 7 (12.3%), 7 (12.3%), 22 (38.6) and 21 patients (36.8%), respectively. Intraoperatively bladder perforation occurred in 2 patients, as visualized by contrast leakage from the bladder through the cannula and on the fluoroscopic image. On each occasion the trocar and cannula were removed and repositioned via a more lateral access, and balloons were inserted with a urethral catheter retained for 48 hours. No postoperative analgesia was required and all patients were discharged home within 24 hours of surgery.

There was a statistically significant improvement in quality of life based on component from the baseline of 27.2 points at each postoperative evaluation point ($p = <0.001$, table 1). Pad count significantly decreased from 5.6 daily at baseline to 1.24 at 12 months, which was maintained with time (table 1).

Table 1

	No. Pts	Mean ± SD Incontinence Quality of Life	Mean ± SD Pads (No./day)	Mean ± SD Pt Global Impression Index
Baseline	57	27.2 ± 15	5.6 ± 2.28	
12 Mos	52	65.9 ± 17	1.61 ± 2.10	2.33 ± 1.04
24 Mos	52	70.4 ± 16	1.24 ± 1.45	1.98 ± 0.92
36 Mos	51	70.4 ± 16	1.14 ± 1.84	1.78 ± 0.86
48 Mos	41	76.1 ± 17	1 ± 1.72	1.88 ± 1.29
60 Mos	34	78.4 ± 17	0.65 ± 1.10	1.76 ± 1.0
72 Mos	29	78.6 ± 18	0.41 ± 0.78	1.62 ± 0.94

Patient self-perception reported on the visual analogue scale improved by 50% within 3 months and continued to improve with time as further adjustment improved continence. Patient overall impression of postoperative symptoms at last followup showed that 62% were dry, 30% were improved greater than 50% and 8% were unchanged or improved less than 50% (table 1).

The Patient Global Impression Index questionnaire on procedural outcomes showed that 64% of patients were very much improved, 23% were much improved and 13% were minimally improved or unchanged. No patient worsened.

Postoperatively adjustments were made when incontinence persisted or recurred, or until optimum continence was achieved. No postoperative adjustment was needed in 18 patients (31.6%) while the remaining 68.4% required single or multiple adjustments (mean 3.8, range 1 to 11) during the 6-year course, demonstrating the ability to titrate the ACT balloons in the long term.

Postoperatively 12-month urodynamic data available on 30 patients showed a statistically significant increase in VLPP from a mean baseline of 51.06 ± 2 4.38 to 86.0 ± 21.44 cm H₂O ($p < 0.01$). However, there was no statistically significant change in MUCP from baseline to postoperatively (47.39 ± 24.35 vs 51.06 ± 19.31 cm H₂O).

Early complications included labial hematoma, de novo urgency and portal erosion, which were managed without device removal. Postoperative complications necessitating device removal included migration, erosion and device failure. Of the total of 114 balloons 15 (13.2%) were removed in 12 of 57 patients (21.1%), of whom only 3 required bilateral removal and 9 required unilateral removal. Removal was done on an outpatient basis in the office using topical anesthesia only. Table 2 lists complication details.

There were no reports of pain. No patient reported sexual function deterioration. Our earlier cadaveric studies showed that the triangular area where the trocar passes through the pelvic floor tends to be atrophic in older patients who present with more severe ISD and a fixed urethra.^{6,14}

Table 2. Complications

Complication	No. Pts (%) / No. Devices	Management	Outcome
Less than 3 mos:			
Labial hematoma	3 (5.3)	None needed	Spontaneously reabsorbed, no sexual function deterioration
Migration	10 (17.5) / 10	All devices removed, reimplantation in 5 pts	5 Pts dry or significantly improved with 1 device + no reimplantation, 2/5 reimplanted were significantly improved + 3/5 unchanged
Urethral erosion	2 (3.5) / 2	Devices removed	Further treatment refused
Port erosion	2 (3.5) / 2	Cleaned with antibiotics + resutured	No further infection or erosion
De novo urgency	6 (10.5)	Observation, vol related	Resolved without anticholinergics
Device failure	- / 3	Devices removed + reimplanted	Reimplantation successful, dry at last followup
3 Yrs or greater (device failure)	- / 2	Balloons retained, remaining balloon conservative titration	Pts became dry with 1 device

DISCUSSION

Reported positive outcomes of tension-free tape for female stress urinary incontinence have given rise to a larger number of patients undergoing this procedure, as done by an increasing number of surgeons across a number of specialties.¹⁵ Recent literature reviews suggest a dichotomy between patient satisfaction and the dry rate with 1 study of different commercially available slings indicating dry rates of 36.1% to 45.2%.¹⁶ This finding suggests that a proportion of women may require further intervention for persistent incontinence and should be offered an alternative treatment option.

Bulking agents provide a relatively noninvasive method of stress urinary incontinence treatment. Short-term data suggests a 59% cure rate with an additional 16% improvement rate at 12 months.¹⁷ Longer term results suggest a greater decrease in the success rate than for retropubic suspension and sling procedures.¹⁸ Although the exact mechanism of periurethral injectable placement has not been defined, an obstructive effect has been described that supports the entire wall, thereby increasing urethral resistance, although in the short term. In our experience ACT results have not decreased with time.

There may be a number of reasons why ACT appears to be of benefit. 1) The primary reason is that continence is not a static state in women, whose anatomy may alter due to weight fluctuation, estrogen changes, aging and unassociated surgery. The opportunity to postoperatively regulate urethral resistance is beneficial to patient and physician. 2) Previous anti-incontinence surgery had failed in 47.4% of the patients in our group, decreasing the likelihood of successful further surgery.¹⁹ 3) In a previous study using magnetic resonance imaging we noted that increasing proximal urethral resistance resulted in less bladder neck mobility.²⁰ 4) The ability to perform a titratable procedure that can easily be reversed without sequelae when necessary is attractive, in contrast to the removal of other

prosthetic devices implanted for stress urinary incontinence.²¹

During the study course we implemented a number of minor modifications to the operative technique, which in other studies have decreased the incidence of migration.^{14,20} 1) We now ensure that initial balloon volume is only 1 to 2 ml with an adjustment of 0.5 to 1 ml at each time beyond 6 weeks. This may decrease the risk of migration and since transient de novo urgency is volume related, its incidence may be lessened by smaller initial volumes. 2) We now avoid contact between the balloon and the bladder trigone since we believe that this minimizes the incidence of de novo urgency. 3) We ensure that all ports are oriented in a superior cephalic position to avoid the risk of patients sitting on the ports, thereby risking erosion. Also, the use of 6 cm devices has been discontinued to avoid this potential.

This study shows the value of ACT balloons to improve continence and quality of life in women in whom prior pelvic surgery has failed and who are more susceptible to an increased risk of adverse events.¹⁶ The ability to postoperatively adjust according to individual needs seems essential if we are to manage continence needs. Titration may also be done to decrease volume in patients with symptomatic voiding dysfunction secondary to bladder outlet obstruction. Of note was our ability to easily adjust the balloons at any time during followup.

The minimal dissection required for balloon insertion makes this an ideal technique in patients in whom previous incontinence surgeries have failed and who present with existing autologous or heterologous material.

CONCLUSIONS

Dealing with recurrent stress urinary incontinence or incontinence after pelvic surgery has enormous social implications for the patient and represents a great surgical challenge for the physician. Our find-

ings are encouraging, particularly in terms of patient subjective outcomes, but our study was limited by the number of patients treated, the modification in procedural technique during the study and the lack of more objective data. We will continue to perform further studies to establish the actual ACT mechanism of action in previously failed surgical

cases and more closely monitor objective outcomes in the light of procedural and postoperative management.

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