

The Adjustable Continence Therapy System for Recurrent Female Stress Urinary Incontinence: 1-Year Results of the North America Clinical Study Group

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Purpose: We determined the efficacy, safety, adjustability and technical feasibility of the adjustable continence therapy device (Uromedica, Plymouth, Minnesota) for the treatment of recurrent female stress urinary incontinence.

Materials and Methods: Female patients with recurrent stress urinary incontinence were enrolled in the study and a defined set of exclusionary criteria were followed. Baseline and regular followup tests to determine eligibility, and to measure subjective and objective improvement were performed. A trocar was passed fluoroscopically and with digital vaginal guidance to the urethrovesical junction through small incisions between the labia majora and minora. The adjustable continence therapy device was delivered and the balloons were filled with isotonic contrast. The injection ports for balloon inflation were placed in a subcutaneous pocket in each labia majora. Device adjustments were performed percutaneously in the clinic postoperatively. An approved investigational device exemption Food and Drug Administration protocol was followed to record all adverse events.

Results: A total of 162 subjects underwent implantation with 1 year of data available on 140. Mean Stamey score improved by 1 grade or more in 76.4% (107 of 140) of subjects. Improvement in the mean incontinence quality of life questionnaire score was noted at 36.5 to 70.7 ($p < 0.001$). Reductions in mean Urogenital Distress Inventory (60.3 to 33.4) and Incontinence Impact Questionnaire (54.4 to 23.4) scores also occurred ($p < 0.001$). Mean provocative pad weight decreased from 49.6 to 11.2 gm ($p < 0.001$). Of the patients 52% (67 of 130) were dry at 1 year (less than 2 gm on provocative pad weight testing) and 80% (102 of 126) were improved (greater than 50% reduction on provocative pad weight testing). Complications occurred in 24.4% (38 of 156) of patients. Explantation was required in 18.3% (28 of 153) of the patients during 1 year. In terms of the complications 96.0% were considered to be mild or moderate.

Conclusions: The Uromedica adjustable continence therapy device is an effective, simple, safe and minimally invasive treatment for recurrent female stress urinary incontinence. It can be easily adjusted percutaneously to enhance efficacy and complications are usually easily manageable. Explantation does not preclude later repeat implantation.

Key Words: urinary incontinence, stress; recurrence; therapeutics; urethra

Abbreviations and Acronyms

ACT = adjustable continence therapy

AUS = artificial urinary sphincter

IIQ = Incontinence Impact Questionnaire

IQOL = Incontinence Quality of Life

SUI = stress urinary incontinence

TVT = transvaginal tape

UDI = Urogenital Distress Inventory

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THE management of female stress urinary incontinence can be challenging. Multiple procedures have been developed and have evolved over time. While some have fallen into disfavor and are used infrequently, several others continue to be used by incontinence surgeons.¹ These include minimally invasive procedures such as periurethral bulking agents to more invasive urethropexy procedures, suburethral slings of various types and the AUS. Variable success rates have been reported in the literature for these procedures from 60% to more than 90% depending on length of followup and definitions of cure.²⁻⁵ Suburethral slings in particular can be technically difficult as proper placement and adjustment of tension require significant experience. Incorrect technique may result in persistent incontinence, urinary retention and variable degrees of voiding dysfunction. Despite the diverse modalities of treatment, failures do occur and can necessitate secondary surgical procedures. One study examining the durability of Burch colposuspension demonstrated a 30% failure rate at a mean followup of 13.8 years.⁴ Fialkow et al retrospectively reviewed a cohort of more than 41,000 women treated with Burch colposuspension or a sling and found a cumulative hazard of reoperation of 8.6%.⁶ The ACT system is a novel device that is pending Food and Drug Administration approval for the treatment of recurrent female SUI. It is a minimally invasive implantable device that provides support at the urethrovesical junction and enhances urethral coaptation. It has the unique advantage of being easily adjusted in the office with a percutaneous needle injection to optimize continence. There has already been some published experience in Europe in assessing the role of ACT as a minimally invasive treatment for women with urinary incontinence.⁷⁻⁹ We present our experience with the ACT which represents the largest published series to date to our knowledge.

MATERIALS AND METHODS

All female patients with SUI in whom at least 6 months of prior treatment (surgical and nonsurgical) failed were

considered for enrollment in the study at 10 centers in the United States and 2 in Canada from November 2001 through July 2007. Those patients with insulin dependent diabetes mellitus, autoimmune disease, pregnancy, urinary tract infection, prior pelvic radiotherapy, detrusor dysfunction (neurogenic overactivity, nonneurogenic overactivity refractory to medical treatment, hypocontractility, poor compliance), untreated bladder pathology and untreated grade 3/4 pelvic prolapse were excluded from participation. Baseline preoperative tests included urinalysis, urodynamics, cystourethroscopy, provocative pad weight, 3-day voiding diary, Stamey score, direct visual stress test and validated questionnaires (IQOL, IIQ and the UDI). These tests were repeated at 1 year except cystourethroscopy. Provocative pad weight, 3-day voiding diary, Stamey score, direct visual stress test, urinalysis and validated questionnaires (IQOL, IIQ and the UDI) were also obtained at 6 weeks, and at 3, 6 and 9 months postoperatively. The ACT device was placed bilaterally through 2 small incisions between the labia majora and minora at the level of the urethral meatus. A specially designed delivery trocar was passed under fluoroscopic and digital vaginal guidance through each incision and just distal to the urethrovesical junction (fig. 1, A). After placement of each device, the balloons were inflated with 1.5 ml isotonic contrast solution and repeat fluoroscopy was used to confirm proper positioning of the balloons (fig. 1, B). The associated ports were then placed in a subcutaneous pocket in each labia majora and the skin closed with a subcuticular absorbable suture. Balloon adjustments commenced 6 weeks postoperatively in the clinic by percutaneously accessing each subcutaneous port. Balloons were adjusted (using the same isotonic solution as at implant) until adequate continence was achieved as measured by subjective and objective criteria. Per Food and Drug Administration protocol all adverse events and complications were reported and analyzed.

RESULTS

A total of 162 subjects (mean age 67.4 years, range 31 to 94) have been implanted to date. Followup data for 1 year were available on 140 patients. Eight patients were lost to followup, 6 missed followup and

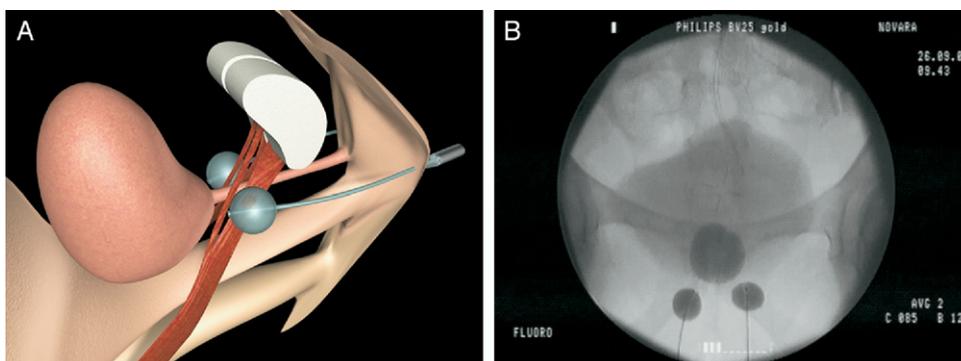


Figure 1. A, percutaneous placement of ACT device. B, fluoroscopy showing position of Foley and ACT balloons

1 is deceased. Mean time from diagnosis of stress urinary incontinence to implantation was 56 months. Of the implanted patients 84% (136 of 162) and 44% (71 of 162) had previously undergone at least 1 or more than 1 prior unsuccessful incontinence surgery, respectively. Anti-incontinence procedures included Burch colposuspension, suburethral slings, needle suspension, TVT, periurethral bulking agents and the AUS (table 1). Nonoperative management of SUI failed in a small proportion, 16% (26 of 162) of our patients and, thus, they were offered the ACT implant (this was based on patient preference as they were offered all other available surgical options). Nonoperative management included pharmacotherapy, biofeedback, E-stim and behavioral modification. Of the implanted patients 52.5% had associated urethral hypermobility (85 of 162). The majority of the ACT implants were placed with the patients under a general anesthetic.

The data show that the Stamey score improved by at least 1 grade in 76.4% (107 of 140) of patients. Mean provocative pad weight decreased in 84.9% (107 of 126) of patients at 1 year with a mean numeric improvement from 49.6 to 11.2 gm (fig. 2). More than 80% (102 of 126) of patients had a greater than 50% reduction in provocative pad weight and 52% (67 of 130) met the definition of dry of less than 2 gm.^{10,11}

Implanted patients experienced an improvement in quality of life as determined by several validated questionnaire scores at 1 year. The IQOL, UDI and IIQ scores improved in 84.4% (114 of 135), 82.5% (113 of 137) and 78.3% (108 of 138) of patients, respectively. Figure 3 illustrates the improved mean numeric questionnaire scores at 1 year (higher IQOL, and lower UDI and IIQ).

Mean number of balloon volume adjustments per device before 1 year was 2.3 (range 0 to 9). The majority of adjustments occurred in the outpatient setting within 9 months of implantation. Mean volume in each balloon at 1 year was 3.45 ml (range 1.0 to 10.0).

Complications were reported in 24.4% (38 of 156) of subjects through 1 year and 96% were considered to be mild or moderate in nature. The frequencies of the various types of device related complications that occurred (some patients experienced more than 1 type of complication) are listed in figure 4. The

Table 1. Types of operative treatment

	No. (%)
Bulking agents	47 (29)
Sling	94 (58)
Vaginal/retropubic suspension	73 (45)
AUS	1 (0.6)
Interstim®	1 (0.6)

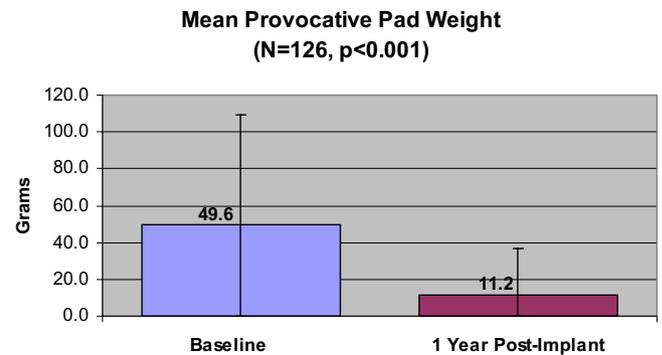


Figure 2. Provocative pad weight

most common complications were port erosion, urinary retention, balloon migration and balloon erosion. These complications occurred earlier in the study period suggesting a technical related learning curve. Device infection and device failure were relatively uncommon. Of our patients 18.3% (28 of 153) underwent explantation during 1 year. Table 2 details the frequency and specific types of events leading to explantation. Of the explanted cases 50% (14 of 28) were reimplemented within 12 months. Subset analysis was performed with several variables to determine if there was any relationship with the incidence of complications. Of the examined variables only sexual activity and previous incontinence surgery were associated with a higher complication rate. Complications most frequently associated with sexual activity were vaginal and port erosions. Patients who did not have any previous surgery for incontinence had fewer complications than those with previous surgical procedures at 7.7% (2 of 26) vs 27.7% (36 of 130), respectively. With respect to the technical ease of implantation 61% of the procedures were rated by the surgeons as being of mild difficulty, 30% as moderate and 9% as severely difficult.

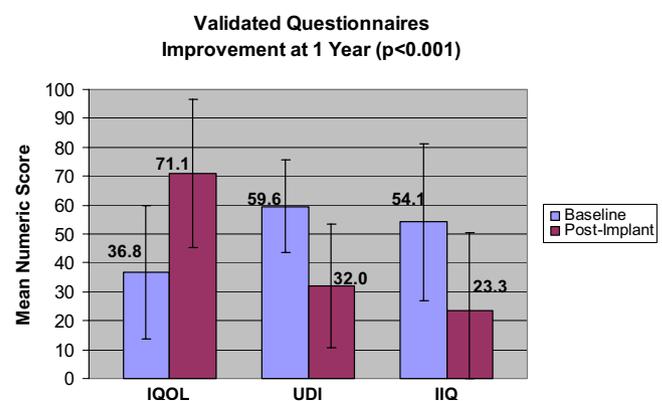


Figure 3. IQOL, UDI and IIQ scores

Complication Rate (N=162)

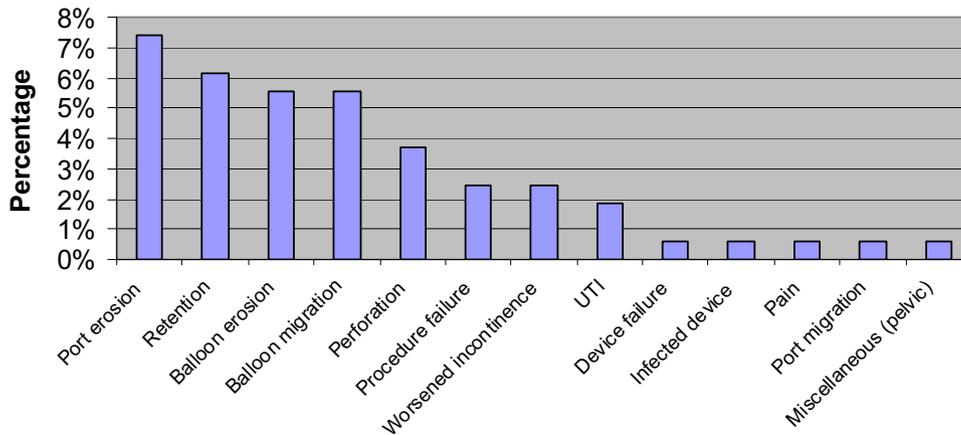


Figure 4. List of complications. UTI, urinary tract infection

DISCUSSION

Stress urinary incontinence continues to affect a large proportion of the female population. The magnitude of this problem has in turn led to the genesis of multiple procedures. Of the many approaches and types of incontinence procedures that are available, there is still no consensus on the preferred procedure. More recently the technical ease, interest in minimal invasiveness and high success rates (80% to 90%) achieved with mid urethral slings (TVT, transobturator, percutaneous vaginal tape) have made them an attractive choice for primary cases.²⁻⁵ Although these techniques have relatively low reported complications, major vascular and bowel injury, in addition to bladder perforation and late complications such as erosion and failure to relieve incontinence, have been recently reported.^{2-5,12}

Several authors have examined the outcomes of anti-incontinence procedures in the treatment of recurrent stress urinary incontinence. Amaye-Obu and Drutz reported 70% to 78% cure rates when performing an abdominovaginal polypropylene sling procedure, a modified urethral sling procedure or Burch colposuspension.¹³ One study in 2001 demonstrated

an 82% cure rate using TVT for recurrent stress incontinence, which decreased to 61% to 77% in patients with associated intrinsic sphincter deficiency.⁵ More recently in 2008 Eandi et al reported excellent results as determined by a validated questionnaire of 10 patients in whom a prior mid urethral sling failed and who were treated with TVT.¹⁴ With respect to complications, bladder perforation was reported in a relatively high percentage (31%) of patients with recurrent stress incontinence treated with TVT in some series.⁵ In a 1995 retrospective review Morgan et al reported an 85% subjective cure rate in 88 patients with recurrent incontinence treated with a polypropylene pubovaginal sling with no reported major complications.¹⁵ In 1997 Breen et al performed a retrospective analysis of the fascia lata suburethral sling in which they reported a 90% subjective cure in 60 patients with followup of 3.5 years.¹⁶ It appears that the proper adjustment of sling tension can be difficult as urinary retention was reported in 30% of patients with 13% (8 of 60) requiring sling release. The Burch colposuspension has also been described in the treatment of recurrent stress incontinence. In 1999 Maher et al evaluated 53 patients, and reported an 89% subjective improvement and an 81% objective cure rate after a median followup of 9 months.¹⁷ Complications included bladder perforation, incisional hernia and obturator vein injury.

We report our prospective 1-year data on female patients with recurrent stress urinary incontinence treated with the minimally invasive ACT device. Our data appear to compare favorably to the previously reported ACT literature. Chartier-Kastler et al reported 87% clear improvement,⁷ Kocjancic et al reported 68% dry and 16% improved,⁸ and Wachter et al reported that 59% of patients showed significant im-

Table 2. Types of events leading to explantation

	No.
Port erosion	11
Balloon migration	9
Balloon erosion	8
Worsening incontinence	2
Pain	1
Device failure	1
Infected device	1
Port migration	1
Other pelvic	1

provement.⁹ The results of these studies in comparison to our data differ somewhat due to variability in the study populations and the assessment of different efficacy end points. Efficacy as measured by objective and subjective criteria in our study was good, with a statistically and clinically significant decrease in provocative pad weight, Stamey score and several improved validated questionnaire scores (IQOL, UDI, IIQ). Our reported objective efficacy with the ACT device may not appear to compare favorably to the cure rates using other techniques for recurrent stress incontinence with 52% of our patients dry and 80% improved. However, it is difficult to make true comparisons given the varied study designs, definitions of success and length of followup. The strict definition of dry in the present study of less than 2 gm on a provocative pad weight test may explain our lower dry rate compared to other studies in addition to the complexity of our patient population with respect to prior surgery.^{10,11} A major advantage of this device is the ease of percutaneous adjustments to balloon volume to achieve continence with changes that may occur over time in individual patients. This is in contrast to previously reported results in Europe with nonadjustable injectable microballoons which have been found to lose volume over time as determined by magnetic resonance imaging.¹⁸

With respect to safety of the ACT there have been no major complications such as bowel perforation or

vascular injury reported with the use or placement of this device. The majority of complications are related to port erosion, urinary retention, balloon migration away from the bladder neck and balloon erosion (in most cases vaginal), similar to previously reported complications with the ACT.⁷⁻⁹ We believe that some of these complications may be explained by technique as the majority occurred early in the study period. Nonetheless most complications were easily rectified in the office setting. Of note, there is minimal risk of voiding dysfunction associated with this device. Of the 28 patients who did require explantation, this was typically done in the office setting without difficulty. Explantation did not preclude additional treatment as nearly 50% of those who underwent explantation received a new device within 12 months.

CONCLUSIONS

Our data suggest that implantation of the Uromedica ACT device is an effective, simple, safe and minimally invasive treatment for recurrent female SUI. The balloons are easily adjusted percutaneously to enhance efficacy. Complications are usually mild in nature and can be easily managed. The need for explantation does not preclude repeat implantation. Additional followup will determine the long-term durability of this device.

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