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

Sherif R. Aboseif,* Ethan I. Franke, Steven D. Nash,† Joel N. Slutsky,‡ Neil H. Baum, Le Mai Tu, Niall T. Galloway, Peter J. Pommerville, Suzette E. Sutherland§ and John F. Bresette

From the Department of Urology, Kaiser Permanente, Los Angeles, California (SRA), Kansas City Urology Care, Leawood, Kansas (EIF), Urological Surgeons, Kankakee, Illinois (SDN, JNS), Neil Baum Urology, New Orleans, Louisiana (NHB), Emory University School of Medicine, Atlanta, Georgia (NTG), Metropolitan Urologic Specialists, Plymouth, Minnesota (SES), The Lahey Clinic, Burlington, Massachusetts (JFB), CHUS-Fleurimont, Quebec (LMT), and Can-Med Clinical Research Inc., Victoria, British Columbia (PJP), Canada

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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* Correspondence: Reconstructive and Neurourology, Kaiser Permanente Medical Center, 4900 Sunset Blvd., 2nd Floor, Los Angeles, California 90027 (telephone: 323-783-5861; FAX: 323-783-7272; e-mail: sherif.r.aboseif@kp.org).

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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

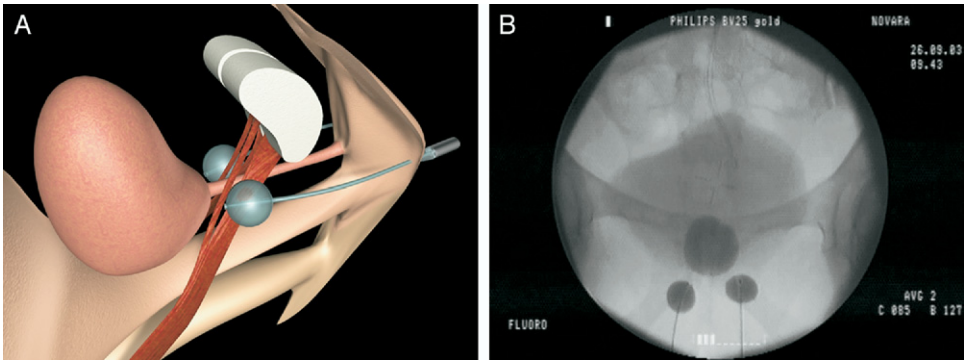

Figure 1. *A*, percutaneous placement of ACT device. *B*, fluoroscopy showing position of Foley and ACT balloons