The Safety and Efficacy of a New Adjustable Single Incision Sling for Female Stress Urinary Incontinence

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Purpose: We describe the safety and efficacy of the Altis® Single Incision Sling System for the treatment of female stress urinary incontinence through 12 months.

Materials and Methods: In this study we collected a variety of safety and efficacy measures relevant to the assessment of urinary incontinence. The primary efficacy end point was improvement in 24-hour pad weight test. Other efficacy measures included the cough stress test, Urogenital Distress Inventory-Short Form, Incontinence Impact Questionnaire-Short Form, Patient Global Impression of Improvement and 3-day voiding diary. Safety was evaluated through assessment of device and procedure related adverse events.

Results: Of 116 surgical attempts 113 subjects were implanted with the Altis sling. Of these patients 103 had primary efficacy data at baseline and 6 months, and 101 had efficacy data at baseline and 12 months. Consequently 88 (85.4%) subjects at 6 months and 91 (90.1%) at 12 months achieved a 50% or greater reduction in pad weight. The cough stress test was negative for 95 (92.2%) subjects at 6 months and 91 (90.1%) at 12 months. A decrease in median leaks per day was observed at 6 months and improvements in all patient reported measures were observed through 12 months. A majority of subjects reported feeling much better or very much better at 6 and 12 months, respectively. There were no reports of mesh erosion or migration and no unanticipated adverse events through 12 months.

Conclusions: The Altis sling appears to be safe and efficacious, and performs as intended in the treatment of stress urinary incontinence through 12 months.

Key Words: urinary incontinence, stress; surgical procedures, minimally invasive; suburethral slings; female

Abbreviations and Acronyms

CST = cough stress test

IIQ-7 = Incontinence Impact Questionnaire-Short Form

PGI-I = Patient Global Impression of Improvement

PWT = pad weight test

SAE = serious adverse event

SUI = stress urinary incontinence

UDI-6 = Urogenital Distress Inventory-Short Form

U.S. = United States

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Urinary incontinence affects up to 50% of women[1,2] and of these women 50% to 80% are identified as having stress urinary incontinence.[3,4] An estimated 4% to 10% of women in the United States undergo surgery to restore continence and this rate has increased steadily during the last 20 years.[5]

Traditional surgical techniques such as Burch colposuspension and autologous sling procedures achieve positive results but require general anesthesia and hospitalization. In 1996 the tension-free vaginal technique transformed the way female SUI was treated. Petros and Ulmsten presented an integral theory of the

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physiopathology of stress urinary incontinence,[6] and introduced a modified intravaginal slingplasty procedure to treat SUI. The procedure was less invasive and feasible with the patient under local anesthesia, and eventually was suitable as an in-office procedure.[7] The cure rate was durable years after the operation, but retropubic tension-free sling procedures were associated with increased morbidity such as bladder perforation, pain, voiding dysfunction and de novo urge incontinence, as well as rare serious complications such as vascular, nerve or bowel injury and death.[8,9]

The transobturator approach was developed in 2001 to minimize the morbidity associated with blind passage of the needle in the retropubic space.[10] Randomized clinical studies comparing retropubic and transobturator tension-free procedures have shown that both procedures have a similar efficacy.[11]

Abdel-Fattah et al recently proposed classification of mid urethral slings into 3 generations.[12] The first generation is represented by tension-free retropubic slings, the second generation includes devices using the transobturator route (outside-in and inside-out) and the third generation is represented by single incision slings. Single incision slings vary in size, surgical technique and fixation technology, with the common feature of a single vaginal incision.

In this study we assess the safety and efficacy of the Altis single incision sling system for the treatment of female SUI. The Altis sling is an adjustable, low elasticity, minimally invasive single incision sling. The device was cleared to market in the U.S. in November 2012.

MATERIALS AND METHODS

This prospective, single arm, multicenter study included 17 sites in the U.S. and Canada. All sites received institutional review board approval and all subjects provided written informed consent before study enrollment.

Inclusion criteria were women at least age 18, with SUI confirmed through the CST or urodynamic evaluation, and in whom 2 noninvasive incontinence therapies had failed (eg Kegel exercises, behavior modification, biofeedback etc). Subjects were excluded from analysis if they had neurogenic or urge predominant incontinence, active urogenital infection, pelvic organ prolapse stage II or greater, atonic bladder or post-void residual volume consistently greater than 100 ml, prior surgical treatment for incontinence, or if they were pregnant or planning to become pregnant.

At baseline a physical examination was performed and medical history was documented. A 24-hour PWT was completed. A standardized CST was performed with subjects in the lithotomy and standing positions after filling the bladder to functional capacity with normal saline. Subjects were asked to cough 5 times in each position and any leakage was considered a positive test. Post-void residual volumes were determined by bladder scan, ultrasound or catheter. The presence of urge predominant incontinence was assessed through clinical evaluation, medical history and prior nonstudy testing as available. Validated questionnaires consisting of UDI-6 and IIQ-7 were obtained.

The Altis sling is a 7.75 cm polypropylene mesh attached to suture extending to 1 static and 1 dynamic anchor (fig. 1). The dynamic anchor allows intraoperative adjustability and tensioning to achieve continence. A set of helical-type disposable introducers are used to position the anchors.

Surgery was performed in hospitals, ambulatory care centers or in-office with the patient under general, spinal or local anesthesia. No concomitant pelvic floor surgical procedures were allowed. The Altis sling was implanted according to the instructions for use. All surgeons had prior experience implanting other sling systems and received product specific surgical training. The surgical procedure consisted of a mid urethral incision on the anterior vaginal wall with bilateral dissection to the obturator internus fascia at the point of the medial border of the inferior ramus. Using the introducer, the static anchor was placed through the obturator membrane with an inside-out approach. The dynamic anchor was then placed on the contralateral side, ensuring that the sling was lying tension-free and flat under the mid urethra. The bladder was filled with saline and depending on the level of anesthesia the subject was instructed to cough or a Credé maneuver was performed while the sling was tensioned to the desired level of continence.

In-clinic standardized followup visits occurred at 3, 6 and 12 months with physical examination and urodynamic studies, including 24-hour PWT, CST, inspection of vaginal incision, UDI-6, IIQ-7 and PGI-I collected at each visit. Additionally, a 3-day voiding diary was collected at baseline and 6 months. Safety was evaluated

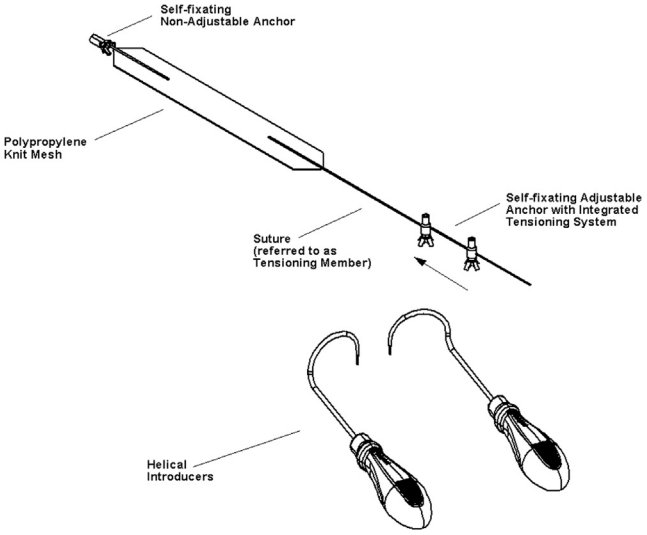

Figure 1. Altis single incision sling system