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Safety and Efficacy of the Solyx™ Single-Incision Sling for the Treatment of Stress Urinary Incontinence: Preliminary Results

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ABSTRACT

INTRODUCTION: The objective of this study was to assess the short-term safety and efficacy of the Solyx single-incision sling (Boston Scientific Corp; Natick, MA, USA).

METHODS: A prospective study of 21 women with stress urinary incontinence (SUI) and no evidence of detrusor instability was conducted at 2 medical centers between July 2009 and March 2010. All patients underwent preoperative urodynamic testing and had urethral hypermobility. Patients with recurrent SUI or fixed urethras were excluded. All participants had surgery with the Solyx sling. Outcome measures were device-related adverse events, sling efficacy (based on a standing cough stress test at a fill volume of 300 mL, measured at postoperative week 12), and sling tolerability (based on Urogenital Distress Inventory, version 6 [UDI-6] and Incontinence-Quality of Life [I-QOL] questionnaire results at postoperative weeks 6 and 12). Satisfaction with surgery was also assessed with a rating scale.

RESULTS: Mean patient age was 60.2 years (range, 39-82 years). All sling procedures took < 10 minutes to perform and had blood loss of < 60 mL. A total of 10 patients had concomitant procedures. Nineteen of the 21 patients completed the study with a mean follow-up of 13.68 weeks (range, 8.71-18.86 weeks). There were no intraoperative or postoperative complications. Twelve weeks after surgery, 18/19 patients had a negative standing cough stress test and were no longer wearing pads. One patient developed de novo urgency and had resolution of her symptoms with anticholinergic medication. There were no differences in the success rates of the patients who underwent slings alone versus those that had concomitant surgery. I-QOL and UDI-6 mean preoperative scores differed significantly from both the 6-week and 12-week mean postoperative scores (both with P <.0001); there was no significant difference in mean scores at 6 and 12 weeks. Nineteen patients reported satisfaction with their surgical outcomes 12 weeks after surgery (5/19 completely satisfied, 10/19 very satisfied, 3/19 satisfied, 1/19 somewhat satisfied, 0/19 not satisfied).

CONCLUSIONS: Preliminary evidence suggests that the Solyx SIS is a safe and effective treatment for SUI.

Abbreviations and Acronyms

I-QOL, Incontinence-Quality of Life
SIS, single-incision sling
SUI, stress urinary incontinence
TFS, tissue fixation system
TVT, tension-free vaginal tape
UDI-6, Urogenital Distress Inventory, version 6

KEYWORDS: Single incision sling; Stress urinary incontinence

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original study

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INTRODUCTION

The treatment of stress urinary incontinence (SUI) has changed dramatically as a result of the contributions of Ulmsten et al [1]. They demonstrated to the urogynecology and urology communities that SUI can be corrected by using a piece of polypropylene mesh anchored via the retropubic space. Unfortunately, retropubic correction of SUI with a tension-free vaginal tape (TVT) has inherent risks such as bowel, vascular, and bladder injury [2,3]. These complications are due to the blind passage of trocars through the retropubic space. In order to reduce the surgical complications and minimize invasiveness of tension-free midurethral slings, the single-incision sling (SIS) was developed.

The SIS technique allows a small piece of polypropylene mesh to be introduced via a single vaginal incision without skin incisions. Single-incision slings were first introduced approximately 5 years ago, with lengths of 8-8.5 cm. Many did not include any specific anchor to fixate the sling as scarring developed. In addition, techniques for placement of previous single-incision slings were not uniform. The early devices used for single-incision slings had mixed results; therefore, their efficacy and safety were questionable. More recent retrospective studies on second-generation SIS systems have demonstrated minimal morbidity and relatively high efficacy [4].

The Solyx sling (Boston Scientific Corp; Natick, MA, USA) is a single-incision midurethral sling. It is 9 cm in length and has nonabsorbable polypropylene darts on each end. The Solyx sling is long enough to support the midurethra but not so long that it would enter the retropubic space, perforate muscles of the lower extremity, or approach the obturator nerves. The sling is positioned in the obturator muscle tissue via an introducer that allows for precise placement. Polypropylene darts anchor the sling in the obturator muscle until tissue ingrowth permanently fixes the mesh in place.

The technique for placing the Solyx sling has been standardized to permit reproducible placement into the obturator internus muscle. However, prospective research regarding its efficacy is needed. The goal of the present study is to assess the short-term safety and efficacy of the Solyx SIS sling system in women with SUI.

METHODS

The present prospective study evaluating the safety and tolerability of the Solyx sling was conducted at North Shore-Long Island Jewish Hospital and Norwalk Hospital between July 2009 and March 2010. Institutional Review Board approval was obtained at both institutions. All participants provided informed consent.

Participants

The study population included women with SUI and no evidence of detrusor instability that elected to undergo surgical treatment. All patients underwent preoperative urodynamic testing and had urethral hypermobility, which was defined as a Q-tip test angle of ≥ 30 degrees from the parallel with straining or a change of ≥ 30 degrees with straining. Patients with recurrent SUI or fixed urethras (ie, with the absence of hypermobility) were excluded. The detailed inclusion and exclusion criteria are shown in Figure 1. A total of 21 participants were enrolled in the investigation.

Surgical Procedures

All patients underwent surgery with the Solyx SIS System (Figure 2) for treatment of stress urinary incontinence. Intravenous antibiotics were administered preoperatively. The procedure was performed in the operating room.

Patients were placed in the dorsal lithotomy position and general, regional, or local anaesthesia was administered at the discretion of the operating surgeon and anesthesiologist. The bladder was entirely drained and a 1-2 cm incision was made in the anterior vaginal wall at the level of the midurethra. The vaginal epithelium was then bilaterally undermined and separated from the endopelvic fascia using sharp dissection to the level of the inferior pubic rami. This created a pathway for delivery of the sling arms. The tip of the delivery device was placed into the mesh tip carrier. The deployment mechanism (consisting of a plastic handle and stainless steel trocar) was inserted into the dissected pathway at a 45° angle and used to pass the distal arm anchors through the obturator internus muscle behind the pubic ramus. The anchors were advanced until the midline marking on the trocar reached the patient's midline under the urethra. Once positioning was optimized, the anchoring carrier was deployed from the trocar by stabilizing the delivery trocar with one hand and pulling the device handle with the opposite hand. This was repeated in similar fashion on the opposite side. In effect, the mesh carriers (acting as mesh anchors) were deposited into the obturator muscle tissue and the sling was brought to rest at the level of the midurethra without tension. The surgeon verified that the mesh was not twisted prior to deployment of the second mesh arm, and that a small instrument could easily be passed between the urethra and the mesh once both arms were deployed. Bladder integrity was verified with cystoscopy in all patients after placement of the sling. The vaginal incision was then sutured closed with delayed absorbable sutures. Patients were discharged within 24

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Figure 1. Inclusion and Exclusion Criteria for the Study.
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INCLUSION CRITERIA

Age ≥ 18 years
Female gender
Clinical diagnosis of stress urinary incontinence by a study physician
Clinical diagnosis of urethral hypermobility
Valsalva leak point pressure ≥ 60 cm H2O
No history of surgical treatment in the past for stress urinary incontinence
Ability to provide informed consent and complete all study requirements

EXCLUSION CRITERIA

Life expectancy < 12 months
Current pregnancy; considering future pregnancy
Detrusor instability
Q-tip angle < 30 degrees
Postvoid residual > 100 mL
Previous stress urinary incontinence procedure
Previous urethral surgery
History of pelvic irradiation
Current urinary tract infection
History of chronic urinary tract infections with stricture
History of chronic pyelonephritis
Previous urethral surgery
History of interstitial cystitis
Immunosuppression
Collagen vascular disease
Stage IV pelvic organ prolapse
Potential for future growth
Soft tissue pathology into which the implant is to be placed
Any pathology that would compromise implant placement
Any pathology that would limit blood supply or infections that would compromise healing
Overweight women (weight parameters determined by the physician)
Blood coagulation disorder
Compromised immune system or any other condition that would compromise healing
Renal insufficiency or upper urinary tract obstruction

hours of the procedure.

Outcome Measures

The primary safety endpoint was device-related adverse events. These were assessed perioperatively and at 2 weeks, 6 weeks, and 12 weeks after surgery. Perioperative complications were documented by the operating surgeon. Postoperative complications were assessed at the physician's follow-up examination. Any adverse events were summarized.

The secondary endpoints were sling efficacy and sling tolerability. Sling efficacy was based on a standing cough stress test at a fill volume of 300 mL, measured at postoperative week 12. These measures were summarized. Sling tolerability was assessed through patient-satisfaction ratings. Patients completed the Urogenital Distress Inventory, version 6 (UDI-6) [5] and Incontinence-Quality of Life (I-QOL) [6] questionnaires at 6 weeks and 12 weeks after surgery. Preoperative and postoperative UDI-6 and I-QOL scores were compared using a mixed model repeated-measures analysis of variance (RM-ANOVA). The analysis was conducted using Statistical Analysis Software (SAS) version 8.2 (SAS Institute Inc; Cary, NC, USA). Patients also completed a surgical satisfaction rating scale at the 12-week follow-up examination. They indicated if they

Figure 2. Solyx Single-Incision Sling System (Boston Scientific Corp; Natick, MA, USA).
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were completely satisfied, very satisfied, satisfied, somewhat satisfied, or not satisfied with their surgery.

RESULTS

Participant Characteristics

Twenty-one patients underwent placement of the Solyx sling by one of 2 experienced surgeons. The mean patient age was 60.0 years (range, 39-82 years). The mean parity was 2.7 (range 1-4). Eight patients had pelvic organ prolapse that ranged from stage 2-4 (based on pelvic organ prolapse quantification [POPQ] staging).

Nineteen of the 21 patients completed the study. Two patients were lost to follow-up at 6 weeks. A total of 10 patients had concomitant procedures including cystocele repair with mesh augmentation (n = 3), total vaginal hysterectomy and cystocele repair with mesh augmentation (n = 4), myomectomy (n = 1), supracervical hysterectomy with bilateral salpingoophorectomy (n = 1), and combined anterior repair with mesh and posterior repair (n = 1).

Outcome Measures

All sling procedures took < 10 minutes to perform and had blood loss of < 60 mL. Results were based on a mean follow-up of 13.68 weeks (range, 8.71-18.86 weeks).

Adverse events. None of the patients developed urinary retention and no patients required postoperative catheterization. No complications of the procedure occurred and no pain related to the implant was reported. None of the patients developed urinary retention.

Sling efficacy. Efficacy of the Solyx system was based on a standing cough stress test at a fill volume of 300 mL. Twelve weeks after surgery, 18/19 patients had a negative standing cough stress test and were no longer wearing pads. One patient developed de novo urgency and had resolution of her symptoms with anticholinergic medication. There were no differences in the success rates of the patients who underwent slings alone versus those that had concomitant surgery.

Sling tolerability. RM-ANOVA was used to compare the IQOL and UDI-6 from baseline to the 6-week follow-up and baseline to the 12-week follow-up evaluations, separately. The results are contained in Table 1. Preoperative mean questionnaire scores were significantly lower than both the 6-week and 12-week postoperative mean scores (both with $P < .0001$). However, there were no significant differences between mean I-QOL and UDI-6 scores at 6 weeks and 12 weeks after surgery ($P = .9005$ and $P = .8345$, respectively). Nineteen patients reported satisfaction with their surgical outcomes 12 weeks after surgery (5/19 completely satisfied, 10/19 very satisfied, 3/19 satisfied, 1/19 somewhat satisfied, 0/19 not satisfied).

DISCUSSION

The goal of the tension-free midurethral sling is to improve the quality of life in women with incontinence by accomplishing surgery with minimal morbidity and complications. Retropubic and transobturator slings have favorable results, but require 3 incisions and blind passage of trocars. This blind needle passage has the potential risk of visceral and vascular damage [7-12]. Single-incision slings are appealing because of their minimal

Table 1. Mean Incontinence-Quality of Life (I-QOL) and Urogenital Distress Inventory (UDI-6) Scores Before Surgery and at 6-Weeks and 12-Weeks After Surgery.
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Test	Presurgery (N = 21)		6 Weeks Postsurgery (N = 21)		*P*	12 Weeks Postsurgery (n = 19)		*P*
	Mean	Range	Mean	Range		Mean	Range	
I-QOL, score	74	29-105	102.1	62-110	<.0001	102.4	89-110	.90
UDI-6, score	50	16.7-77.7	28.7	0-44.4	<.0001	8.2	0-27.8	.84

invasiveness (even less than with TVT or transobturator slings) and their potential for decreased morbidity.

Single-incision sling technology has been evolving over the last 5 years. Innovations have occurred that have considerably improved the procedure. However, there have been mixed results in terms of success and morbidity. This may be attributed to a difference in sling devices as well as variability in surgical techniques.

One of the first single-incision slings was the tissue fixation system (TFS), which anchors the sling to soft tissue below the pubic bone using 2 small plastic anchors. Petros and Richardson [13] reviewed 3-year data using the TFS sling and found success rates of 80% in the 31 patients that were studied. Promising results have also been achieved with the Ophira arcus minisling (Promedon; Cordoba, Argentina). In a study of 18 women with SUI, 88% of patients were dry and 5.5% had improved continence at 12 months [14]. An observational series of 76 women treated with the Minitape (Smartmesh Technology, Mpathy Medical; Raynham, MA, USA) demonstrated a 97% continence rate at 21 weeks [15]. Retrospective data have also been reported on 61 patients with SUI treated at a single center with the MiniArc single-incision sling (American Medical Systems; Minnetonka, MN, USA) [16]. An overall cure rate of 91.4% was reported at 12 months. There were no intraoperative complications and there was only 1 postoperative adverse event secondary to urinary retention.

Lower success rates were reported with the TVT-Secur minitape (Ethicon Inc; Blue Ash, OH, USA). Results of a study of 91 patients with the TVT-Secur showed subjective and objective cure rates of 78% and 81%, respectively [17]. Postoperative complications included voiding difficulty, recurrent urinary tract infections, de novo urgency incontinence, and dyspareunia. Cornu et al [18] recently reported a high failure rate of 42% using the TVT-Secur. These poor success rates were also seen by Basu and Duckett [19] when they compared a minisling technique to a retropubic TVT and found higher failure rates with the minisling. However, it should be noted that De Ridder et al [20] compared the miniarc sling to the monarc sling and found similar favorable success rates with these 2 procedures.

A 95% postoperative continence rate was reported in a retrospective study of the Solyx SIS procedure [4]. This rate is comparable to those associated with full-length slings. Unlike the full-length slings, no perioperative or postoperative complications were reported at a mean follow-up of 6.5 months. Remarkably, patients did not report any significant pain related to the sling procedure. It is our belief that the different sling devices and the surgical techniques used to place the slings can affect success rates and morbidity. The sling and surgical technique used in the present study resulted in favorable findings.

The present prospective study showed that 95% of patients with a Solyx SIS had had a successful continence outcome, as determined by a negative cough test. The I-QOL and UDI-6 scores at both 6 and 12 weeks showed statistically significant improvement in the quality of life of these patients, and all patients reported some degree of satisfaction with their surgical outcomes. There were no significant intraoperative or postoperative complications. Finally, patients did not report any implant-related pain postoperatively, which further confirms the minimally invasive nature of the device.

Patients in this study did not experience any episodes of transient or permanent urinary retention. This finding may be explained by the fact that this sling is placed laterally to the urethra with very little upward force. The lack of compression suggests that the sling would be unlikely to cause retention or significant voiding dysfunction, as is shown in this study.
The strengths of this study are its prospective design and comparatively large sample size. Limitations of this study include a relatively short follow-up period, lack of a control group or randomization of participants, and the presence of concomitant procedures in nearly 50% of the participants. Larger randomized controlled trials are warranted to confirm the safety and long-term efficacy of the Solyx SIS system.

CONCLUSION

Our preliminary findings support the use of single-incision slings for the treatment of SUI. The Solyx sling provided excellent continence rates, which led to improved quality of life. Placement was achieved through a small, single vaginal incision with minimal tissue disruption, which led to minimal postoperative discomfort. The Solyx SIS appears to be a safe and effective procedure to correct SUI, based on the lack of postoperative pain, urinary retention, or significant complications experienced by the patients and its ease of placement for the surgeon.

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Conflict of Interest

Scott Serels and Lawrence R Lind: speakers and consultants for Boston Scientific Corporation.

Sandy B Nosseir and Harvey A Winkler: no conflict declared.

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