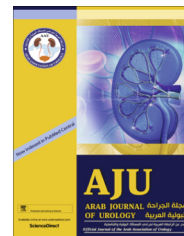




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VOIDING DYSFUNCTION/FEMALE UROLOGY
ORIGINAL ARTICLE

Use of surgeon-tailored polypropylene mesh as a needle-less single-incision sling for treating female stress urinary incontinence: Preliminary results



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KEYWORDS

Female;
Stress urinary
incontinence;
Polypropylene mesh;
Single incision

ABBREVIATIONS

ALPP, abdominal
leak-point pressure;
CST, cough stress test;
DO, detrusor overac-
tivity;
ISD, intrinsic sphincter

Abstract Objective: To evaluate the safety and efficacy of a procedure using surgeon-tailored polypropylene mesh (STM) through a needle-less single-incision technique for treating stress urinary incontinence (SUI), aiming to decrease the cost of treatment, which is important in developing countries.

Patients and methods: In all, 43 women diagnosed using a cough stress test were treated from January 2011 to June 2013 at the Urology and Gynaecology Departments (dual-centre), Cairo University Hospitals. Previous surgery was not a contra-indication. Patients with a postvoid residual urine volume of > 100 mL, a bladder capacity of < 300 mL, impaired compliance or neurological lesions were excluded. The Stress and Urge incontinence Quality of life Questionnaire (SUIQQ) and urodynamic variables were compared before and after surgery. The variables were compared between the baseline and postoperative follow-up values using a paired *t*-test, a Wilcoxon signed-rank test or McNemar's test.

Results: The mean age was 42.7 years and 20 (47%) patients had associated urgency UI (UUI), whilst 21 (49%) had intrinsic sphincter deficiency. The median

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deficiency;
(M)(U)(S)UI, (mixed)
(urge) (stress) urinary
incontinence;
 $P_{det}Q_{max}$, detrusor
pressure at maximum
urinary flow rate;
PVR, postvoid residual
urine;
 Q_{max} , maximum
urinary flow rate;
QoL, quality of life;
STM, surgeon-tailored
ordinary polypropy-
lene mesh;
NSIT, needle-less
single-incision
technique;
SUI, stress urinary
incontinence;
SUIQQ, Stress and
Urge Incontinence
Quality of life
Questionnaire;
TVT, tension-free
vaginal tape

(range) operative duration was 14 (5–35) min. There were no complications during surgery. The mean (SD, range) follow-up was 28.1 (5.1, 18–36) months. Postoperative complications were vaginal discharge (5%), failure of wound healing (5%), dyspareunia (5%) and UTI (5%). The sling was removed in one case. SUI, UI and quality-of-life indices improved significantly after surgery. There were no significant differences in pressure-flow studies before and after surgery. In all, 38 (88%) patients were cured, four (9%) improved and in one only the treatment failed (2%).

Conclusion: This technique is simple, safe, effective, reproducible and economical for treating SUI. The STM was easy to insert in a short operation.

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Introduction

The tension-free vaginal tape (TVT) was first described in 1996 by Ulmsten et al. [1] for treating stress urinary incontinence (SUI). The TVT was associated with several complications, including bladder perforation, haematoma, bowel perforation, vascular and nerve lesions. These different complications were due to the passage of the needles through the retropubic space [2]. Consequently, transobturator tapes were developed, which are less invasive procedures with fewer complications [3]. However, the procedure still involves passing the needles through the groin, which might result in groin pain [4,5]. Furthermore, there are potential vascular and neurological complications related to the passage of needles through the obturator foramen [6]. Thus mini-slings (i.e., the TVT-Secur or MiniArc) were introduced to further reduce these potential complications [7]. A more recent technique in the use of mid-urethral tapes was the Contasure needle-less technique (Neomedic International, Inc., Spain). It avoids the complications resulting from the passage of needles through the obturator foramen or retropubic space. It requires only one incision in the vagina and no incisions in the abdomen or groin. The support is provided through the pocket-shaped termination at both ends of the mesh by anchoring to the surrounding tissues [8].

Although satisfactory outcomes have been reported with most of these surgical techniques, their cost is still

high for most patients in developing countries. Therefore, the aim of the present study was to describe our procedure using the surgeon-tailored ordinary polypropylene mesh (STM) through the needle-less single-incision technique (NSIT) to reduce the cost of treating SUI, and to evaluate its safety and efficacy.

Patients and methods

The STM was inserted through NSIT in 43 women between January 2011 and June 2013 at the Urology and Gynaecology Departments (dual-centre), Cairo University Hospitals. This open prospective study was approved by the local ethics committee, and informed consent was obtained from each patient.

Female patients with SUI (involuntary loss of urine on effort or physical exertion, or on sneezing or coughing) were included in the present study if the cough stress test (CST) was positive. A complete urogynaecological history and examination were done for all patients. The quality of life (QoL) and different symptoms were evaluated according to the Stress and Urge Incontinence Quality of Life Questionnaire (SUIQQ) [9], which consists of the QoL Index (score 0–16), a SUI Index (0–12) and the urge UI (UI) Index (0–8). The postvoid residual urine volume (PVR) was evaluated using abdominal ultrasonography. Several urodynamic variables were compared before and after surgery, including free uroflowmetry, maximum

cystometric capacity, compliance, maximum urinary flow rate (Q_{\max}) and the detrusor pressure at Q_{\max} ($P_{\det Q_{\max}}$). The presence of detrusor overactivity (DO) was reported. The abdominal leak-point pressure (ALPP) was also determined.

We excluded patients with neurological lesions, impaired bladder capacity (< 300 mL) or compliance, or a PVR of > 100 mL. Any patient with a UTI was treated before surgery. The presence of urogenital prolapse was not an exclusion criterion unless it was more than of second degree (according to the Baden and Walker [10] classification). Associated prolapse was repaired when symptomatic. We did not exclude patients with previous surgery or mixed UI (MUI) provided that the associated UUI (involuntary loss of urine associated with urgency) was not the predominant component.

We used the commercially available ordinary 15×15 cm non-absorbable monofilament mesh used in herniorrhaphy (polypropylene mesh; Prolene, Ethicon Ltd., UK) after tailoring it to give a strip 15 cm long and 2.5 cm wide. Each strip was further prepared to give T-pocket shape extremes by decreasing the width of the central 10 cm to ≈ 1.2 cm whilst folding each 2.5 cm extreme on itself transversely. The T-pocket shape extremes were then preserved by using knots at the edges of the pockets. The final shape of STM was composed of the two T-pocket extremes (2.5×1.25 cm) and the middle part (10×1.2 cm). Thus the total length was 12.5 cm. Two traction threads were inserted into the central part of the sling to help intraoperative repositioning of the STM. Our STM was very similar in shape and size to the original Contasure-Needleless sling (114×12 mm) with its wide extremes (22 mm) [8,11–14].

The repair was carried out with the patient in the lithotomy position. Whilst the patient was given spinal anaesthesia and positioned the STM was tailored. Antibiotic prophylaxis was administered before the procedure (1 g of third-generation cephalosporin). A urethral catheter was inserted to evacuate the bladder. A 1 cm vaginal incision was made midway between the urethral meatus and bladder neck. The paraurethral spaces were bluntly dissected (at the 10 and 2 o'clock positions) until the descending ischiopubic ramus was reached at each side. The STM was folded into a surgical forceps by placing the forceps inside the T-pocket, followed by opening and closing of the forceps. The forceps with the folded mesh were introduced by a controlled push at 45° from the horizontal plane in the previously dissected paraurethral space, until a crack was felt that signified the penetration of the internal obturator fascia. The T-pocket was then extended inside the internal obturator muscles by opening the forceps. The forceps were then closed and pulled off the vagina. The same manoeuvre was made on the contralateral side to complete STM insertion without twisting it. If more support to the urethra was needed, the STM was

repositioned upwards by introducing again the tip of the forceps into the pocket and pushing it further up. The two sutures in the middle of the mesh can be pulled at any time to decrease the support. The pulling sutures were removed after full positioning of the STM. This was followed by closure of the vaginal incision using interrupted absorbable 3/0 sutures. A urethral catheter was inserted for 12 h. Patients were discharged if no PVR was detected. If an associated prolapse was repaired the bladder catheterisation was prolonged to the second day after surgery.

Patients were followed up every 2 weeks during the first month, then every 3 months. The SUIQQ and urodynamic studies were repeated after 12 months of follow-up.

The patient was considered cured if the SUI resolved with no complaints of leakage and if the CST was negative. When SUI was still present but with an improved SUIQQ or ALPP, the condition was considered as 'improved'. The procedure was deemed to have failed if the SUIQQ and ALPP were the same or worse than before.

Quantitative variables were compared between the baseline and follow-up using a paired *t*-test (if normally distributed) or the Wilcoxon signed-rank test (if not normally distributed). Dichotomous variables were compared using McNemar's test. Categorical data were compared between the study groups using the chi-squared test. In all tests $P < 0.05$ was considered to indicate statistical significance.

Results

Perioperative data are shown in Table 1; there were no complications during surgery. Any vaginal discharge after surgery was treated with oral antibiotics, local metronidazole and local antiseptics. Local oestrogen together with antibiotics were given for patients in whom the wound did not heal, but this failed, and after controlling any infection, the wound was closed in two layers after trimming the edges. There were no obstructive complications, with a negligible PVR after removing the urethral catheter in all patients. The STM was not complicated by erosions or mesh exposure (Table 1).

Thirty-eight (88%) patients were cured, four (9%) were improved and in one the procedure failed (2%). The last patient had a cysto-rectocele grade 2 and severe intrinsic sphincter deficiency (ISD) (ALPP, 32 cmH₂O) before surgery, with a SUI score of 12. This patient also had an associated combined colporrhaphy.

There was no statistically significant difference in the outcome between patients with and without ISD ($P = 0.582$), associated prolapse ($P = 0.079$) and associated prolapse repair ($P = 0.117$; Table 2). Five patients (12%) had a history of previous surgery (anterior and/or posterior colporrhaphy) and the SUI was cured in four of them.

Table 1 Perioperative data.

Variable	Mean (SD), median (range) or n (%)
Age (years)	42.74 (9.34, 26–66)
Parity	3 (2–7)
Vaginal deliveries	3 (1–7)
Premenopausal	28 (65)
Postmenopausal	15 (35)
SUI duration (years)	6 (1–25)
Preoperative UTI	7 (16)
ALPP (cmH ₂ O)	66 (30–232)
ALPP > 60	22 (51)
ALPP ≤ 60	21 (49)
Previous surgery (anterior and/or posterior colporrhaphy)	5 (12)
Cystocele	9/43 (21)
Grade 1	2/43 (5)
Grade 2	7/43 (16)
Rectocele:	11/43 (26)
Grade 1	6/43 (14)
Grade 2	5/43 (12)
Uterine prolapse	2/43 (5)
Prolapse (total)	21/43 (49)
Operative duration (NSIT) (min)	14 (5–35)
Op. blood loss (mL)	47.4 (17.04, 15–90)
Associated surgery	
Combined anterior and Posterior colporrhaphy	1 (2)
Anterior colporrhaphy	4 (9)
Posterior colporrhaphy	4 (9)
Vaginal hysterectomy	2 (5)
Total	11 (26)
Follow-up (months)	28.13 (5.1, 18–36)
Complications (Clavien classification system)	
Grade 1	
Dyspareunia	2 (5)
Grade 2	
Vaginal discharge + wound infection	2 (5)
UTI	2 (5)
Grade 3	
Failure of wound healing (mesh exposure)	1 (2)
Sling removal	1 (2)

The mean (SD, range) follow-up was 28.1 (5.1, 18–36) months. The SUI, UII and QoL indices were improved significantly (Table 3). There were no significant differences before and after surgery in bladder capacity, compliance, flow rates and P_{detQ_{max}} (Table 3).

There was a significant reduction in the number of patients with urgency ($P < 0.001$) and UII ($P = 0.008$), and no de novo urgency or de novo UII was reported. Eight (19%) patients had DO before surgery, with associated UII. After surgery two patients were cured, five were cured on anticholinergic medication, whilst the DO persisted in the last patient. This improvement in patients with DO was significant ($P = 0.016$; Table 3). The sling was removed after 1 year in the last patient with persistent DO, but with no improvement in her symptoms.

The cost of the tailored mesh was ≈US\$10, which is significantly cheaper than other commercially available mid-urethral slings (≈US\$500).

Discussion

Synthetic slings have increasingly been used for treating female SUI [1–8,11–14], and although these commercially available kits are highly effective their cost-effectiveness has been questioned [15–17]. To reduce this cost many surgeons have used ‘off-the-shelf’ polypropylene mesh and tailored it as a mid-urethral tape [15–19]. This reduction in the material cost is very important in developing countries where healthcare resources are limited. Polypropylene tapes are constructed from a permanent monofilament and macroporous mesh with pore sizes of > 75 µm. The large pores allow the passage of macrophages, fibroblasts and collagen fibrils to permit immune permeability and ingrowth of tissue. Because of the large pores and monofilament construction, polypropylene has lower exposure rates than other materials (microporous or multi-filamentous) [20]. Yildirim et al. [21] compared the mesh-to-tissue attachment strength and evaluated tissue reactions to five sling materials used in TVT, intravaginal slingplasty,

Table 2 Effect of ISD, associated urogenital prolapse and associated urogenital prolapse repair on the success rate.

Variable	n/N (%) patients				P
	Total	Cure	Improved	Failure	
ISD					
Yes	21/43 (49)	18/21 (86)	2/21 (10)	1/21 (5)	0.582
No	22/43 (51)	20/22 (91)	2/22 (9)	0	
Associated urogenital prolapse					
Yes	21/43 (49)	20/21 (95)	0	1/21 (5)	0.079
No	22/43 (51)	18/22 (82)	4/22 (18)	0	
Associated prolapse repair					
Yes	11/43 (26)	10/11	0	1/11	0.117
No	32/43 (74)	28/32 (88)	4/32 (13)	0	

Table 3 The SUIQQ scores, urodynamic variables, urgency, UII and DO before and after surgery.

Variable	Mean (SD, range) or n (%)		P
	Before	After	
SUIQQ			
SUI index	7.81 (2.9, 3–12)	0.79 (2.5, 0–12)	< 0.001*
UII index	3.42 (3.74, 0–8) ^a	1.67 (2.9, 0–8)	0.002*
QoL index	3.0 (1.04, 0–5)	1.05 (1.73, 0–5)	< 0.001*
Urodynamics			
Free Q _{max} (mL/s)	25.06 (5.47, 10–40)	25.30 (5.61, 10–38)	0.462
Bladder capacity (mL)	429.3 (92.5, 300–600)	441.2 (85.5, 300–570)	0.159
Compliance (mL/cmH ₂ O)	38.55 (12.44, 18–70)	39.73 (15.40, 20–80)	0.910
Q _{max} (mL/s)	25.02 (5.71, 10–44)	25.34 (5.2, 12–39)	0.120
P _{det} Q _{max} (cmH ₂ O)	22.37 (8.95, 5–40)	23.25 (8.77, 6–40)	0.075
Urgency	24 (56)	12 (28)	< 0.001*
UII	20 (47)	12 (28)	0.008*
DO	8 (19) ^b	1 (2) ^c	0.016*

* Significant.

^a 20 patients had UII (UII score 6 in four patients, 7 in five and 8 in 11).^b 5/6 patients with postoperative DO were cured on anticholinergic medication.^c The involuntary contractions were mild (< 20 cmH₂O).

polypropylene mesh hernia repair, the suprapubic approach to suburethral polypropylene tape (SPARC) and cadaveric fascia lata procedures in 20 female rabbits. All five synthetic sling materials produced similar tissue reactions. When comparing the four polypropylene mesh materials, the attachment capacity of TVT was superior and that of intravaginal slingplasty had the least capacity of the four. TVT was statistically better than intravaginal slingplasty at all data points. SPARC and hernia mesh provided results similar to those of TVT. Based on similar histological and biomechanical properties noted in that study, the authors reported that surgical hernia mesh, with an affordable price, may be a good alternative to pre-packaged polypropylene kits [21]. Krause et al. [22] evaluated the biocompatibility of eight different types of mesh, i.e., Atrium, Dexon, Gynemesh, intravaginal slingplasty, Prolene, SPARC, TVT and Vypro II. They were implanted into the abdominal walls of rats for 3 months. Explanted meshes were assessed using light microscopy for variables of rejection and incorporation. The inflammatory cellular response and fibrosis at the interface of mesh and host tissue were most marked with type 3 (Vypro II and intravaginal slingplasty). All type 1 meshes (Atrium, Gynemesh, Prolene, SPARC and TVT) had similar cellular responses [22].

Shah et al. [16] evaluated the 5-year outcome of STM as a pubovaginal sling. Of their 49 patients, 40 (82%) were dry and two (4%) improved. De novo urgency and UII were reported in one patient each. Three patients (8%) had recurrent SUI, whilst prolonged retention developed with subsequent urethrolisis required in two (4%). None of the patients had an infection, failed healing or erosion of the synthetic slings. The

STM was associated with a significant reduction of the surgical cost [15,16]. Amrute et al. [23] reported an 89% cure and improvement rate, with 15.7% de novo urgency and 2.1% vaginal mesh erosion at 7 and 12 months after surgery with the STM. Hom et al. [24] evaluated a pubovaginal sling procedure using STM in 35 women with SUI; 32 (91%) were dry, one improved and two remained incontinent. De novo urgency developed in three patients, and seven required prolonged suprapubic tube drainage, but no patient remained in permanent retention. There was no infection or erosion. Rodrigues et al. [25] evaluated a pubovaginal sling using STM in 118 women. At a mean follow-up of 42 months there were three vaginal extrusions of the mesh, 81.3% of the patients were considered cured, whilst 9.3% had a significant improvement. The safety and efficacy of STM polypropylene mesh has been confirmed when used as a transobturator tape [16–19]. Elgamasy et al. [17] evaluated the use of the traditional polypropylene mesh used in hernia repair, as a TOT in 40 patients; 35 (88%) were cured and two (5%) were significantly improved, but the procedure failed in three (8%), with removal of the slings because of vaginal erosion. ElSheemy et al. [19] evaluated the long-term safety and efficacy of ordinary polypropylene mesh as TVT-O. The complications were vaginal discharge (6%), dyspareunia (1%), groin pain (20%), UTI (3%) and obstructive symptoms (1%). They had no cases of erosions or de novo urgency. Of the 59 women, 91% were cured, 5% improved and in 3% the procedure failed.

The present study is possibly the first to evaluate the use of the STM using NSIT. The first generation of suburethral tapes was TVT, followed by the second generation of tapes through the transobturator approach,

aiming to decrease the potential complications of TVT. The 'minibands' (TVT-Secur and MiniArc) were developed later. These third-generation tapes reduced the length of the first two from 20 cm to 8 cm [7,11]. Although the placement of these tapes required less penetration of the tissues, which significantly reduced pain and complications, it was associated with a lower efficacy. The Contasure-Needleless sling can be considered a 'hybrid' of the second-generation and third-generation meshes. It reduces the complications resulting from the transobturator passage of the needles, but maintains the stability of the mesh by the termination in the shape of pockets and greater length when compared with 'mini-meshes' [8,11,13].

There are few studies discussing NSIT [8,11–14,26]. The assessment of cure in these six studies included objective (urodynamics, CST) and/or subjective (clinical history and scores of different indices, patient satisfaction) variables. In the present study we used the CST and urodynamic variables such as the ALPP as an objective assessment, whilst the SUIQQ was used as a subjective variable.

Navazo et al. [8] assessed the Contasure-Needleless method in 120 patients (mean age 55 years) after a follow-up of 2 years. The success rate was 84%, with 8% improved and an 8% failure rate. The mean (range) operative duration was 9 (4–12) min. Tardiu et al. [13] compared transobturator tape vs. Contasure-Needleless (72 patients) in 132 patients. The success rate (assessed by the CST) was 87.5% in the Contasure-Needleless group. Navalón et al. [11] evaluated the Contasure-Needleless under local anaesthesia-sedation in an outpatient regimen. They included 96 patients with a mean age of 62.3 years. The operative duration was <10 min (range 4–9) and the mean (SD, range) follow-up was 45 (12, 3–60) months. The cure rate was 89% (assessed by a CST) with improvement in 8% of patients and failure in the remaining 3%. Baya and Janin [14] reported on 58 patients (mean age 61.8 years) after a minimum follow-up of 2 years, with cure and improvement rates of 88% and 3%, respectively. The mean (range) operative duration was 7 (4–20) min. In all, 230 patients (mean age 51 years) were treated with the Contasure-Needleless technique by Cabrera et al. [12]. After a mean follow-up of 12 months 198 patients (86%) were objectively cured, 14 (6%) were improved and 18 (8%) were classified as failures. The mean (range) operative duration was 9 (7–14) min. Karateke et al. [26] evaluated the Contasure-Needleless System on the quality of life in 50 consecutive women with urodynamically proved SUI and a mean age of 50.84 years. The mean ALPP was 146.4 cmH₂O, the mean (range) operative duration was 24.4 (22–26) min and the mean (SD) follow-up was 433.5 (44.1) days. After surgery 40 (80%) patients were continent (urodynamically), eight (16%) improved and in two (4%) the treatment failed.

The present results were similar to those in these studies, with 88% of patients cured, 9% improved and 2.3% failed, with a comparable operative duration (14 min), but with relatively younger patients.

Some studies excluded patients with ISD [8,13]. The present study included 21 (49%) patients with ISD, but with no significant difference in the outcome. Some studies excluded patients with associated prolapse [11], previous anti-incontinence surgery or previous prolapse repair [13,26]. Other studies did not exclude associated prolapse [13,26], or previous anti-incontinence surgery [11]. The outcome of the present study was unaffected by including these patients. Navalón et al. [11] reported that the Contasure-Needleless mesh can be used safely and effectively for pelvic floor repair.

Similar to some published studies on the Contasure-Needleless system [11,13,14], we included patients with MUI but after excluding patients with a predominant urge component. There was a significant improvement in urgency, UII and DO after surgery, with no de novo urgency or UII. Tardiu et al. [13] reported de novo UII in seven of 72 patients, whilst Baya and Janin [14] reported de novo UII in two of 58. Karateke et al. [26] excluded patients with DO or symptoms of an overactive bladder, and no de novo DO was reported in the 50 patients in their study.

We had no patients with mesh erosion, similar to the results of two published studies on Contasure-Needleless system [11,13]. The remaining four studies reported mesh exposure, which was solved with local oestrogen treatment [8,12,14] or by mucosal repair [26]. The reported rate of mesh exposure in these studies ranged from two of 230 [12] and three of 120 patients [8], to two of 58 [14] and three of 50 [26]. We had one patient with delayed healing of the wound, which was treated by local oestrogen then mucosal repair.

Urinary retention and/or voiding difficulties immediately after surgery were reported in some studies on the Contasure-Needleless system. The reported cases in these studies ranged from five of 230 [12] and two of 120 patients [8], to four of 72 [13] and five of 50 [26]. This was relieved by short-term catheterisation [8,13]. Other studies reported no voiding difficulties after surgery, as in the present study [11,14]. One study compared urodynamic variables and reported no significant difference between before and after surgery in the mean urinary flow rate and $P_{det}Q_{max}$, but Q_{max} decreased significantly [26]. In the present study there was no significant difference before and after surgery in the urodynamic variables.

As in the present study, no bladder lesions, intraoperative complications or inguinal pain occurred in most studies using the Contasure-Needleless system [8,11,12,14,26]. Mild haematoma was reported in two studies [12,14]. Tardiu et al. [13] reported an intraoperative bladder injury in one of 72 patients.

Pelvic floor disorders seldom cause significant morbidity or mortality, and it is the impairment of QoL that provokes the decision to seek treatment [26]. Therefore, the surgical treatment should be as noninvasive as possible, with the objective to improve QoL without compromising the efficacy of treatment [26]. Karateke et al. [26] evaluated the effect of the Contasure-Needleless on the QoL in 50 women; all aspects of QoL improved significantly, as noted in the present study in which there was a significant improvement in the QoL scores.

The present study is limited by the relatively few patients and the short follow-up (28 months). As it is a descriptive series there was no control group and our results were compared with other published studies on Contasure-Needleless system. However, the strengths of the study are that it was prospective with a uniform assessment of SUI, UI and QoL using standardised questionnaires, in addition to the use of urodynamic variables for an objective evaluation of the severity of incontinence, any associated DO and the occurrence of any degree of obstruction. Despite the good outcome in the present study, further controlled studies with more patients and a long-term follow-up are needed to confirm our preliminary results.

In conclusion, our STM using NSIT is a simple, safe, effective, reproducible and economical surgical procedure for treating SUI. The presence of ISD, associated prolapse, or associated surgery does not appear to influence the success rate.

Conflict of interest

None.

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None.

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