International Urogynecology Journal (2019) 30:1509–1517
https://doi.org/10.1007/s00192-018-3826-9

ORIGINAL ARTICLE

Clinical outcomes on tension-releasing suture appendage on single-incision sling devices for postoperative voiding dysfunction involving undue tape tension

Tsia-Shu Lo[1,2,3] · Sandy Chua[4,5] · Ling-Hong Tseng[2,3] · Cheng-Yu Long[6] · Chuan-Chi Kao[1,3] · Wu-Chiao Hsieh[1,2]

Received: 29 July 2018 / Accepted: 9 November 2018 / Published online: 28 November 2018

Abstract

Introduction and hypothesis To determine the clinical outcomes of adding a tension-releasing suture (TRS) appendage for manipulation of over-tensioned single-incision slings (SIS) as a means to relieve postoperative voiding dysfunction.

Methods A retrospective observational study conducted from January 2010 to July 2017. The records of patients with urodynamic stress incontinence (USI) without needing concurrent procedures who underwent anti-incontinence surgery using MiniArc, Solyx, and Ajust with voiding dysfunction were collated and analyzed. The primary outcome measure was the recovery of normal post-void residual urine (PVR) after TRS manipulation. The secondary outcome measures were the pain intensity noted during manipulation (quantified by visual analog scale) and the continence rate [assessed by (1) objective cure: 1-h pad test weight < 2 g and absence of USI; (2) subjective cure index score ≤ 1 on question 3 of the UDI-6: "Urine leakage related to physical activity, coughing, or sneezing?"].

Results There were 73 patients with high post-void residual (PVR) urine. The 42 (9.5%) patients with over-tensioned slings were managed with TRS manipulation while the 31 patients (7%) with high PVR and no sling over-tension were managed with intermittent catheterization. All patients in both groups regained normal PVR. The TRS-manipulated group demonstrated an objective cure rate of 92.9% (39/42) and subjective cure rate of 91% (38/42). Pain experienced during TRS manipulation was significantly higher with the Ajust system ($p = 0.018$). Three patients had persistence of USI, two with MiniArc and one with Solyx.

Conclusions The TRS manipulation is a well-tolerated procedure that can effectively relieve voiding dysfunction for over-tensioned SIS without affecting continence cure rates.

Keywords Mini-slings · Stress incontinence · Voiding dysfunction · Urine retention

✉ Tsia-Shu Lo
2378@cgmh.org.tw

[1] Department of Obstetrics and Gynaecology, Chang Gung Memorial Hospital Keelung, Keelung Medical Centre, 222, Maijin Road, Keelung, Taiwan 204, Republic of China

[2] Division of Urogynecology, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Linkou Medical Center, Taoyuan, Taiwan, Republic of China

[3] Chang Gung University, School of Medicine, Taoyuan, Taiwan, Republic of China

[4] Fellow, Division of Urogynecology, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Linkou Medical Center, Taoyuan, Taiwan, Republic of China

[5] Department of Obstetrics and Gynecology, Cebu Institute of Medicine, Cebu Velez General Hospital, Cebu City, Philippines

[6] Graduate Institute of Medicine, Center of Excellence for Environmental Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan, Republic of China

Introduction

The midurethral sling (MUS) has become the gold standard for surgical treatment of stress urinary incontinence (SUI) [1]. It has undergone a variety of evolutionary changes from retropubic tension-free vaginal tape (TVT) to transobturaor tape (TOT) and single-incision slings (SIS). Regardless of the procedure, MUS can change the bladder outlet resistance. A common and bothersome side effect is urinary retention or postoperative voiding dysfunction, which can occur in 3–10% of patients [2].

Voiding dysfunction is defined as an abnormally slow and/or incomplete micturition with high post-void residual urine (PVR) in which the cause may be related to outlet obstruction or failure to store urine [3]. Most cases of voiding dysfunction from MUS insertion are due to over-tensioned slings. Some are mild and resolve with expectant management through intermittent catheterization. However, up to 8% of women will

have urine retention lasting > 6 months [4], and contemporary studies have indicated that symptoms persisting > 4 weeks rarely resolve on their own [5]. Thus, sling lysis and/or sling mobilization is performed to resolve the problem. Seeing that these procedures are performed in the operating room, patients usually perceive them as another surgery, making them depressed, anxious, and dissatisfied. This prompted Shoebiri and Nihira [6] to develop a technique for an office-based procedure to relieve voiding dysfunction or urine retention. A polypropylene loop suture is attached in the midline of the TVT tape exteriorized into the vagina. When necessary, the sling is loosened by pulling downward on the loop with the index finger. If normal voiding has not resumed, the sling is taken down by pulling on the polypropylene loop and making a midline incision in the anterior vaginal wall after 2–3 weeks to allow permanent fixation of the sling to take place.

Similarly, Lo et al. [7] applied the same concept to MiniArc SIS with an absorbable suture attached to one end of the anchoring tip. However, the self-fixing tip design of MiniArc poses a great challenge when pulling the sling to relieve voiding dysfunction since the placement is dependent on the anchoring tip not on the effect of fibrosis. Positively, results of the study have shown a 92% cure rate of immediate voiding dysfunction with maintenance of continence: objective cure rate of 90.5% and subjective cure rate of 88.9%.

Currently, MiniArc™ (American Medical Systems, Minnetonka, MN, USA) is no longer on the market. The recently available SISs are Solyx™ (Boston Scientific Corp., Marlborough, MA, USA), Ophira™ (Promedon Group, Cordoba, Argentina), and Ajust™ (CR Bard, Inc., Muarray Hill, NJ, USA), which use the self-fixing tip design with slight differences in the anchoring tip size, design, and mesh length. Since the tension-releasing suture (TRS) manipulation yielded positive results in relieving immediate voiding dysfunction with the MiniArc SIS, the present study primarily aims to determine the effectiveness of TRS manipulation in resumption of normal voiding function for other over-tensioned SIS kits. The secondary aim is to determine the effect on continence cure rate, lower urinary tract symptoms, and quality of life after TRS manipulation.

Materials and methods

This is a retrospective observational study conducted from January 2010 to July 2017. Approval from the Ethics Committee of the Institutional Review Board of Chang Gung Memorial Hospital was obtained (IRB no. 201700320B0C601). The medical records of the patients with urodynamic stress incontinence (USI) without needing concurrent procedures who underwent anti-incontinence surgery using MiniArc, Solyx, and Ajust with voiding dysfunction were collated. The cohort of patients reported in our previous study was included [7]. Patients with PVR volume above the normal defined range after SIS anti-incontinence surgery were excluded.

Preoperative evaluation included medical history, physical examination, pelvic examination, urinalysis, and cough stress test. Patients were asked to complete a 72-h voiding diary and answer validated subjective questionnaires, e.g., the Urinary Distress Inventory Questionnaire (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Objective evaluation was assessed through multi-channel urodynamic study and 1-h pad test. Patients with PVR >100 ml, urodynamic findings that would suggest bladder outlet obstruction (BOO), or detrusor underactivity (DU) were not offered MUS insertion. Multichannel urodynamic study included uroflowmetry, filling and voiding cystometry, surface electrode electromyography, and urethral pressure profile. Evaluation of uroflowmetry was done by allowing patients to freely void in a special funnel once they felt their bladder was comfortably full. When the voided volume was < 200 ml, a repeat test was done to confirm small functional bladder capacity. The PVR was then measured immediately after free-flow uroflowmetry. All conditions, methods, and definitions were in accordance with the standards set by the International Continence Society [8].

USI was diagnosed based on the presence of demonstrable involuntary leakage of urine during increased abdominal pressure in the absence of detrusor contraction during filling cystometry. Intrinsic sphincter deficiency (ISD) was defined as a pressure increase from baseline causing urinary incontinence during Valsalva or cough, with leak-point pressure of ≤ 60 cmH_2O [9]. Detrusor overactivity (DO) was defined as spontaneous or provoked involuntary detrusor contraction during filling cystometry. BOO was determined using the nomogram described by Blaivas and Groutz [10]. DU was defined as detrusor pressure at maximum flow (Dmax) ≤ 10 cmH_20 and peak flow rate (Qmax) of ≤ 12 ml/s [11].

Outcome measures

The primary outcome measure was having a PVR within the normal defined range after TRS manipulation. PVR was considered within the normal range when the amount was < 150 ml or < 20% of the bladder volume on bladder scan. The secondary outcome measures were pain intensity noted during manipulation quantified using the 10-cm visual analog scale (VAS), which was rated by the patient with 10 as the worst pain and 0 as no pain [12]. Maintenance of continence was assessed objectively and subjectively. Objective cure was determined through 1-h pad test weight < 2 g and absence of demonstrable involuntary leakage of urine during increased abdominal pressure in the absence of detrusor contraction during filling cystometry. Subjective cure was determined

through an assessment index score of ≤ 1 on question 3 of the UDI-6 (Urine leakage related to physical activity, coughing, or sneezing?). In addition, voiding dysfunction was also subjectively assessed through UDI-6 question 5 (Do you experience and, if so, how much are you bothered by difficulty emptying your bladder?). An assessment index score > 1 indicates that the patient is subjectively experiencing it. Urodynamic parameters related to urethral function were evaluated as well.

Surgical procedure

Insertion of the MUS was performed under general anesthesia. The procedure for MiniArc was carried out as described by Moore [13], for Solyx as described by Serels et al. [14], and for the adjustable Ajust as described by Abdel-Fattah el al. [15]. Cystoscopy was performed at the end of the procedure to check for integrity of the bladder. Intravenous antibiotic prophylaxis was given as per institutional protocol. A tension-releasing suture (TRS) was added to all SISs prior to insertion (Fig. 1a). The concept was adapted from our previous study [7]. The TRS was prepared by attaching a 1–0 absorbable polyglactin suture on one end of the anchoring tip and looped into the midline of the tape. The sling was then placed following standard insertion techniques. The free end of the TRS was exteriorized through the anterior vaginal wall with approximately 2 cm of the TRS protruding out. No indwelling Foley catheter was used (Fig. 1b).

Postoperatively, PVR urine volume was checked using the bladder scan (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA). For PVR ≥ 150 ml or > 20% bladder volume for three consecutive measurements, introital ultrasonography was performed using the 3.5-MHz curved linear array transducer (Philips HD11XE; Philips, Ltd., The Netherlands). The morphology of the sling was observed in a sagittal plane together with identification of urethral indentation or urethral elevation over the sub-urethral sling, which would indicate an over-tensioned sling (Fig. 1c, d). If the sling was over-tensioned as described above, accompanied with PVR above the normal defined range, manipulation of the TRS was done. The exposed suture end of the TRS was gently pulled downward with the help of a hemostatic clamp until the TRS lengthened. Lengthening of the TRS signified movement of the anchoring tip. The procedure was repeated until the normal defined PVR was achieved or no urethral indentation or elevation was noted on ultrasound. On the other

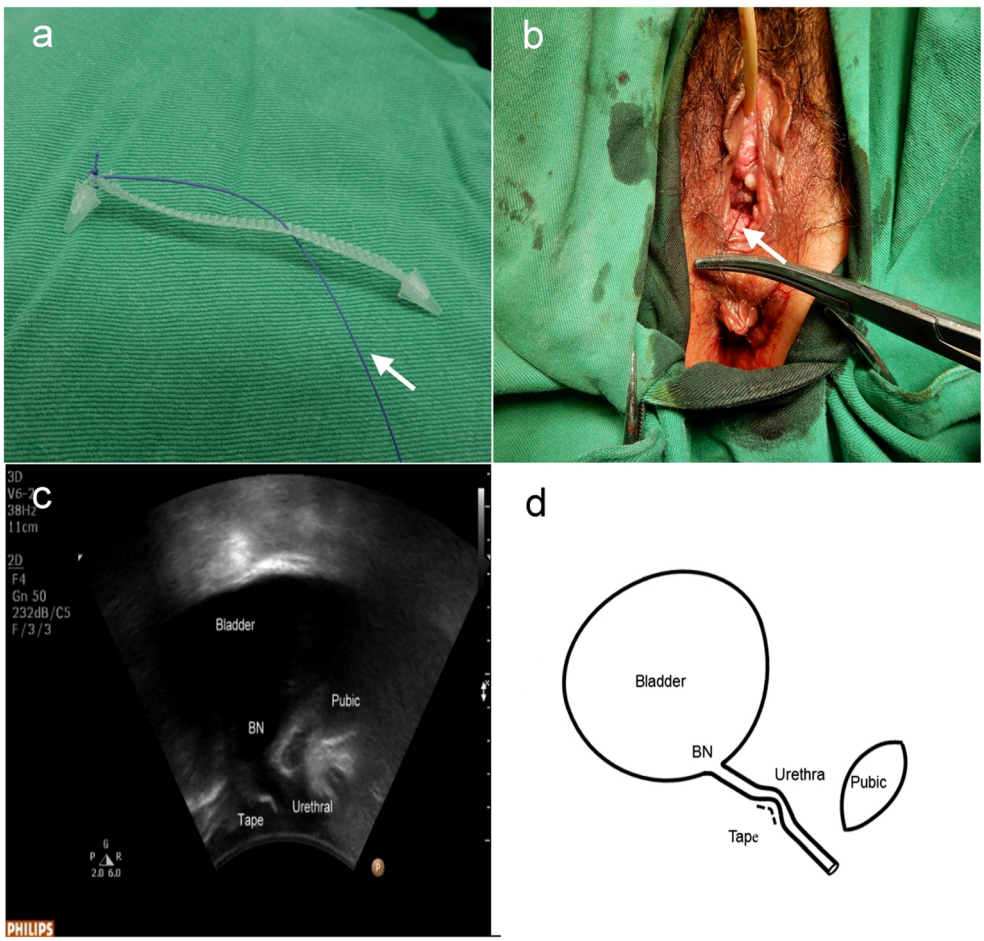

Fig. 1 **a** TRS is prepared by appending a 1–0 absorbable polyglactin (Vicryl) suture attached to one side of the SIS near the anchoring tip. **b** The free end of the TRS exteriorized in the anterior vaginal wall. Surface epithelium incision closed with 2–0 polyglactin absorbable suture. **c** Introital ultrasound demonstrating urethral indentation or urethral elevation over the sub-urethral sling in transverse view. **d** Schematic diagram demonstrating urethral indentation. BN, bladder neck

hand, if no urethral indentation or elevation was noted yet the PVR was high, sterile intermittent catheterization was done. If the ideal PVR could not be achieved in 5 days, clean intermittent self-catheterization was taught prior to discharge.

Patient follow-up was done at 1 week, 1 month, 3 months, 6 months, and annually thereafter. Pelvic examination, urinalysis, and PVR urine measurement were done. Multichannel urodynamic study was performed 6–12 months postoperatively. Validated subjective questionnaires were assessed annually. Patients unable to participate in clinic follow-up were called via telephone by a credentialed nurse to inquire about their current situation.

Statistical analysis

Descriptive statistics were used for demographic and perioperative data. For comparison of pre- and postoperative continuous and categorical data, paired samples *t-test* and either the X^2 or Fischer exact test were used. Inter- and intra-group comparison was analyzed as well. All statistical methods were performed using the SPSS commercial software, version 17. $P < 0.05$ was considered statistically significant for all comparisons.

Results

There were 443 consecutive patients diagnosed with USI who were offered SIS surgery (Fig. 2). Of these, 243 were treated using MiniArc, 145 using Solyx, and 55 using Ajust SIS insertion. On the 1st postoperative day, 370 (84%) patients had normal PVR, while 73 (17%) had high PVR. All 73 patients underwent introital ultrasonography. Forty-two (9.5%, 42/443) patients had over-tensioned slings and were managed with TRS manipulation, of which 23 had MiniArc, 5 had Ajust, and 14 had Solyx. The remaining 31 patients (7%, 7/443) who also had high PVR but no sling over-tension were managed with continuous intermittent catheterization. All patients in both groups regained normal PVR. No patient did self-catheterization after discharge.

At the 1-year postoperative follow-up, the TRS group showed an objective cure rate of 92.9% (39/42) and subjective cure rate of 91% (38/42), while the intermittent catheterization group had an objective and subjective cure rate of 97% (29/31). Comparison of objective and subjective cure rates between the two groups showed no statistical difference ($p = 0.643$; $p = 0.491$, respectively). However, two patients in the continuous intermittent catheterization group had subjective postoperative voiding dysfunction following the MiniArc procedure, which was resolved with medications (Fig. 2).

Table 1 demonstrates the baseline characteristics of the patients with USI undergoing SIS surgery manipulated with TRS for voiding dysfunction. Mean age, parity, and body mass index (BMI) of the patients did not significantly differ among the three different SIS kits used. Several patients had prior pelvic surgeries: five in the MiniArc, one in the Solyx, and one in the Ajust group. Most of the patients were postmenopausal with medical diseases such as hypertension and diabetes. Mean operating time and intraoperative blood loss were not significantly different among the SIS kits. Postoperative hospital stay for Ajust SIS was significantly longer with a mean stay of 1.60 ± 0.55 days ($p = 0.007$) compared with the MiniArc SIS with a mean stay of 1.10 ± 0.27 days and Solyx with 1.07 ± 0.7 days. The follow-up period for the MiniArc was 45.0 ± 23.0 months, for the Solyx 17.5 ± 4.0 months, and for the Ajust 47.0 ± 4.8 months. A significantly shorter follow-up period was noted with the Solyx SIS because it is the most recent SIS released on the market. The manipulation of the TRS was mostly done once in the MiniArc and Solyx, while the Ajust needed further manipulations of the TRS. Three patients in the Ajust had more than two manipulations of the TRS. Pain experienced during TRS manipulation was significantly increased with the Ajust system, having a VAS score of 3.60 ± 1.14 ($P = 0.018$). In comparison, the MiniArc SIS had a VAS score of 1.74 ± 0.54 and the Solyx of 2.14 ± 0.66. No mesh extrusions or repeat MUS surgery was noted. Objective cure rates at 1 year for each sling system were 91% for MiniArc, 93% for Solyx, and 100% for Ajust. Subjective cure was 87% for MiniArc, 93% for Solyx, and 100% for Ajust.

Urodynamic evaluation of pre- and postoperative clinical outcome was demonstrated in Table 2. Comparison of peak flow rates (Qmax), maximum urethral closure pressure (MUCP), functional urethral length (FUL), residual urine (RU), and detrusor pressure at maximal flow (Dmax) showed no significant difference among the three SIS systems. Postoperatively, USI significantly improved. However, two patients in the MiniArc and one in Solyx had persistence of USI. Patients with ISD were improved as well. No patient had DO/ detrusor overacitivty incontinence (DOI) and/or BOO. One-hour pad test significantly improved with all three SIS systems.

Subjective measurement done through assessment of validated questionnaires (UDI-6, IIQ-7, and PISQ-12) showed significant improvement in all SIS kits postoperatively with no significant difference when compared to each other (Table 3).

Discussion

The reason for adding a tension-releasing suture [7] was to provide a convenient, easy, and non-invasive way to relieve voiding dysfunction from over-tensioned slings. A key to successful manipulation of the TRS is to accurately identify cases

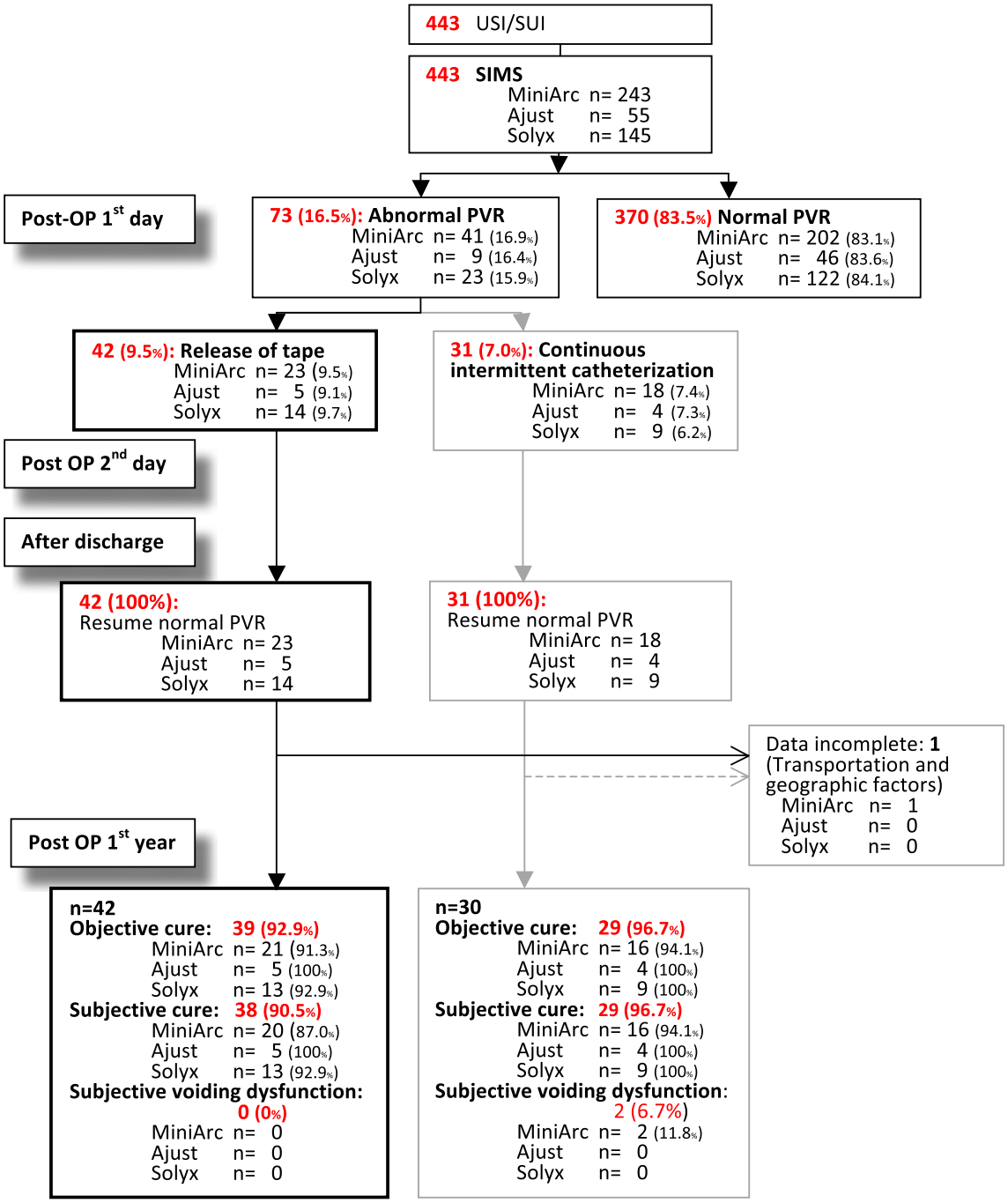

Fig. 2 Flow chart of patient outcomes after SIS procedure

of over-tensioned sling [7]. In a previous study by Lo et al. [16], pronounced mid-urethral angulation was noted on ultrasound in patients with over-tensioned slings from the TVT procedure. As a result, imaging is done prior to proceeding with TRS manipulation to be able to identify eligible patients who can benefit the most and avoid unnecessary manipulations that could result in sling failure, since not all voiding dysfunction in patients is due to over-tensioned slings.

The TRS manipulation is considered effective if normal PVR is achieved without affecting continence. The present study shows 42 (9.5%) patients being managed with TRS manipulation from over-tensioned slings. All of these patients

Table 1 Baseline characteristic of 42 USI patients undergoing SIS surgery

	MiniArc,	*n* = 23	Solyx,	*n* = 14	*P* value	Ajust,	*n* = 5	P value
Mean age (years)	55.5 ± 11.1	(50.7–60.3)	53.9 ± 11.0	(47.5–60.2)	0.668	56.2 ± 5.8	(49.0–63.4)	0.890
Mean parity	2.3 ± 1.0	(1.9–2.8)	2.8 ± 1.0	(2.2–3.4)	1.96	2.6 ± 0.5	(1.9–3.3)	0.587
Mean BMI (kg/m2)	24.5 ± 3.7	(22.9–26.1)	24.0 ± 3.2	(22.1–25.8)	0.648	23.6 ± 2.5	(20.5–26.6)	0.591
Urodynamic								
USI	21		13		0.684	4		0.459
USI and ISD	2		1			1		
Prior pelvic surgery	5	21.7%	1	7.1%	0.264	1	20.0%	0.715
VH + SS	1	4.3%						
VH + uphold			1	7.1%				
VH + perigee+ SS + A-P	1	4.3%						
AH	2	8.7%				1		
TOT	1	4.3%						
Medical disease	9	39.1%	6	42.9%	0.546	1	20.0%	0.399
DM	2	8.7%	3	21.4%		0		
HT	5	21.7%	3	21.4%		1	20.0%	
Asthma	2	8.7%	0			0		
Post-menopausal	18	78.3%	9	64.3%	0.290	5	100%	0.342
Operating time (min)	30.7 ± 8.1	(28.5–32.9)	28.4 ± 10.6	(25.8–31.9)	0.451	31.7 ± 7.1	(28.1–33.9)	0.761
Intra-OP BL (ml)	12.6 ± 4.9	(11.4–13.6)	11.4 ± 3.5	(10.1–13.1)	0.183	12.0 ± 4.5	(11.4–13.1)	0.557
Hb difference (g/dl)	0.92 ± 0.54	(0.69–1.15)	0.78 ± 0.51	(0.59–0.98)	0.352	0.86 ± 0.37	(0.73–0.98)	0.523
Post-OP HS (days)	1.10 ± 0.27	(1.0–1.2)	1.07 ± 0.27	(1.0–1.2)	0.744	1.60 ± 0.55	(1.0–1.2)	**0.007**
Period of FU (months)	45 ± 23.0	(35.7–55.7)	17.5 ± 4.0	(15.9–20.1)	**<0.001**	47.0 ± 4.8	(45.9–24.2)	0.399
TRS								
Once	21	91.3%	13	92.9%	0.867	2	40.0%	**0.027**
≧ 2	2	8.7%	1	7.1%		3	60.0%	
VAS, pain score	1.74 ± 0.54	(1.50–1.97)	2.14 ± 0.66	(1.76–2.52)	0.734	3.60 ± 1.14	(2.18–5.02)	**0.018**
Complications,	0	0%	0	0%		0	0%	
Repeat MUS	0	0%	0	0%		0	0%	
Mesh extrusion	0	0%	0	0%		0	0%	
Objective cure at 1 year								
Cure	21	91.3%	13	92.9%	0.821	5	100%	0.669
Fail	2	8.7%	1	7.1%		0	0%	
Subjective cure at 1 year								
Cure	20	87.0%	13	92.9%	0.531	5	100%	0.669
Fail	3	13.0%	1	7.1%		0	0%	

Data are listed as mean ± standard deviation with 95% CI in parentheses or number with percentage within parentheses

BMI body mass index; *TAH* total abdominal hysterectomy; *VH* vaginal hysterectomy; *LH* laparoscopic hysterectomy; *TOT* trans-obturator tape; *Hb* hemoglobin; *BL* blood loss; *HS* hospital stay; *FU* follow-up; *VAS* visual analog scale

(100%) had normal PVR after manipulation. Continence was maintained at 1 year with objective and subjective cure rates of 93% and 90%, respectively. Although the fixed anchoring tip was released from its original position, continence was still maintained since these SISs were inserted deep into the muscle layers. During manipulation, the muscle fibers of the original location were cut through and the anchoring tip fixed to another location of the muscle layer lower than the original placement with the depth more shallow. Since the anchoring tip was designed to prevent easy slippage, applying outside force on the anchoring tip allowed it to cut through into the muscle fibers. However, when too much traction is applied, the anchoring tip cuts through to all muscle layers that it cannot fix to another location, causing it to dislodge and lose its fixation. The persistence of USI in three (7%) patients could have resulted from too much traction on the TRS. The force applied during manipulation needs to be controlled gently until the fixed tip is released but not so much as to dislodge

Table 2 Comparison of pre- and post-clinical outcomes

	MiniArc,	n = 23	Solyx,	n = 14	P value (Inter-group)	Ajust,	n = 5	P value (Inter-group)
Qmax, Pre	23.7 ± 12.6	(18.2–29.1)	22.2 ± 9.4	(16.7–27.6)	0.338	25.2 ± 7.7	(18.6–32.7)	0.802
Post	22.4 ± 8.6	(18.7–26.1)	20.7 ± 7.2	(16.5–24.9)	0.542	23.7 ± 8.9	(18.6–29.8)	0.450
P value (intra-group)	0.316		0.332			0.529		
RU, pre	20.2 ± 17.5	(12.6–27.8)	21.9 ± 8.0	(17.2–26.5)	0.358	18.6 ± 17.6	(3.3–40.5)	0.857
Post	22.4 ± 14.8	(16.0–28.8)	26.4 ± 12.2	(19.6–32.2)	0.166	19.2 ± 10.6	(6.0–32.4)	0.653
P value (intra-group)	0.621		0.159			0.950		
CC, pre	396.2 ± 91.1	(348.2–444.2)	419.5 ± 66.4	(381.2–457.8)	0.429	359.2 ± 66.2	(317.0–399.4)	0.283
Post	398.9 ± 71.3	(368.1–429.7)	424.1 ± 82.1	(359.3–488.8)	0.460	364.8 ± 76.6	(269.7–459.9)	0.347
P value (intra-group)	0.914		0.896			0.212		
MUCP, pre	56.3 ± 33.1	(42.0–70.6)	55.1 ± 17.7	(44.9–65.3)	0.451	48.4 ± 12.5	(32.8–64.2)	0.250
Post	55.5 ± 24.6	(44.9–66.1)	52.1 ± 20.6	(40.2–63.9)	0.667	46.8 ± 7.4	(37.6–56.0)	0.447
P value (intra-group)	0.338		0.635			0.744		
FUL, Pre	23.5 ± 4.3	(21.6–25.4)	24.8 ± 3.4	(20.8–28.7)	0.530	24.8 ± 3.4	(20.6–29.0)	0.530
Post	22.7 ± 5.6	(20.3–25.1)	22.6 ± 2.1	(21.6–25.4)	0.950	22.6 ± 2.6	(20.2–25.2)	0.971
P value (intra-group)	0.559		0.742			0.108		
Dmax, Pre	15.0 ± 7.1	(12.0–18.1)	13.4 ± 5.1	(10.4–16.3)	0.444	16.0 ± 8.0	(9.1–21.9)	0.791
Post	13.7 ± 4.7	(11.6–15.7)	14.4 ± 4.2	(11.9–16.8)	0.084	14.0 ± 3.8	(9.3–18.7)	0.304
P value (intra-group)	0.126		0.613			0.663		
UDs diagnosis		n = 23		n = 14			n = 5	
USI, pre	23	100%	14	100%		5	100%	
Post	2	8.7%	1	7.1%	0.821	0	0%	0.669
ISD, pre	2	8.7%	1	7.1%	0.684	1	20%	0.459
Post	0	0%	0	0%		0	0%	
DO/DOI, pre	0	0%	0	0%		0	0%	
Post	0	0%	0	0%		0	0%	
BOO, pre	0	0%	0	0%		0	0%	
Post	0	0%	0	0%		0	0%	
1-h pad test								
Pre	31.7 ± 27.2	(20.0–43.5)	23.2 ± 23.5	(9.6–36.7)	0.336	22.7 ± 33.6	(−19.1–64.4)	0.522
Post	1.6 ± 5.9	(0.9–4.2)	0.9 ± 2.3	(0.4–2.3)	0.665	0.4 ± 0.5	(−0.3.-1.1)	0.638
P value (inter-group)	< 0.001		< 0.001			< 0.001		

Qmax maximum urinary flow (m/s); *RU* postvoid residual urine (ml); *CC* cystometric capacity (ml); *MUCP* maximum urethral closure pressure (cmH_2O); *FUL* functional urethral length (cm); *Dmax* detrusor pressure at maximum flow (cmH_2O); *UDI-6* Urinary Distress Inventory; *IIQ-7* Incontinence Impact Questionnaire; *PISQ-12* Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire

Data listed as mean ± standard deviation (95% confidence interval)

*Fisher exact test

it from the muscle. However, controlling the traction force is experience dependent [7]. However, the cure rates of patients with high PVR managed with intermittent catheterization were no different from those of TRS-manipulated patients.

Since mini-slings are designed to be shorter than the standard mid-urethral slings (TVT and TOT), fixation in the obturator complex needs to be strong and stable. The anchoring system should hook tightly to the tissue to provide stable tissue fixation. Because of this, correct sling placement is essential to achieving success [17, 18]. Modifications of the different SISs are mainly in the anchoring tip. The differences in the size, design, and placement in the muscle affect the traction force needed to move the sling during TRS manipulation. The anchoring tip of the MiniArc is 0.8 cm long and 0.5 cm wide with a two-barb design, the Solyx is 1.3 cm long and 0.4 cm wide with three barbs, while the Ajust is 0.9 cm long and 0.6 cm wide with two barbs (Fig. 3). The Ajust system has the biggest anchoring tip size when placed inside the obturator internus muscle. Placement of the sling is done parallel to the muscle with the whole anchor inside the muscle

Table 3 UDI-6, IIQ-7, POPDI-6, and PISQ-12 scores pre- and postoperatively

	MiniArc,	n = 23	Solyx,	n = 14	P value (Inter-group)	Ajust,	n = 5	P value (Inter-group)
UDI-6, Pre	7.9 ± 3.1	(6.5–9.4)	7.6 ± 3.9	(5.3–9.8)	0.778	8.0 ± 2.5	(18.6–32.7)	0.957
Post	2.6 ± 3.2	(18.7–26.1)	2.5 ± 1.6	(1.6–3.4)	0.906	2.6 ± 1.3	(18.6–29.8)	0.683
P value (intra-group)	<0.001		0.001			0.010		
IIQ-7, pre	8.4 ± 4.1	(6.7–8.2)	8.1 ± 2.5	(6.7–9.6)	0.811	5.4 ± 2.4	(3.3–40.5)	0.314
Post	2.3 ± 3.4	(0.8–3.8)	2.6 ± 2.5	(1.2–4.1)	0.751	2.0 ± 1.4	(6.0–32.4)	0.417
P value (intra-group)	< 0.001		0.001			0.013		
PISQ-12, pre	30.7 ± 5.9	(26.4–35.0)	29.5 ± 5.2	(21.2–36.8)	0.587	28.3 ± 1.5	(24.5–32.1)	0.283
Post	35.5 ± 6.6	(30.8–40.3)	34.3 ± 5.7	(25.1–43.4)	0.847	34.0 ± 4.4	(23.2–44.8)	0.347
P value (intra-group)	0.014	*n* = 10	0.023	n = 5		0.093	*n* = 3	

Data listed as mean ± standard deviation with 95% CI in parentheses

UDI-6 Urinary Distress Inventory; *IIQ-7* Incontinence Impact Questionnaire; *PISQ-12* Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire

Paired-samples *t* test; $P < 0.05$ was considered statistically significant

lying horizontally, giving the system a high pull-out force of 8.63 lbs [19]. More than one manipulation of the TRS is usually done because of this greater pull-out force. Pain was concurrently noted to be significantly greater compared with others. In contrast, the MiniArc SIS has the smallest size with a pull-out force of 5.5 lbs [19]. Placement of the anchoring tip is perpendicular to the muscle, with two barbs holding the sling in place. This makes TRS manipulation easier with the least amount of pain. The most recently introduced SIS, Solyx, has the biggest anchoring size. Anchor fixation in the muscle is identical to the MiniArc but with three barbs holding the tip in place. TRS manipulation was mostly done once but pain was much greater than with the MiniArc. This might be due to its bigger size and stronger grip though no published data could be gathered on its pull-out force.

The follow-up period differed greatly because of the availability period of the SIS in the market. Thus, a mean 1-year follow-up was considered in the study for comparison and evaluation of continence cure rates. The manipulation of the TRS should be done immediately within 7 days before local scarring and tissue fibrosis take place. Simultaneously, the TRS used is a polyglactin absorbable suture with a knot pull tensile strength of 8.5 lbs [20] that is totally absorbed in 42 days. With this, the suture undergoes degradation and loses its tensile strength to hold a traction pull for the anchoring tip. Hence, TRS manipulation is mainly for relieving voiding

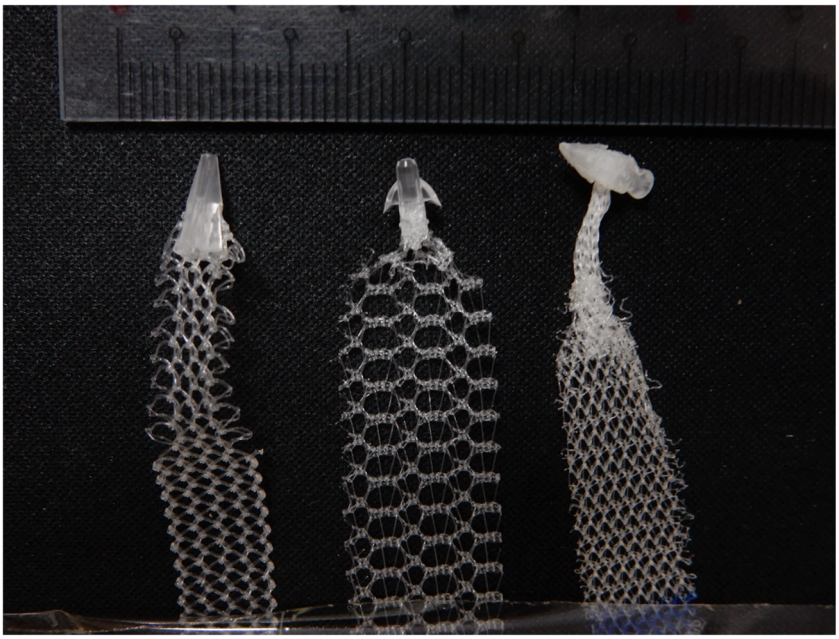

Fig. 3 Anchoring tip of the Solyx (right), MiniArc (center), and Ajust (left)

dysfunction in the immediate postoperative period within a week at most. Most voiding dysfunction also usually occurs during this period.

Since fixed-length mini-slings can be too tight in some women, it causes them to have low-grade obstruction and undergo pathologic changes in the detrusor muscle [21]. With TRS manipulation for the over-tensioned sling, obstruction is relieved before detrusor instability occurs. This explains the results of the present study with no patient having lower urinary tract symptoms on urodynamic studies. No patient had DO/DOI and BOO. The peak flow rate did not significantly differ from the preoperative value. Residual urine and maximum bladder capacity were within normal limits. Patient quality of life significantly improved as well.

Strengths and limitations

The chief limitations of the study include: retrospective study design, single-arm study, and lack of a control group. The strengths of the study are the moderate sample size, standard evaluation protocol, use of validated questionnaires, and urodynamic evaluation that can mimic prospective case-control studies.

Conclusion

The TRS manipulation for immediate postoperative voiding dysfunction is an effective management technique for over-tensioned single-incision slings that does not affect continence cure rates. Pain associated with the procedure is well tolerated. No adverse events or lower urinary tract symptoms were noted.

Compliance with ethical standards

Conflict of interest None.

References

1. Dmochowski RR, Blaivas JM, Gormley EA, Juma S, Karram DJ, Lightner DJ, et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. J Urol. 2010;183:1906–14.
2. Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol. 2003;10(5):929–32.
3. Haylen BT, de Ridder D, Freeman RM, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn. 2010;29:4–20.
4. Dawson T, Lawton V, Adams E, Richmond D. Factors predictive for post-TVT voiding dysfunction. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18(11):1297–302.
5. Rosenblum N, Nitti VW. Post-urethral suspension obstruction. Curr Opin Urol. 2001;11(4):411–6.
6. Shoebeiri SA, Nihira MA. Attachment of a sling rescue suture to mid-urethral tape for management of potential postoperative voiding dysfunction. Neurourol Urodyn. 2009;28:990–4.
7. Lo TS, Pue BL, Tan YL, et al. Tension-releasing suture appendage on single-incision sling device: a novel approach to postoperative voiding dysfunction. Taiwan J Obstet Gynecol. 2016;55:519–24.
8. Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. Int Urogynecol J. 2011;22:3–15.
9. Lose G. Urethral pressure measurement. Acta Obstet Gynecol Scand Suppl. 1997;166:39–42.
10. Blaivas J, Groutz A. Bladder outlet obstruction nomogram for women with lower urinary tract symptomatology. Neurourol Urodyn. 2000;19:553e64.
11. Jeong SJ, Kim HJ, Lee YJ, et al. Prevalence and clinical features of detrusor underactivity among elderly with lower urinary tract symptoms: a comparison between men and women. Korean J Urol. 2012;53:342–8.
12. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: visual analog scale for pain (VAS), numeric rating scale for pain (NRS pain), McGill pain questionnaire (MPQ), short-form McGill pain questionnaire (SF-MPQ), chronic pain grade scale (CPGS), short form- 36 bodily pain scale (SF). Arthritis Care Res. 2011;63:240–52.
13. Moore RD, Mitchell GK, Miklos JR. Single-center retrospective study of the technique safety and 12-month efficacy of the MiniArc single-incision sling: a new minimally invasive procedure for the treatment of female SUI. Surg Technol Int. 2009;18:175–81.
14. Serels S, Nosseir SB, Lind LR, Winkler HA. Safety and efficacy of the Solyx single-incision sling for the treatment of stress urinary incontinence: preliminary results. UroToday Int J. 2011;4:art5.
15. Abdel-Fattah M, Agur W, Abdel-All M, et al. Prospective multi-Centre study of adjustable single-incision mini-sling Ajust in the management of stress urinary incontinence in women: 1-year follow-up study. BJU Int. 2012;109:880–6.
16. Lo TS, Wang AC, Horng SG, Liang CC, Soong YK. Ultrasonographic and urodynamic evaluation after tension free vaginal tape procedure (TVT). Acta Obstet Gynecol Scand. 2001;80:65–70.
17. Palma P, Siniscalchi RT, Maciel LC, et al. Primary fixation of mini-slings: a comparative biomechanical study in vivo. Int Braz J Urol. 2012;38:258–65.
18. Alinsod R. Recent advances in tape slings for female urinary stress incontinence. Rev Obstet Gynecol. 2009;2:46–50.
19. Lenz F, Doll S, Sohn C, Brocker K. Single-incision mini-slings: obturator complex pull-out-force measurements. Gynecol Obstet Investig. 2017;82:376–81.
20. Greenberg J, Clark R. Advances in suture material for obstetrics and gynecologic surgery. Rev Obstet Gynecol. 2009;2:146–58.
21. Speakman MJ, Brading AF, Guilpin CJ, et al. Bladder outflow obstruction: a cause of denervation supersensitivity. J Urol. 1987;138:1461–6.