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Original Article

Tension-releasing suture appendage on single-incision sling device: A novel approach to postoperative voiding dysfunctions

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ABSTRACT

Objective: Voiding dysfunction following a midurethral sling procedure is still a relevant consequence that can affect patients' quality of life. Various invasive methods have been described to manage this problem. We hypothesize that we if we could diagnose the condition early using noninvasive tools, we would be able to offer appropriate effective management. We sought to study the effectiveness of attaching a tension-releasing suture on a single-incision sling (SIS) tape as a prophylactic measure for the treatment of immediate postoperative voiding dysfunctions, and secondarily, to evaluate the objective and subjective cure rates of the treatment for stress urinary incontinence.

Materials and Methods: It is a prospective observational study. A tension-releasing suture was prepared by appending a polyglactin suture to one end of the MiniArc sling tip fiber, which could be used to manipulate the sling tip when postoperative voiding dysfunction was identified. Primary outcome measure was the number of patients requiring tension-releasing suture manipulation to treat postoperative voiding dysfunctions successfully.

Results: Twelve of the 131 (9.2%) patients who underwent SIS procedure for urodynamic stress incontinence surgery required tension-releasing suture manipulation due to voiding dysfunction during the immediate postoperative period with a good outcome. Postoperative overall objective and subjective cure rates were 90.5% and 88.9% (126 available patients at 1-year follow up, mean 19.2 ± 8.0 months), respectively. The subanalysis of the objective and subjective cure rates of the group with tension-releasing suture manipulation were 91.7% (11/12) and 91.7% (11/12), and those of the group without tension-releasing suture manipulation were 90.4% (103/114) and 88.6% (101/114), respectively, at 1-year follow up.

Conclusion: Tension-releasing suture is effective in the management of immediate postoperative voiding dysfunction in an SIS procedure. SIS operation has good short-term objective and subjective cure rates for female urodynamic stress incontinence.

Introduction

The treatment of stress urinary incontinence had been revolutionized since the introduction of the minimally invasive tension-free vaginal sling procedure (TVT) by Ulf Ulmsten almost 2 decades ago, with good objective and subjective stress urinary

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incontinence cure rates (80–90%) after more than 11 years of follow up [1,2]. Although TVT is minimally invasive, it is not without complications; thus, the search for an alternative approach for suburethral sling application began in an attempt to minimize perioperative complications. The MiniArc single-incision sling system, a version of midurethral TVT, appears to be a promising treatment option for female urodynamic stress incontinence (USI) [3,4]. It uses a single-incision approach and self-fixating anchoring tips in the obturator internus muscle and membrane [3,4], reducing postoperative complications such as bladder perforation, vascular injuries, perineal fasciitis, and postoperative pain [5,6].

A systematic review of TVT revealed that urinary retention associated with the TVT-only procedure ranged from 1% to 17%, while that with TVT performed concurrently with prolapse surgeries ranged from 11% to 43% [7,8]. Urinary retention was also reported following the transobturator tape sling (TOT)-only procedure as well as the TOT performed concurrently with prolapse surgeries [9,10]. The MiniArc single-incision sling system mimicked the inside-out TOT tape insertion technique without advancing the anchoring tips through the obturator externus muscle [4,10]; therefore, postoperative voiding dysfunction following the MiniArc procedure was a potential complication.

Management options for postoperative voiding dysfunction following the placement of a midurethral sling include prolonged catheterization [11], suprapubic catheter placement [11], Hegar's dilator for pushing the proximal urethra [12], and take-down procedure or cutting the sling [13]. The fundamental concept for resolving the voiding dysfunction developed after placement of the midurethral sling is to release the undue tension of the suburethral sling. Attaching a suture to the suburethral sling with the suture tail protruding out from the vaginal closing incision would allow manipulation of the postimplanted retropubic and nonanchor sling introduced by Shobeiri and Nihira [14]. We adopted that idea in the case of the MiniArc device for surgical correction of female stress incontinence. The primary aim of the present study is to evaluate the effectiveness of tension-releasing suture (TRS) appendage on MiniArc as a tension-releasing mechanism for postoperative voiding dysfunction, and secondarily, to evaluate the objective and subjective cure rates of the MiniArc single-incision sling system for treating female stress incontinence.

Materials and methods

Women with urodynamic stress urinary incontinence who failed the trial of conservative management for USI from February 2009 to October 2012 in our institutions and were offered surgical treatment were considered for enrolment in this study. Women with USI who agreed to participate in this study after careful explanations of potential benefits and risks of undergoing this procedure were included. Exclusion criteria included dysfunctional voiding related to neurologic factors and pelvic organ prolapse of $\geq$Stage 2 [15]. Informed consent was obtained from all women who agreed to participate. Approval of the ethical committee was obtained from the institutional review board of Chang-Gung Memorial Hospital, Linko before conducting this study (IRB No. 102-0484B).

Preoperative evaluation included appropriate medical history, urine analysis, physical examination, and pelvic examination. All women were asked to complete a 72-hour voiding diary, the Incontinence Impact Questionnaire-7 [16], and the Urogenital Distress Inventory-6 questionnaire [17] as part of the subjective evaluation. The objective evaluation included complete multichannel urodynamics and a 1-hour pad test. Vaginal examinations were performed with the patients in a semisupine lithotomic position. All conditions were defined according to the standards of the International Continence Society [15]. A diagnosis of USI was made on the basis of demonstrable involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction observed during filling cystometry.

Surgical procedure

The MiniArc (American Medical Systems, Minnetonka, MN, USA) device designed for a single-incision surgery for treatment of USI was adopted in this study. The MiniArc procedure was carried out as described previously by Moore et al [3] with an addition of a TRS attachment to the MiniArc sling before the surgery. The TRS was prepared by appending a 1-0 absorbable polyglactin suture (Coated Vicryl Plus Antibacterial Suture; Ethicon, West Somerville, NJ, USA) to one end of the MiniArc sling fiber attached to the anchoring tip (Figure 1A). The sling was placed in close contact with the vaginal tissue below the midurethra without elevation of the midurethra under visual estimation. No provocative stress test facilitating the adjustment of the vaginal tape was performed intraoperatively. Precaution was taken to exteriorize the free end of the TRS suture through the anterior vaginal surface epithelium incision, which was closed with a 2.0 polyglactin interrupted suture (Figure 1B). To facilitate subsequent postoperative manipulation if sling tension release was indicated, approximately 2 cm of the TRS was left protruding on the vaginal wall. Cystoscopic evaluation for the integrity of the lower urinary tract was performed on all patients at the end of surgery.

Neither a Foley drain nor a vaginal pack was placed. The bladder was scanned (BVI 3000; Diagnostic Ultrasound Corp., Bothell, WA, USA) for postvoid residuals (PVRs). In the event of PVR > 100 mL and >20% of that from self-voiding, sterile intermittent catheterization was offered. Introital ultrasonographic surveillance on the urethra was performed to evaluate the vagina tape morphology. Introital ultrasonography was performed with the patient in a semisupine position. A 3.5-MHz curved linear array transducer (Philips HD11XE; Philips Ltd., Eindhoven, The Netherlands) was positioned adjacent to the vaginal introitus for investigating the morphology of the implanted mesh in sagittal planes [12]. TRS manipulation was indicated if urethral indentation or urethral elevation over the suburethral sling was observed ultrasonographically in patients who required sterile intermittent catheterization for four times consecutively (Figures 1C and 2).

TRS manipulation was performed by gently pulling the exposed suture end downward with the help of a hemostatic clamp in the outpatient office setting without any anesthesia. Lengthening of the TRS was taken as a sign that the anchoring tip had moved and thus the sling had been released. Bladder scan for PVR and introital ultrasonographic surveillance on the suburethral sling after TRS manipulation were repeated as necessary. The TRS manipulation procedure was deemed successful if the woman had PVR < 100 mL or <20% of that from self-voiding for four consecutive times. Women with a residual urine volume of >150 mL persistently for more than 5 days were taught clean intermittent self-catheterization (sterile intermittent catheterization).

The routine postoperative care follow up was scheduled at 2 weeks, 3 months, 6 months, and 1 year after surgery. For study purposes, all patients provided objective and subjective evaluations at 1 year postoperatively. A subjective cure was defined as an assessment index score of $\leq$1 for Question 3 of Urogenital Distress Inventory-6. Patients with pad weight < 2 g/h and without any urinary leakage by urethral pressure profilometry (cough profile) were defined as objectively cured. Bladder outlet obstruction for women was determined using bladder outlet obstruction nomograms, as suggested by Blaivas and Groutz [18]. The Student *t* test and paired two-tailed test were employed to compare the

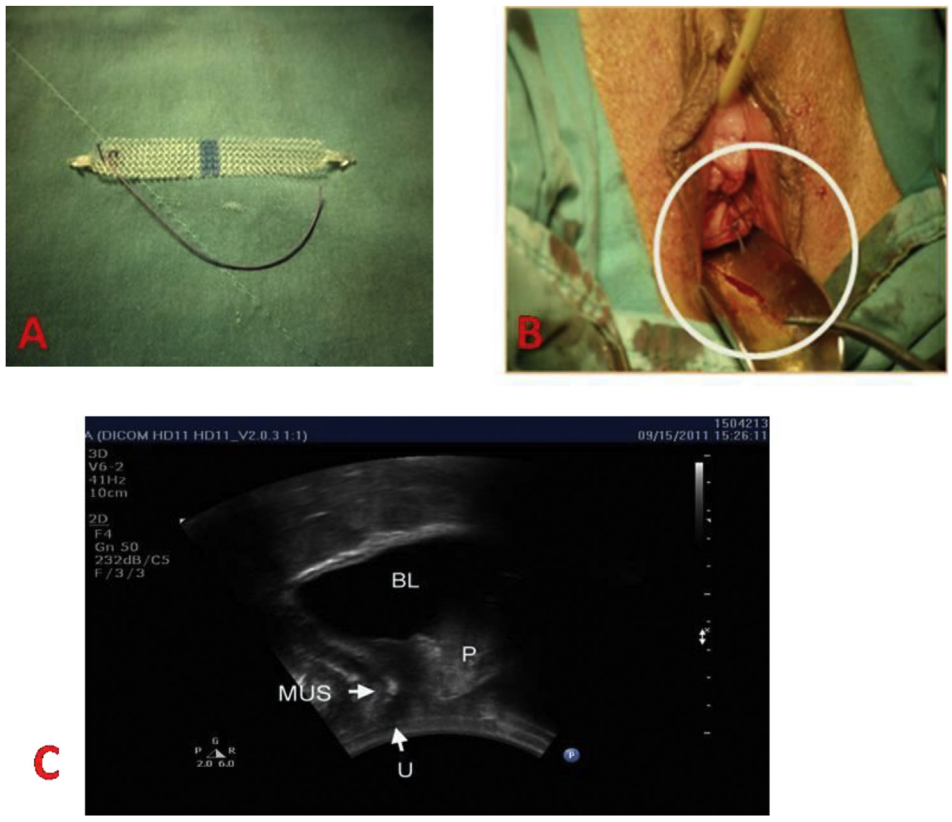

Figure 1. (A) TRS is prepared by appending a 1-0 absorbable polyglactin (Vicryl) suture to one side of the MiniArc sling fiber attached to the anchoring tip. (B) The free end of the TRS suture exteriorized through the anterior vaginal surface epithelium incision, which was closed with a 2.0 polyglactin suture. (C) Introital ultrasound demonstrated urethral indentation or urethral elevation over the suburethral sling in a transverse view. BL = bladder; BN = bladder neck; MUS = midurethral sling (MiniArc sling); P = pubic; TRS = tension-releasing suture; U = urethra.

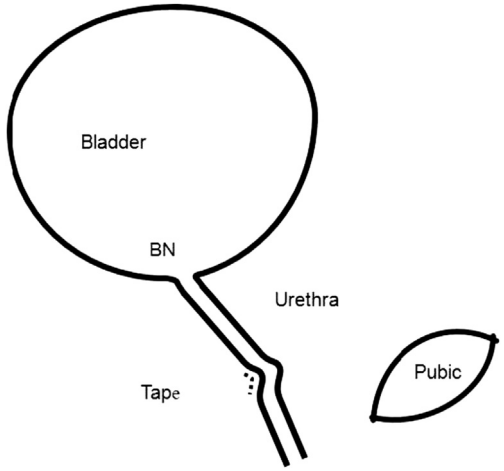

Figure 2. Schematic diagram demonstrating urethral indentation or urethral elevation over the suburethral sling in a transverse view. BN = bladder neck.

differences between urodynamic parameters pre- and post-operatively. A difference of $p < 0.05$ was considered statistically significant.

Results

The MiniArc operation with TRS attached was accomplished in 131 consecutive USI patients. Of all patients with observed urinary leakage during filling cystometry, 85 showed a significant degree of urinary incontinence (i.e., leak on 1-hour pad test >10 g). The demographic and perioperative data are summarized in Table 1.

Immediately after surgery, 25 patients (19.1%) had difficulty in voiding with an elevated PVR volume, requiring catheterization for their first void. Twelve (9.2%) women were unable to void adequately and met the criteria for TRS manipulation. All 12 women were managed successfully with TRS manipulation; 10 women needed only single TRS manipulation, while two required repeated TRS manipulation. Ultrasonographic examination following TRS manipulation in all the women showed no urethral indentation/elevation. No complication was observed on TRS manipulation. By contrast, 13 patients (9.9%) did not meet the criteria for TRS manipulation and were offered intermittent catheterization. Among them, 11 stopped bladder scan and catheterization in <24 hours, and two maintained intermittent catheterization for >72 hours. No patient required self-catheterization after discharge (Figure 3).

The mean period of follow up was 19.2 ± 8.0 months. Within the follow-up period, no defective healing of vaginal wounds or rejection of the polypropylene tapes occurred. Five patients were lost to follow up owing to long traveling distances. Only 126 patients were available for objective and subjective evaluations on surgical outcomes, with objective cure in 114 patients [90.5%, 95% confidence interval (CI) 76–97] and failure in 12. Urine leakage observed on the pad test was significantly reduced from a mean of 37.1 ± 34.1 (95% CI 30.0–45.0) prior to surgery, to a mean of 2.55 ± 8.57 (95% CI 0.68–4.47) after surgery ($p < 0.001$). Among the failures, three were classified as having intrinsic sphincter deficiency with severe USI (pad test > 10 g/h) preoperatively. One of the

Table 1
Demographics of the patients and prior pelvic surgery (n = 131).

	No. of patients	Percentage
Mean age (y)[a]	57.8 ± 11.5 (55.4–60.1)	
Median parity[a]	3 (1–9)	
Mean BMI (kg/m^2)[a]	24.9 ± 3.4 (24.2–25.6)	
Postmenopausal	91	69.4
Urodynamic		
USI	125	
USI & ISD	*6*	
Prior pelvic surgery	13	9.9
VTH + Prolift total + A-P	3	
VTH + Perigee + SS + A-P	5	
Laparoscopic burch	1	
Mudurethral sling	3	
Needle suspension	1	
Mean operating time (min)[a]	21.4 ± 7.1 (18.9–22.8)	
Mean intraoperative blood loss (mL)[a]	24.4 ± 27.6 (18.7–30.0)	
Mean hemoglobin difference (g/dL)[a]	0.467 ± 0.216 (0.423–0.511)	
Mean hospital stay (d)[a]	1.04 ± 0.29 (0.98–1.10)	
Mean period of follow up (mo)[a]	19.2 ± 8.0 (16.5–25.8)	
Concurrent surgery		
MiniArc + A	52	36.7

A-P = anterior and posterior colporrhaphy; BMI = body mass index; CI = confidence interval; ISD = intrinsic sphincter deficiency; MiniArc + A: MiniArc and anterior colporraphy; SS = sacrospinous ligament fixation; USI = urodynamic stress incontinence; VTH = vaginal total hysterectomy.
[a] Data listed as mean ± standard deviation and range in brackets with 95% CI in parenthesis.

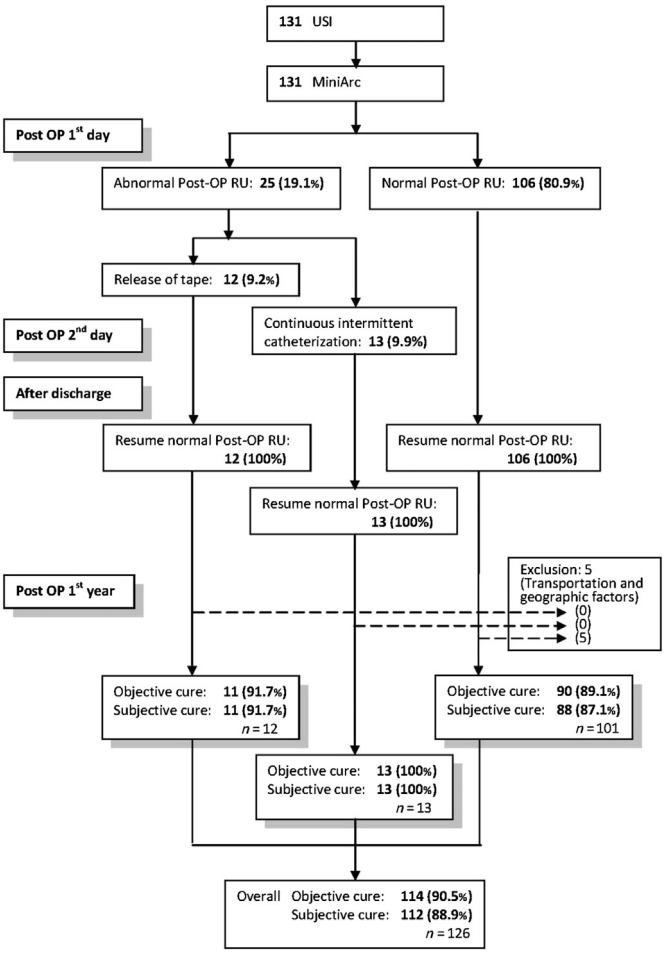

Figure 3. Flow chart on outcomes after patients received MiniArc procedure. Post-OP RU = postvoid residual urine; USI = urodynamic stress incontinence.

failed patients had the TRS manipulated. The subjective cure rate was 88.9% (112/126). The analysis of surgical outcomes cure rates was further broken down according to TRS manipulation. The objective and subjective cure rates of the group with TRS manipulation were both 91.7% (11/12). Conversely, the objective and subjective cure rates of the group without TRS manipulation were 90.4% (103/114) and 88.6% (101/114), respectively (Figure 3). The results of the pre- and postoperative Urogenital Distress Inventory-6, Incontinence Impact Questionnaire-7, and multichannel urodynamic assessment were compared (Table 2). The resting urethral pressure profile, mean functional urethral length, maximum urethral closure pressure, detrusor pressure at maximum flow, and PVR volume did not show any significant alteration after surgery. However, one patient who had intermittent catheterization for 3 days with no TRS manipulation developed mild bladder outlet obstruction. *De novo* detrusor instability was observed during filling cystometry in five patients. Among them, three were clinically asymptomatic and two were prescribed with anticholinergic medications.

Discussion

In this series, the overall objective and subjective cure rates of the patients who had a MiniArc procedure performed under intravenous general anesthesia at 1 year after surgery were 90.5% (114 out of 126) and 88.9% (112 out of 126), respectively. When the study group was divided into the group with TRS manipulation and that without TRS manipulation, the objective cure rates of 91.7% and 89.1%, and subjective cure rates of 91.7% and 87.1% were observed, respectively. These results are comparable with the previous performance of the MiniArc procedures, which showed a success rate of 77.8–91.4% [3–6,19–21]. Our observed outcomes have further ascertained the efficacy of TRS manipulation in both resolving postoperative urine voiding dysfunction and maintaining postoperative urinary continence.

Along 25 out of 113 patients (19.1%) noted with immediate postsurgical voiding dysfunction in the present study, 12 (9.2%) was related to overtensioned sling. These results are higher than

Table 2
Comparison between pre- and postoperative symptoms, QoL scores (UDI-6 and IIQ-7), pad test, and urodynamic evaluation results ($n = 126$).

Parameter	Preoperative	Postoperative at 1 y	Paired *t* test *p*
UDI-6[a]	87.3% (110/126)	34.9% (44/126)	<0.001
IIQ-7[b]	84.9% (107/126)	37.3% (47/126)	<0.001
Pad test	37.1 ± 34.1 (30.0–45.0)	2.55 ± 8.57 (0.68–4.47)	<0.001
Urodynamics			
Qmax	28.22 ± 11.7 (25.7–30.8)	26.4 ± 17.8 (22.5–30.3)	0.371
Res	31.0 ± 126.3 (25.2–36.8)	31.1 ± 20.9 (26.5–35.7)	0.973
CC	412.9 ± 128.3 (384.7–441.1)	396.4 ± 102.4 (369.9–422.8)	0.203
MUCP	73.7 ± 30.9 (66.9–80.5)	70.8 ± 31.0 (64.0–77.6)	0.289
FUL	22.0 ± 6.4 (20.6–23.5)	22.4 ± 5.9 (21.1–23.7)	0.625
Dmax	14.6 ± 8.4 (12.7–16.4)	15.6 ± 11.9 (13.0–18.3)	0.446

CC = cystometric capacity (mL); Dmax = detrusor pressure at maximum flow (cmH_2O); FUL = functional urethral length (cm); IIQ-7 = Incontinence Impact Questionnaire-7; MUCP = maximum urethral closure pressure (cmH_2O); Qmax = maximum urinary flow (m/s); QoL = quality of life; Res = postvoid residual urine (mL); UDI-6 = Urinary Distress Inventory-6.
Data listed as mean ± standard deviation with 95% CI within parentheses.
[a] UDI-6 total score >7.
[b] IIQ-7 total score >7.

previously reported outcomes on the MiniArc procedure ranging from 2.1% to 17% [3–6,19–21]. In theory, an undertensioned sling results in a surgical failure, while an overtensioned sling signifies voiding dysfunctions. To date, the suggested guideline for a sling placement is based mainly on an objective estimation. Thus, the surgeon's judgment is most important in sling placement. The tendency to avoid a higher number of failures would result in an immediate increase in overtensioning and hence voiding difficulties. This may explain the findings of this study. Bladder atony, undue urethral elevation, urethral stricture, and anxiety are various explanations for urinary retention after anti-incontinence operation [9,11–13]. The keys to success on relieving the consequence of voiding dysfunction from undue sling tension without compromising the surgically achieved continent effect are identifying the cases with the tape overtensioned accurately and applying an appropriate procedure for prompt release of sling tension [11,13].

Ultrasonographic evaluation of the urethra has been considered a suitable technique for visualizing the results of midurethral tape operation [12,21,22]. Lo et al [12,21,22] reported pronounced midurethral angulation on ultrasound in patients who developed immediate postoperative voiding difficulty after TVT procedures and further observed the similar phenomenon in patients who developed similar postoperative voiding symptoms after the MiniArc procedure. In this study, postoperative ultrasonography surveillance was used for patients with voiding dysfunction following the MiniArc surgery. Visualization of urethra elevation by a suburethra tape then served as an indication for sling release. The measured length of the elevated suburethra provided valuable information and served as a guide for the distance that the attached TRS needed to be manipulated for the undue tension sling without jeopardizing the continence.

Management of iatrogenic postoperative voiding dysfunction after the MiniArc procedure involved prolonged catheterization and alpha-blocker administration [3–6,19–21]. The reported methods on reliving overtensioned midurethra sling surgeries are on TVT and TOT sling but single-incision sling [11–13,23] Yet, we could consider adopting them on single-incision sling procedure as it has been proven on the efficacy on TVT and TOT. Hegar's dilator has been utilized for pushing the proximal urethra downward to release the overtensioned midurethral sling immediately after the TVT procedure [11,12]. Klutke et al [13] reported that the overtensioned midurethral mesh can be released by pulling the sling down, but a small vaginal incision is needed for the hooking up of the suburethral sling. Transvaginal excision of the tape is an ultimate method for resolving the undue tension of the tape [11,12,23]. While undue tension is resolved, the tape is devastated. All the treatment options mentioned above are both invasive and stressful to the patient. A TRS could easily be preattached on the sling and pulled out when needed for releasing the tensioned sling [14]. Twelve patients with voiding dysfunction related to MiniArc sling overtension promptly received TRS manipulation, which effectively helped restore normal voiding function. All the affected patients had their PVRs returned to the range of normal volume at the following one or two voids. No patient had complications or distress, or complained of pain during tape manipulation by TRS. With the aid of ultrasonography estimation, patients suitable for TRS manipulation could be selected, and overcorrection of the sling tension was avoided as only one surgical failure, arising from the TRS-manipulated group, was observed.

There was no history of mesh infection, although the suture was left outside with a connection to the mesh. This may be due to several factors. First, the type of suture used had an antibacterial coating; second, the surrounding vaginal mucosa was closed with a suture having similar properties and healing occurred properly with no breakup events; and third, owing to their physical properties, synthetic polyglactin sutures could degrade *in vivo* through hydrolysis, resulting in less inflammatory tissue reaction in comparison with natural protein analogs [24].

The reasons for using polyglactin for TRS are its absorbable and tensile properties (on average, its absorption period is 42 days, but this period depends on the type of polyglactin; this period increased to 56–70 days for the suture type used by us [24], making it unnecessary to remove the TRS suture). Furthermore, postoperative voiding dysfunction, if encountered, always occurs within immediate postoperative period and requires a prompt action. The knot pull tensile strength of this suture was found to be around 3.9 kg force (8.5 lbs) [24], which indicates that this thread has sufficient strength to pull the MiniArc sling out from the muscle (the pullout force required to remove the MiniArc is 5.5 lbs (Pounds-force)) [6]. The anchoring mechanism of the MiniArc sling is via its arrow-head tips, which give a firm grip after penetrating the anchoring tissue, compared with the soft holding on conventional TVT and TOT slings, by utilizing the friction force created from the zigzag sling edge and surrounding tissues. The pullout force for moving the arrow-head tips on the MiniArc sling is expected to be higher. Therefore, an appended tension-relief suture adjacent to the arrow-head tip can provide a firm attachment, able to move the sling tip, and avoid mesh distortion and deformation when it is manipulated. Excess traction on the TRS can result in a surgical failure; thus, a gentle and

slow gradual increment in the traction force has to be applied during the process until the fixed tip is released.

The chief limitation of this study includes the lack of a control group, which would ideally include women being randomly allocated to TRS-manipulated and non-TRS-manipulated groups based on voiding dysfunction; a current ongoing study is being conducted taking this factor into consideration. The strengths of our study are the reasonably large population size of 126 women and the use of validated questionnaires to assess subjective improvement, functional outcomes, and quality of life.

In conclusion, TRS appendage on a MiniArc sling is an effective, noninvasive, simple procedure for the management of postoperative voiding dysfunction following an anti-incontinence procedure.

Conflict of interest

The authors have no conflicts of interest relevant to this article.

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