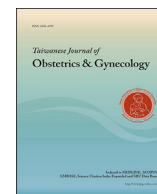




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## Original Article

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

Tsia-Shu Lo <sup>a, b, c, \*</sup>, Leng Boi Pue <sup>d, e</sup>, Yiap Loong Tan <sup>e, f, g</sup>, Cheng-Yu Long <sup>h, i</sup>, Yi-Hao Lin <sup>b, c</sup>, Pei-Ying Wu <sup>a</sup><sup>a</sup> Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Keelung, Medical Center, Keelung, Taiwan<sup>b</sup> Division of Urogynecology, Department of Obstetrics and Gynecology, Chang Gung Memorial Hospital, Linkou Medical Center, Linkou, Taoyuan, Taiwan<sup>c</sup> School of Medicine, Chang Gung University, Taoyuan, Taiwan<sup>d</sup> Department of Obstetrics and Gynecology, Hospital Serdang, Kajang, Selangor, Malaysia<sup>e</sup> Division of Urogynecology, Department of Obstetrics and Gynaecology, Chang Gung Memorial Hospital, Linkou, Taoyuan, Taiwan<sup>f</sup> Kuching Specialist Hospital, KPJ, Kuching, Sarawak, Malaysia<sup>g</sup> Department of Obstetrics and Gynecology, Sarawak General Hospital, Kuching, Sarawak, Malaysia<sup>h</sup> Graduate Institute of Medicine, Center of Excellence for Environmental Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan<sup>i</sup> Department of Obstetrics and Gynecology, Kaohsiung Medical University, Chung-Ho Memorial Hospital, Kaohsiung, Taiwan

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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.

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## 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

\* Corresponding author. Department of Obstetrics and Gynaecology, Chang Gung Memorial Hospital Keelung, Keelung Medical Centre, 222, Maijin Road, Keelung 204, Taiwan.

E-mail address: [2378@cgmh.org.tw](mailto:2378@cgmh.org.tw) (T.-S. Lo).

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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 multi-channel 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

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