

## Original Article

**Retropubic tissue fixation system tensioned mini-sling carried out under local anesthesia cures stress urinary incontinence and intrinsic sphincter deficiency: 1-year data**Ryoko Nakamura,<sup>1,2</sup> Masahiro Yao,<sup>2</sup> Yoshiko Maeda,<sup>1</sup> Akiko Fujisaki<sup>1</sup> and Yuki Sekiguchi<sup>1,2</sup><sup>1</sup>Department of Urology, Yokohama Motomachi Women's Clinic LUNA, and <sup>2</sup>Department of Urology, Yokohama City University Graduate School of Medicine, Yokohama, Japan**Abbreviations & Acronyms**

DO = detrusor overactivity  
EUL = external urethral ligament  
ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form  
ISD = intrinsic sphincter deficiency  
MUCP = maximum urethral closure pressure  
N/A = not available  
OAB = overactive bladder  
PUL = pubourethral ligament  
SUI = stress urinary incontinence  
TFS = tissue fixation system  
TOT = transobturator tape  
TVT = tension-free vaginal tape  
VLPP = Valsalva leak point pressure

**Objectives:** To assess the outcomes of the tissue fixation system midurethral sling for the treatment of intrinsic sphincter deficiency.

**Methods:** We retrospectively studied a total of 96 intrinsic sphincter deficiency patients treated with the tissue fixation system midurethral sling at Yokohama Motomachi Women's Clinic from 2006 to 2015. We evaluated intraoperative and 1-year postoperative results. Regarding the cure rate, we divided patients into three groups: (i) patients with maximum urethral closure pressure <20 and Valsalva leak point pressure <65 combined ( $n = 17$ ); (ii) patients with maximum urethral closure pressure <20 ( $n = 55$ ); and (iii) patients with Valsalva leak point pressure <65 ( $n = 47$ ).

**Results:** The median age was 63 years (range 38–89 years). The median operating time including local anesthesia was 24 min (range 12–55 min) and median blood loss was 5.0 mL (range 3–69 mL). All operations were day surgery under local anesthesia. Postoperative pain was minimal. All patients were discharged the same day. There were no intraoperative complications except one bladder perforation. There were no tape rejections. The 1-year postoperative cure rates were: 88.2% among patients with maximum urethral closure pressure <20 and Valsalva leak point pressure <65, 90.9% for patients with maximum urethral closure pressure <20, and 85.1% among patients with Valsalva leak point pressure <65.

**Conclusions:** The tissue fixation system midurethral sling operation is a simple, safe and effective operation for older women with intrinsic sphincter deficiency, and it can be carried out under local anesthesia.

**Key words:** intrinsic sphincter deficiency, local anesthesia, mini-sling, stress urinary incontinence, tissue fixation system.

**Correspondence:** Ryoko Nakamura, Department of Urology, Yokohama Motomachi Women's Clinic LUNA, Suzuoto Building 2F, 2-96 Motomachi, Naka-ku, Yokohama, Kanagawa 231-0861, Japan.  
Email: ryokosakata@hotmail.com

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**Introduction**

The concept of primary urethral weakness causing urinary incontinence appeared in a classification proposed by Blaivas *et al.*<sup>1</sup> The Blaivas concept has evolved into the more contemporary term “intrinsic sphincter deficiency” (ISD), now generally defined by a MUCP <20 cmH<sub>2</sub>O or VLPP <65 cmH<sub>2</sub>O.

Urine leakage occurs when the detrusor pressure exceeds urethral pressure, and this is more likely to occur with low intrinsic urethral pressure. Such patients are more difficult to treat, with higher failure rates than in patients with more normal MUCP.<sup>2</sup>

Age seems to be a negative factor with TVT surgery for ISD. Rezapour *et al.* reported 74% cure of ISD in 36 patients 4 years after TVT midurethral sling surgery.<sup>3</sup> Almost all the failures were in older patients (>70 years) with very low urethral pressures, of  $\leq 10$  cmH<sub>2</sub>O. These data create a dilemma for Japanese physicians who are obliged to deal with an increasingly aging population. By 2013, 17.59 million Japanese women were aged  $\geq 65$  years, an increase of 7.6% in 4 years.<sup>4</sup> Increasing frailty and associated collateral health problems increase the risks of surgery. Even a TVT can become major surgery in some such patients, thereby creating an imperative for minimally-invasive operations, especially those with ISD. In a previous publication, we reported 90% surgical cure in 44 patients with SUI at 12 months using the minimally-invasive retropubic TFS tensioned mini-sling operation, which was carried out under local anesthesia in a stand-alone

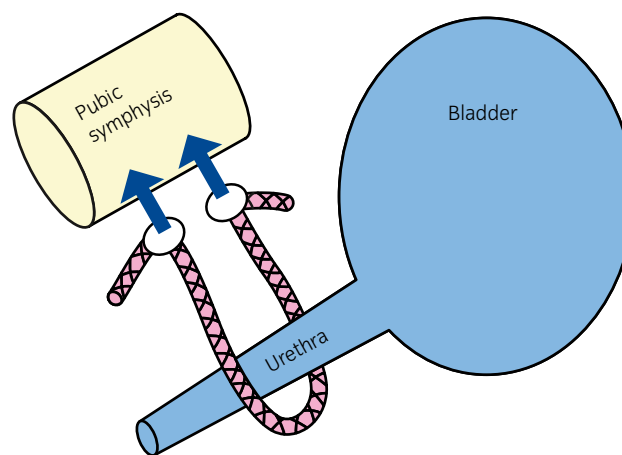
clinic.<sup>5</sup> Of these 44 patients, one-third, 15 patients, had ISD. The cure rate for ISD was the same as the non-ISD patients. The failed patients were successfully cured with repeat TFS surgery. These results ran counter to currently accepted ideas about ISD and especially, mini-slings, which are generally considered to have a far inferior cure rate to standard TVT and TOT operations.<sup>3,6</sup> This is a study of patients with ISD who underwent TFS surgery for their SUI. The aim was to critically examine the effectiveness of the TFS midurethral sling methodology in all patients from Yokohama Motomachi Women's Clinic, Yokohama, Japan, who had ISD and TFS surgery.

## Methods

We studied 96 intrinsic sphincter deficiency patients treated with the tissue fixation system midurethral sling at Yokohama Motomachi Women's Clinic, a free-standing clinic, from 2006 to 2015 retrospectively. A total of 11 patients stopped attending the clinic within 1 year after operation because they lived far away from the clinic and they wanted to consult by the telephone. Therefore, 85 of 96 ISD patients who underwent the TFS midurethral sling operation were included in the present study. We evaluated all patients by urodynamic test (LIT-1000; Laborie Medical Technologies, Mississauga, ON, Canada). The inclusion criteria were maximal urethral closure pressure <20 cmH<sub>2</sub>O or VLPP <65 cmH<sub>2</sub>O. Exclusion criteria were previous urogynecological surgery, pelvic organ prolapse, comorbidities unsuitable for treatment in a free-standing clinic and detrusor overactivity. Patients were not excluded for urgency incontinence. We evaluated intraoperative and 1-year postoperative results. Informed patient consent was obtained, including permission to publish the results. The principles of the Declaration of Helsinki were followed. This study was approved by the ethics committees of the Yokohama Motomachi Women's clinic LUNA in 2006.

## Surgery

The patients were given hydroxyzine hydrochloride 25 mg and atropine sulfate 0.5 mg by intramuscular injection, and a diclofenac sodium 50 mg suppository before the operation. A single shot of Sulperazon 1 g was injected i.v. at induction of the operation. The operations were carried out under local anesthesia by two surgeons, using 1% xylocaine 10 mL + physiological saline 40 mL + vasopressin 10 units. Patients were additionally given a midazolam 2.5-mg i.v. drip. The local anesthesia was injected at the sites of the surgery: anterior vaginal wall, periurethral spaces and below the pubic symphysis, into the tissues behind the perineal membranes (urogenital diaphragm). All operations were carried out on a day-surgery basis. The operation was carried out as described previously.<sup>5</sup> We used the TFS device (TFS; TFS Surgical, Allenby Gardens, SA, Australia). The midurethral TFS sling operation, as shown in Figure 1, is identical to the first part of a midline TVT operation.<sup>7,8</sup> A full thickness midline vaginal incision was made below the urethral meatus to the midurethra. The vagina was dissected off the urethra with dissecting scissors. A tunnel was created below the inferior surface of the pubic symphysis to the urogenital

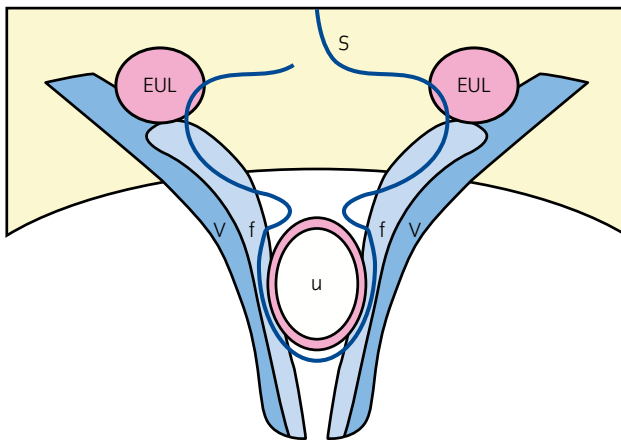


**Fig. 1** The TFS midurethral sling. The TFS anchors have four prongs. The anchors are placed at the origin of the pubourethral ligament, below the space of Retzius, at the lower part of the posterior surface of the pubic symphysis. A 7-mm wide macropore polypropylene tape passes below a trapdoor at the base of the anchor. This creates an accurate one-way tightening system, which can simultaneously shorten and reinforce an elongated or damaged ligament 1 mm at a time.

diaphragm. This was perforated to a depth of approximately 1.5 cm, the space created being just sufficient for the passage of the applicator. The applicator was placed into the dissected space, penetrated the diaphragm and triggered to release the TFS anchor. The tape was pulled with a short sharp movement to set the prongs of the anchor into the tissues. Adequate gripping of the anchor was tested by pulling on the tape. The procedure was repeated on the contralateral side. The tape was tensioned until it was firmly abutting against (but not indenting) the urethra. A number 8 Hegar dilator distended the urethra, so as to prevent excessive tensioning and postoperative urinary retention. The free ends of the tape were cut. The suburethral vaginal fascia and the external ligamentous attachment of the external urethral meatus were now tightened, as shown in Figure 2.<sup>8</sup> A 2-0 Vicryl suture penetrated the ligamentous attachment of the external meatus on the right side, then the smooth muscle layer of the vagina on both sides, finishing into the lateral ligamentous attachment of the meatus on the left side. The suture was gently tightened, so that the fascia covered the tape. At the end of the operation, a number 8 Hegar dilator was inserted to ensure there was no obstruction. Cefcapene pivoxil hydrochloride 300 mg orally was given for 3 days postoperatively, and loxoprofen sodium 180 mg as required for pain relief.

## Outcome measures

The major outcome was the cure rate of SUI 1 year after operation. Patients were divided into three groups: (i) patients with MUCP <20 cmH<sub>2</sub>O and VLPP <65 cmH<sub>2</sub>O combined; (ii) patients with MUCP <20 cmH<sub>2</sub>O and any VLPP; and (iii) patients with any MUCP and VLPP <65 cmH<sub>2</sub>O. We evaluated the cure rate of each group separately. Cure was defined as no patient reports of leakage during coughing, a negative cough stress test carried out with a full bladder, and



**Fig. 2** Tightening the external ligamentous attachments and smooth muscle layer of the vagina “pubocervical fascia.” Anterior to the pubic symphysis; EUL, external urethral ligament; f, fascia; S, suture; U, urethra; v, vagina.

24-h pad test results <3 mg – 3 mg being an average loss from normal vaginal discharge. A woman was considered a treatment failure if she failed any one of the outcome criteria listed previously. The secondary outcome was the change of the total score of the ICIQ-SF between preoperation and 1 year after an operation. Continuous variables are reported with the median and range, whereas categorical variables are presented with the frequency and percentage.

### Statistical analysis

All analyses were carried out using Statcel 3 (OMS-Publish, Saitama, Japan). The 1-year postoperative cure rate of SUI was analyzed using the McNemar test. The preoperative total scores of ICIQ-SF were compared with the 1-year postoperative total scores of the ICIQ-SF using the Mann–Whitney *U*-test. A 5% two-sided significance level was used for all statistical testing.

### Results

The demographics and preoperative tests are shown in Tables 1–3. The median operating time including local anesthesia was 24 min (range 12–55 min), and the median blood loss was 5.0 mL (range 3–69 mL). The median stay time in the clinic was 7.8 h (range 4.4–9.5 h). The patients were discharged after the first urination or 8 h after the operation. Our recovery nurses asked the patients about their pain on discharge. All patients stated that their postoperative pain was minimal. The intraoperative complication was one small bladder perforation, which was resolved by placing an indwelling catheter for 1 week. A total of 14 patients who were judged to bleed >20–30 mL by their surgeon had a gauze tampon inserted in their vagina until their first voiding after operation. A total of 20 patients could not void spontaneously within 8 h of the operation. They were discharged with a special indwelling catheter with an attached DIB cap TM. DIB cap TM is a magnetic plug made by DIB International in Japan, which allows the patient to urinate and dispenses with a urine

**Table 1** Characteristics of 17 patients who have MUCP <20 cmH<sub>2</sub>O and VLPP <65 cmH<sub>2</sub>O combined

Characteristics (n = 17)	Median (range) or n (%)
Age (years)	70 (49–88)
Body mass index (kg/m)	22.8 (19.4–25.6)
Parity	
0 (n)	4 (23.5%)
1 (n)	1 (5.9%)
2 (n)	5 (29.4%)
3 (n)	7 (41.2%)
Hysterectomy (n)	3 (17.6%)
Urgency (n)	2 (11.8%)
24-h pad test (g)	105 (4.0–463)
1-h pad test (g)	20.7 (4.0–80)
Maximum cystometric capacity (mL)	342 (120–674)
Maximum flow rate (mL/s)	28.7 (10.0–29.8)
Average flow rate (mL/s)	15.2 (4.6–9.5)
Residual urine (mL)	0 (0–40)
Bladder compliance (mL/cmH <sub>2</sub> O)	69 (33–132)
Valsalva leak point pressure (cmH <sub>2</sub> O)	44 (10–64)
Maximum urethral closure pressure (cmH <sub>2</sub> O)	16 (1–19)

**Table 2** Characteristics of 55 patients with MUCP <20 cmH<sub>2</sub>O

Characteristics (n = 55)	Median (range) or n (%)
Age (years)	65 (40–89)
Body mass index (kg/m)	22.8 (19.1–33.7)
Parity	
0 (n)	11 (20.0%)
1 (n)	12 (21.8%)
2 (n)	14 (25.5%)
3 (n)	17 (30.9%)
4 (n)	1 (1.8%)
Hysterectomy (n)	4 (7.3%)
Urgency (n)	10 (18.2%)
24-h pad test (g)	50 (2.5–700)
1-h pad test (g)	30 (3–320)
Maximum cystometric capacity (mL)	372 (147–674)
Maximum flow rate (mL/s)	24.4 (9.7–69)
Average flow rate (mL/s)	11.6 (7.9–26.3)
Residual urine (mL)	5.0 (0–52)
Bladder compliance (mL/cmH <sub>2</sub> O)	97 (40–270)
VLPP (cmH <sub>2</sub> O)	82 (30–148)
MUCP (cmH <sub>2</sub> O)	15 (1–19)

bag. A total of 19 patients voided with no difficulty within 2 days. One patient with a small bladder perforation during operation required an indwelling catheter for a week. Three patients voided with difficulty after operation. Two of them were prescribed an  $\alpha$ 1-blocker. One patient recovered 1 month later. The other patient had not recovered using the  $\alpha$ 1-blocker, had self-catheterization for 6 months and finally required tape resection. After that, she remained continent and voided spontaneously. Regarding urology infections, one patient developed cystitis 1 week after the operation and recovered with antibiotics.

All patients were followed for at least 1 year. The median length of follow up was 19 months (range 12–120 months,

median 19 months). The patients were divided into three groups: (i) patients with MUCP <20 and VLPP <65 (Table 1) combined; (ii) patients with MUCP <20 and any VLPP (Table 2); and (iii) patients with any MUCP and VLPP <65 (Table 3). We evaluated the 1-year postoperative cure rate of each group separately. Among patients with MUCP <20 and VLPP <65 combined, 15 out of 17 patients were cured (88.2%). Among patients with MUCP <20 and any VLPP, 50 out of 55 patients were cured (90.9%). Among patients with any MUCP and VLPP <65, 40 out of 47 patients were cured (85.1%). TFS for ISD patients of each group was significantly effective ( $P < 0.0001$ ). The median total score of the preoperative ICIQ-SF of cured cases changed from 15 (5–20, median 15) to 4 (0–12, median 4) 1 year after an operation. The total score of the ICIQ-SF improved significantly ( $P < 0.0001$ ). In the 10 cases that failed, we hypothesized that the tape was loose. We re-operated on eight patients with another TFS midurethral sling within 6 months. Seven patients became continent after re-operation, the other patient was not cured of incontinence, although her subjective

symptom improved after re-operation. Her preoperative VLPP was very low, 36 cmH<sub>2</sub>O. Two patients declined re-operation, because their symptoms were much better than before their TFS operation.

In patients with MUCP of  $\leq 10$  cm, four out of five were cured (Table 4). The failed patient was cured after a second TFS operation 4 months later. A total of 14 patients were

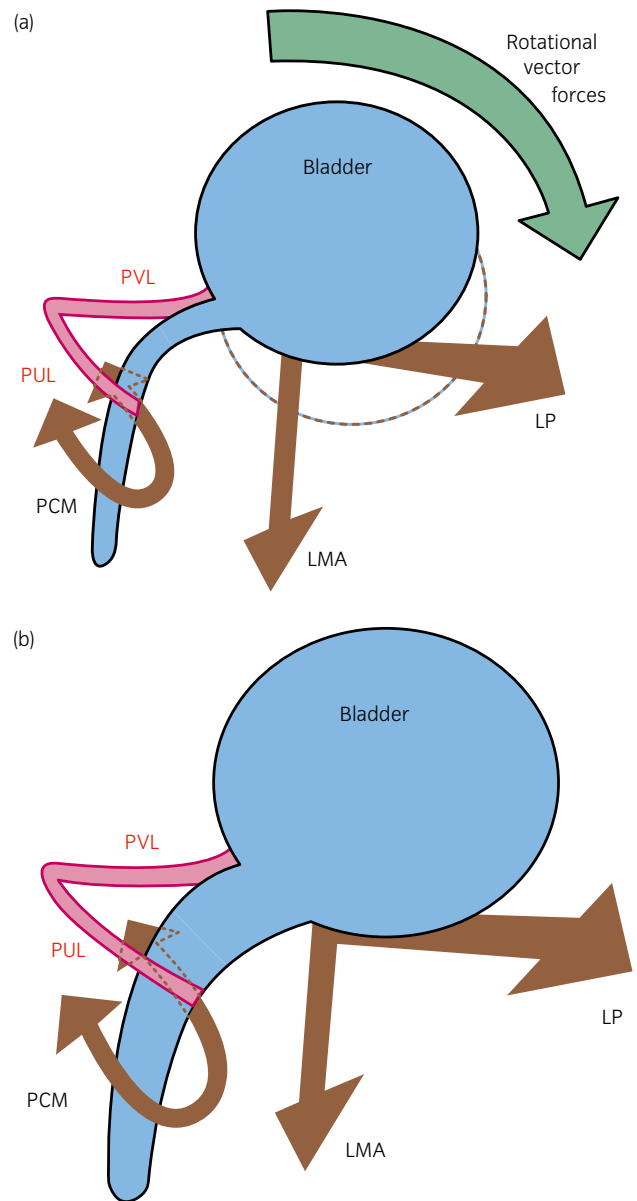
**Table 3** Characteristics of 47 patients with VLPP <65 cmH<sub>2</sub>O

Characteristics (n = 47)	Median (range) or n (%)
Age (years)	63 (38–88)
Body mass index (kg/m)	22.8 (19.4–27.2)
Parity	
0 (n)	8 (17.0%)
1 (n)	10 (21.3%)
2 (n)	18 (38.3%)
3 (n)	10 (21.3%)
4 (n)	1 (2.1%)
Hysterectomy (n)	4 (8.5%)
Urgency (n)	12 (25.5%)
24-h pad test (g)	55 (5–463)
1-h pad test (g)	27 (5–250)
Maximum cystometric capacity (mL)	420 (120–474)
Maximum flow rate (mL/s)	29.8 (11.0–42.0)
Average flow rate (mL/s)	12.7 (5.9–27.3)
Residual urine (mL)	5.0 (0–52)
Bladder compliance (mL/cmH <sub>2</sub> O)	81 (35–263)
VLPP (cmH <sub>2</sub> O)	51 (10–64)
MUCP (cmH <sub>2</sub> O)	18 (1–44)

**Table 4** Patients with MUCP  $\leq 10$  cmH<sub>2</sub>O

Case	Age (years)	MUCP	24-h pad test	1-h pad test	BMI	Result
1	48	10	190	88	21.1	Cured†
2	74	1	130.6	3.7	24	Cured†
3	77	9	130	60	22.4	Failed‡
4	61	10	29	8	22.8	Cured†
5	57	8	N/A	N/A	22	Cured†

†Cure was defined as no patient reports of leakage during coughing, a negative cough stress test carried out with a full bladder and 24-h pad test results <3, 3 mg being an average loss from normal vaginal discharge. ‡Failure was defined if a patient failed any one of the outcome criteria listed previously.



**Fig. 3** Role of a loose PUL in the pathogenesis of stress urinary incontinence. (a) Normal patient (PCM) stretches the distal vagina against PUL to close the distal urethra; the levator plate (LP) stretches the proximal urethra backwards against the PUL; LMA rotates the bladder neck down and around the pubovesical ligament (PVL) insertion into the anterior bladder wall to close the bladder neck “like a ball valve.”<sup>13</sup> (b) SUI – a loose PUL allows the backward forces to open out (“funnel”) the posterior urethral wall. This exponentially lowers the internal resistance to flow inversely by the fourth power (Poiseuille’s law). Urine is lost on effort. A midurethral sling shortens and reinforces the PUL, reversing this cascade of events. LMA, conjoint longitudinal muscle of the anus; LP, levator plate; PCM, the anterior portion of the pubococcygeus muscle.

taking anticholinergics preoperatively for OAB; five patients (36%) improved after TFS operation and stopped their anticholinergics. Six patients experienced de novo urge incontinence postoperatively. These symptoms disappeared entirely at 12 months in three patients. Three remaining patients were treated with anticholinergics. There was no erosion of tape and no tape infections in 85 cases.

## Discussion

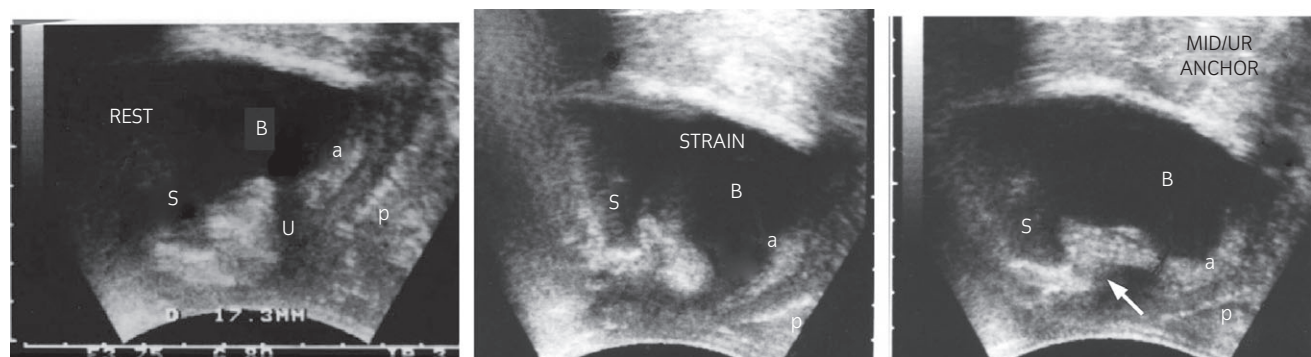
As far as we are aware, this is the first tensioned mini-sling study carried out in patients with ISD. In 2009, we reported 90% cure in 15 ISD patients out of a cohort of 44 patients undergoing the TFS midurethral sling for SUI.<sup>5</sup>

In the present study, we measured both MUCP and VLPP. MUCP and VLPP are both considered to be valid measures of ISD. In Japan, VLPP seems to be the preferred standard. In Europe, especially among urogynecologists, MUCP seems to be the preferred standard. The present study was able to show that ISD was cured, whatever the measure applied – MUCP, VLPP or both combined – with cure rates of 91%, 85% and 88%, respectively.

These results compare favorably with those achieved by Rezapour (74%) and Schierlitz (79%).<sup>3,9</sup>

The high cure rate achieved in the present study begs the question, “why is the TFS achieving such high cure rates for ISD, when the other mini-slings are associated with almost 10 times the odds of failure than the TVT for non-ISD patients?”<sup>7</sup> In an attempt to answer this question, we analyzed the modus operandi of the TFS relative to other slings and existing mechanisms of continence. The 2013 consultation offers several variations of the pressure equalization theory to explain the pathogenesis of SUI.<sup>10</sup> There was no mention of any role for the PUL in De Lancey’s hypothesis.<sup>11</sup> Zacharin did mention a role for the PUL, but only to prevent descent of the urethra below “the intra-abdominal pressure equalization area.”<sup>12</sup> The intra-abdominal pressure equalization theory was invalidated by postoperative X-ray findings in 1990.<sup>13</sup> Even patients whose bladder neck was

below the pubic symphysis postoperatively were cured of SUI.<sup>13</sup> In their 1990 integral theory, Petros and Ulmsten hypothesized that the mechanism for continence comprised two opposite musculoelastic forces stretching the urethral tube against a competent PUL. Incontinence was a consequence of a loose PUL invalidating these closure forces (Fig. 3).<sup>13</sup> A 1999 transperineal ultrasound study showed a firm midurethral anchoring point was required to restore geometry and continence in patients with SUI (Fig. 4).<sup>14</sup> Other theories cannot explain the change in geometry seen with this maneuver.<sup>11,12</sup> Narrowing a tube exponentially increases its resistance to flow,<sup>13</sup> inversely by the fourth power of the radius.<sup>15</sup> It is our view that only stretching/narrowing and “kinking” the urethra at the bladder neck, as shown in Figure 3, can explain the cure of urine loss noted in the 74-year-old patient with a very low MUCP of 1 cm (Table 4). An adequately tightened PUL is required to restore this mechanism.<sup>14</sup> However, this exponential effect works both ways. It means that the tightening of the sling has to be very precise. With any sling operation, excessive tension on the sling will constrict the urethra and cause urinary retention. In contrast, excessive looseness of the sling will cause ongoing SUI. The local anesthesia methodology and non-stretch tape meant that we did not need to make any allowance for postoperative rectus muscle contractions or tape elasticity (e.g. by placing scissors between the tape and the urethra during tightening). It is our view that the main reason for our high cure rate in patients with ISD is that we were able to precisely tighten the tape by millimeters after its insertion, thereby avoiding the exponential effects on the urethral lumen of an over-tight or over-loose sling. We consider that one extra step, tightening the external ligament and suburethral vagina (Fig. 2), was an important contribution to our surgical methodology, as it restored the distal closure mechanism, forward arrow (Fig. 3).<sup>13</sup> These mechanics appear to explain the poor results reported by Basu *et al.* in non-ISD patients.<sup>7</sup> A non-tensioned mini-sling is inherently imprecise. It has to insert and tighten a loose PUL in one movement. Great skill is required to do this. The retropubic nature of the



**Fig. 4** Direct ultrasound proof that a competent PUL is a requirement for cure of SUI.<sup>14</sup> Published with permission of the author. (a) “REST.” S, symphysis; U, urethra; B, bladder; a, anterior vaginal wall; p, posterior vaginal wall. (b) “STRAIN.” Loose PUL. The posterior pelvic muscles stretch the vaginal walls “a” and “p” backwards; this action pulls open the posterior urethral wall. The urethra opens out proximally (funneling) and distally. (c) “MID/UR ANCHOR.” When the PUL length is restored by pressing upwards with a hemostat (arrow), the strength of the muscle forces is restored; “a” and “p” visibly tension; distal and bladder neck closure are restored. Explanation of the above events. In (b), (lax PUL), all three directional forces that act on PUL lengthen and lose contractile strength. (c) Once PUL length is restored by the hemostat (white arrow), all three muscles can now “grip” and close the distal urethra and bladder neck.

tensioned TFS mini-sling appears an optimal methodology for treating ISD. At 3-year review, Schierlitz *et al.* showed that the risk for re-operation in TOT patients with ISD was 15-fold greater than the TVT.<sup>9,16</sup> The authors recommended that only a retropubic sling should be used for patients with ISD.<sup>16</sup>

Gungorduk *et al.* also found the TVT was vastly superior to TOT, but this finding is not universal.<sup>17</sup> Constanti *et al.* found non-significant differences between TVT and TOT, 76% versus 70% ( $P < 0.528$ ).<sup>18</sup>

We were surprised to find no erosions in this group. We attribute this to the anchor holding up the tape and preventing any surfacing. A major limitation was that this was a retrospective study, and there was no comparison with the other patients from our clinic who did not have ISD.

It is our view that, because of its minimal invasiveness and the precision of the tightening mechanism, the TFS retropubic tensioned mini-sling is ideal for patients with ISD, especially in the old and frail, an increasingly prevalent physical condition in the aging population of Japan.

## Conflict of interest

None declared.

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