Repair of damaged ligaments with tissue fixation system minisling is sufficient to cure major prolapse in all three compartments: 5-year data

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Abstract

Aim: The ageing population in Japan brings problems of pelvic organ prolapse (POP), bladder and bowel incontinence, and fragility as regards major pelvic surgery. Existing data from tissue fixation system (TFS) surgery show high cure rates for these conditions, but long-term data are lacking. We aimed to elucidate the usefulness of TFS by assessing 5-year postoperative outcomes.

Methods: A total of 68 patients, mean age 70 years, underwent total pelvic floor repair. Cystocele, apical prolapse, and rectocele were variously addressed by TFS repair of pubourethral, *arcus tendineus fasciae pelvis*, cardinal, uterosacral, and perineal body ligaments using a mean 3.2 tapes per patient (n = 216). Patients were followed up at 12 months then yearly. We included patients with third- or fourth-degree uterine/vaginal prolapse (POP Quantification classification). We excluded patients with serious comorbid conditions.

Results: The mean operating time was 88 min and the mean blood loss was 78 mL. There was minimal postoperative pain and urinary retention, as evidenced by a mean hospital stay of 0.8 days and early return to normal activities. The 5-year cure rates for urinary stress incontinence, urgency, nocturia, and frequency were 82%, 91.7%, 58%, and 52%, respectively. The surgical cure rate for POP was 87.1% at 12 months, falling to 79.0 at 60 months. The cumulative 5-year erosion rate was 0% and 1.7% for all ligaments except the perineal body (25.7%), reducing to 2.6% by year 5 following anchor placement into deep transversus perinei. Two cases of ileus were attributed to incorrect technique.

Conclusion: Reinforcing up to four ligaments with the TFS was sufficient for cure of third- and fourth-degree POP. The technique is minimally invasive, suitable for elderly women, and effective at 5 years for both anatomical and symptom cure.

Key words: cystocele, nocturia, overactive bladder, rectocele, tissue fixation system, uterine prolapse.

Introduction

The Japanese female population is ageing rapidly. By 2013, 17.59 million women were aged 65 years and older, an increase of 7.6% in 4 years.[1] Consequently, an increasing number of women are developing major pelvic organ prolapse (POP). Associated collateral health problems increase the risks of surgery, creating an imperative for minimally invasive operations to safely correct the prolapses. Because of this, our unit began seeking minimally invasive methods for POP surgery from early 2000, when we commenced the minimally invasive infracoccygeal sacropexy operation 'posterior intravaginal slingplasty (IVS).'[2] We found that this operation was very effective as regards uterine prolapse. However, it did not repair cystocele, rectocele, or

perineal body and de novo cystocele occurred in up to 20% of women.[2] Subsequently, we adopted the tissue fixation system (TFS),[3] an evolution of the tension-free vaginal tape (TVT) surgical method, which uses a thin strip of tape to reinforce the pubourethral ligament.[4,5] Strengthening the pubourethral ligaments (PUL) with a tape is a core part of the TVT operation.[4,5]

In 2005, the TFS (TFS Surgical) surgical tool became available (Fig. 1). The TFS can be used to shorten and reinforce any damaged ligament. It works in a similar way to the TVT. A thin strip of mesh tape 7 mm wide is applied directly onto the damaged ligament. A one-way system at its base will shorten and reinforce any loose ligament. In a previous preliminary study,[3] we hypothesized (and demonstrated) that TFS repair of damaged pelvic ligaments, PUL, *arcus tendineus fasciae pelvis* (ATFP), cardinal (CL), uterosacral (USL) ligaments and the deep transversus perinei attachment of the perineal body (PB), as required, was sufficient to repair POP in all three compartments (Figs 1–4).[6–8]
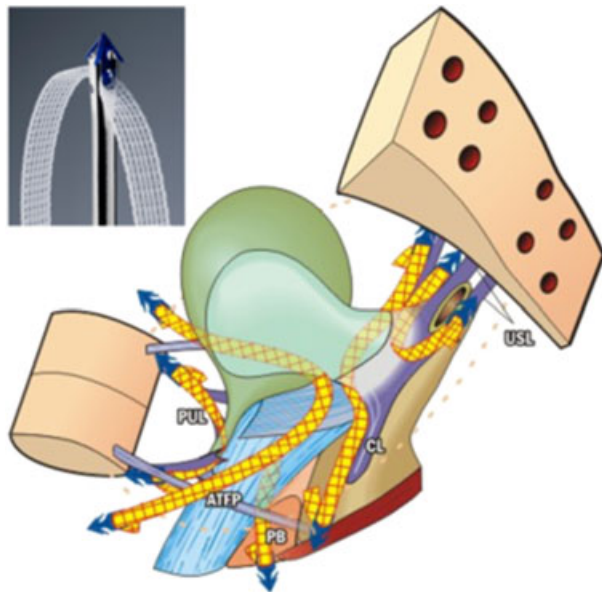

Figure 1 Tissue fixation system (TFS) surgery for creation of artificial collagenous neoligaments. The tape is applied into the loose or damaged ligaments: pubourethral (PUL); *arcus tendineus fasciae pelvis* (ATFP); cardinal (CL); uterosacral (USL); and perineal body (PB). The tape creates a collagenous reaction that strengthens the damaged ligament. Insert: TFS tool. A polypropylene anchor (11 × 4 mm) sits on a stainless steel applicator. A lightweight macropore monofilament tape passes through a one-way system at the anchor base, which shortens and tensions the damaged ligament. By permission TFS Surgical and Petros PE.[12]

Our initial experience[3] also cured or improved nocturia, urgency, frequency, pelvic pain, and fecal incontinence as predicted by the Integral Theory.[9,10]

Our preliminary report on the TFS[3] mainly concerned learning curve, safety, efficacy, and the method's potentiality for cure of POP, bladder, bowel, and pain symptoms with a minimal day-care surgery.

Though existing data using the TFS show high cure rates for these conditions, long-term data are lacking. Our aim was to elucidate the usefulness of TFS from 5-year postoperative outcomes using a total ligament repair approach (Fig. 1).

In contrast to our original report,[3] this 5-year study has used a more evolved surgical technique, tape, and applicator. We performed 'total repair' of all damaged ligaments, as required, in 68 patients, using a mean of 3.2 slings per patient.

The study was approved by the Ethics Committees of Kamakura General Hospital. Written informed consent was obtained from all patients. The principles of the Helsinki Declaration (2008) were followed.

Methods

We carried out a 5-year case series study using a validated questionnaire[11] – the International Consultation on Incontinence Modular Questionnaire Short Form – to assess symptoms, the Integral Theory Diagnostic System to directly identify the damaged ligaments,[12] and the Pelvic Organ Prolapse Quantification (POPQ) to stage the prolapse.[13] These were administered preoperatively and annually.

The TFS consists of an applicator and a non-stretch tape attached to two soft tissue anchors with a one-way adjustable mechanism for the tape, which passes through the base (Fig. 1). The tape is a 7.5-mm-wide lightweight non-stretch type I macropore monofilament polypropylene mesh tape. The TFS sling was applied variously in up to five sites (Figs 2, 3), depending on which ligaments were deemed to be damaged.[12]

How to decide which ligaments to repair

The site of TFS implantation was guided by a symptom-based pictorial algorithm and specific anatomical criteria for damage to each ligament: pubourethral, ATFP, cardinal, uterosacral, and perineal body, as detailed in Chapter 3 of the textbook, *The Female Pelvic Floor: Function, Dysfunction and Management According to the Integral Theory.*[12]

Figure 2 Relative positions of the five tissue fixation system (TFS) tapes. 3-D Panoramic view into the pelvis from above. Standing position. The ligaments attach the organs to the skeleton. The anchors and tapes penetrate, shorten, and strengthen the loose ligaments by creation of an artificial collagenous neoligament. ATFP, *arcus tendineus fasciae pelvis* ('USling'); EUL, external urethral; PB, perineal body; PUL, pubourethral; USL, uterosacral. By permission TFS Surgical.
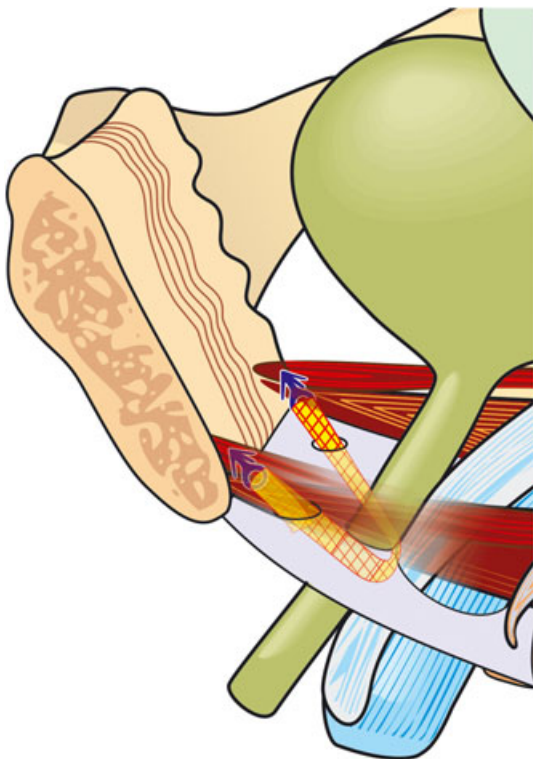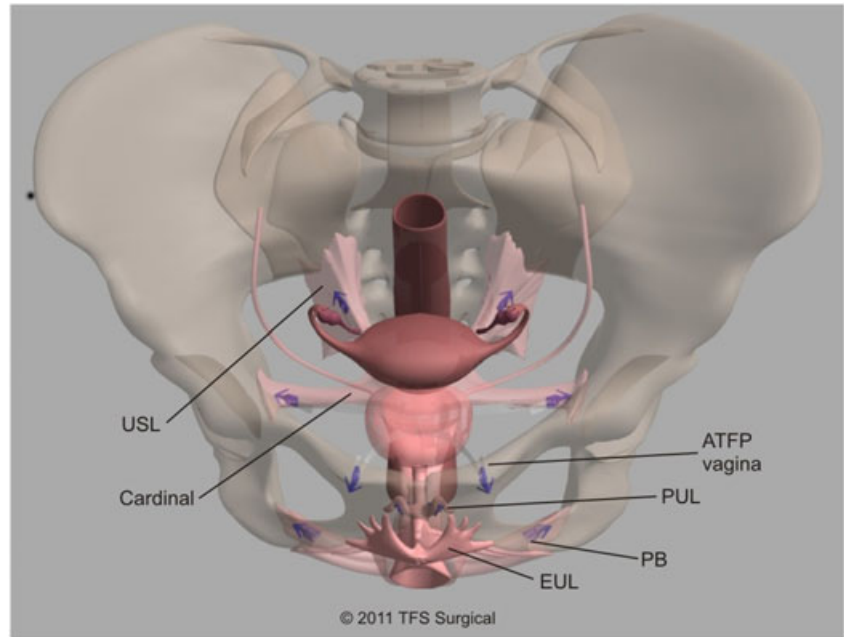

Figure 3 Restoration structural support of the pubourethral ligament (PUL). The anchor is inserted below the Cave of Retzius, into the origin of PUL. By permission Petros PE.[12]

Without exception, the TFS was used in all the operations described in this study. No other devices were used. We included all patients with third- or fourth-degree uterine/vaginal prolapse (POPQ classification). We excluded patients with serious comorbid conditions.

General TFS surgical technique

The surgical technique uses the same technique for all five TFS operations. The vagina is incised. The bladder or rectum is dissected off the ligaments as required. The ligament is identified. A tunnel is made through the ligament with Metzenbaum scissors. The applicator is inserted into the tunnel. The anchor is released. The application is repeated on the contralateral side and the tape is adjusted until tape looseness is removed and a resistance is felt. This indicates return of muscle tone in the muscles, which act on that ligament. The tape is cut and the vagina is closed.

For urinary stress incontinence, a midurethral TFS sling is applied to shorten and reinforce damaged pubourethral ligaments. The technique is retropubic. Like the TVT, it creates a neoligament in the exact position of the pubourethral ligament (Figs 1, 3).

For anterior wall support for cystocele repair (Fig. 1, and see videos in "Supporting information" 1), the TFS ATFP ('U-Sling') repairs a central/ lateral
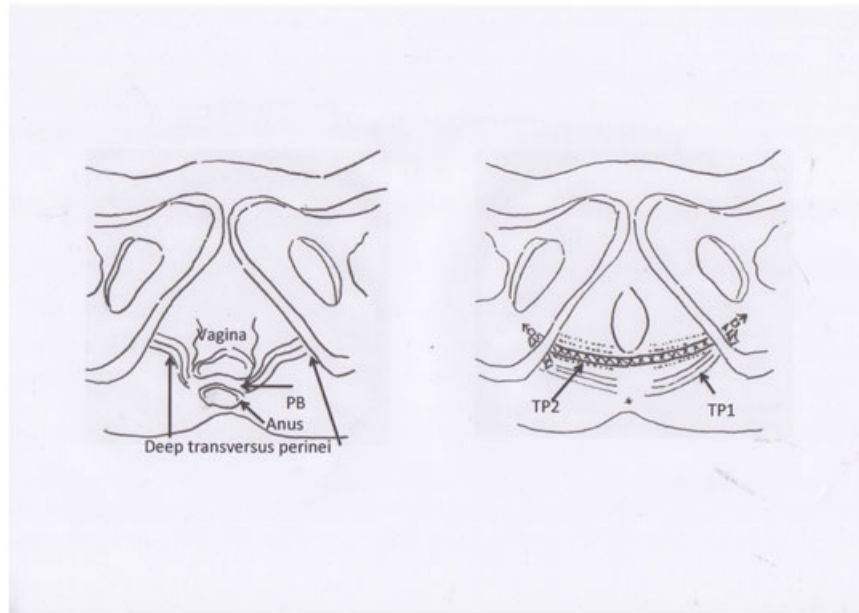
Figure 4 Tissue fixation system (TFS) perineal body (PB) repair. (a) There are two PB, laterally displaced allowing protrusion of rectocele. The PB are suspended from the pubis by the deep transversus perinei ligaments (TP), which insert behind the junction of the upper 2/3 and lower 1/3 of the descending ramus. (b) The TFS needs to penetrate through the TP directly behind the bone for adequate suspension of PB. TP1, position of TP in patients with descending perineal syndrome; TP2, restored position of PB and TP.

defect by reattaching the prolapsed distal vaginal wall to the origin of ATFP immediately above the pubourethral ligament. The cardinal ligament TFS repairs the high or transverse defect. It reattaches the prolapsed pubocervical fascia to the cervical ring, shortens and strengthens the cardinal ligament, and reattaches the proximally displaced ATFP (Delancey[14] reported displacement of the ATFP insertion from the ischial spine in >90% of patients with anterior vaginal wall prolapse.) onto the sidewall above and forward of the ischial spine. The evidence for this is the sudden deepening of the sulcus when the CL TFS is tightened.

Apical support for uterine/apical prolapse (Figs 1, 3) requires both cardinal and uterosacral ligament reconstruction. The cardinal TFS sling reattaches the uterus or apex laterally to the fascia of the sidewall skeleton. The uterosacral TFS attaches it posteriorly to the presacral fascia at the S3–4 level.

For anterior rectal wall support (Figs 1, 3, 4, and see videos in "Supporting information" 2), the uterosacral TFS attaches the cervix to the presacral fascia at the S3–4 level. Because it passes by the lateral wall of the rectum, the rectum is also reattached to the USL, constituting, in effect, a transvaginal rectopexy. At the level of the introitus, the reconstituted perineal body supports 50% of the posterior vaginal wall[15] and is the anterior anatomical support for the anus.[16,17]

Data acquisition, follow-up, and end-point measurements

Outcome measures were assessed at the individual patient level. At each 12-month follow-up, we carried out a full assessment for anatomical repair and symptom cure using specific criteria and the self-administered Integral Theory System Questionnaire.[11]

Criteria for a positive response

The response was considered positive if the following criteria were met.

1 Pain: Due to widely varying pain intensity, often from day to day, patients were asked to give a global self-assessed 80% improvement over the preoperative symptom at the 12-month visit.
2 Nocturia: Reduction from two or more episodes per night to one or zero.
3 Urge incontinence: Zero episodes of wetting prior to arrival at the toilet.
4 Fecal incontinence: Zero episodes of soiling prior to arrival at the toilet.

Statistical Analysis

Paired binary response data (per-patient presence/absence of a specific sign/symptom before vs after surgery) in the total study cohort were analyzed with a McNemar's test, with a null hypothesis of no treatment effect.[18]

The GraphPad Quickcalcs platform was used for this analysis (http://graphpad.com/quickcalcs/mcNemar1/). The sample size (https://www.statstodo.com/SSizMcNemar_Pgm.php) was deemed sufficient to assume a χ^2 distribution. The χ^2 was calculated with one degree of freedom.

Post-hoc estimation of the study power was performed, assuming an alpha error equal to 0.01 (https://www.statstodo.com/SSizMcNemar_Pgm.php). In all cases, the estimated power for this comparison exceeded 0.95 (Table 1).

To evaluate differences between the proportions of patients showing or not showing a specific sign/symptom when treated with TFS, the Z-ratio and the 95% confidence interval for the difference between independent proportions were calculated.[19] The VassarStats platform was used for this analysis (www.vassarstats.net).

Results

In 2009, 68 women underwent POP operations with 216 TFS adjustable minislings (3.2 per patient). Mean age was 70 years (45–89 years); mean parity 2.2 (range 0–6); and mean body mass index 24.2 (range 15.1–39.8).

The patients had multiple defects, including cystocele ($n = 61$), uterine prolapse ($n = 59$), and rectocele ($n = 35$), with at least one defect at stage 3 or 4 POPQ. Twenty-eight patients also had urinary stress incontinence. A paired analysis as regards anatomical cure and the fate of symptoms was performed (Table 1, Fig. 5).

Mean operating time was 87.9 min (39–160 min) and mean blood loss was 78 mL (7–379 mL). There were no major intraoperative complications and no bladder or bowel perforations. There was minimal postoperative pain as evidenced by early discharge from hospital and early return to normal activities: mean hospital stay was 0.8 days (0.2–3 days, with 32% being same-day discharge) and mean return to normal activities was 2.2 days (1–28 days). Two patients had transient dysuria that resolved within 24 h. One patient required postoperative catheterization for 4 days. Three patients were found to have vaginal adhesions at the postoperative visit. These were easily broken down digitally by vaginal examination.

Surgical failure was defined as any compartment prolapse for that patient at or beyond stage 2, according to the POPQ classification. Because total ligament repair of all prolapses was performed, a total approach to reporting the cure/failure rate was adopted. For example, the failure rate of 13% at 12 months refers to the number of patients with any compartment failure. Even one compartment failure different to those performed was deemed an operative failure.

The anatomical cure rate for POP (Table 1) was 49/62 (87.1%) at 12 months, 85.4% at 24 months, 85.4% at 36 months, 82.3% at 48 months, and 79.0% at 60 months.

Table 1 Five-year data from the first cohort of 68 patients

Time After TFS	Cure of prolapse	Cure of USI	Cure of urgency	Cure of nocturia	Cure of day time frequency	Cure of dragging pain	Cure of dysuria	Cure of fecal incontinence
12 months	62/68	29/31	30/31	17/18	30/32	13/14	35/38	16/18
$n = 68$	91.2%	93.5%	96.8%	94.4%	93.8%	92.9%	92.1%	88.9%
	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$
24 months	57/65	26/29	25/30	11/17	26/29	14/15	26/28	12/15
$n = 65$	87.7%	89.7%	82.3%	64.7%	89.7%	93.3%	92.9%	80%
	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$
36 months	48/58	20/23	23/24	14/23	27/30	9/10	25/26	6/7
$n = 58$	82.7%	86.9%	95.8%	60.9%	90%	90%	96.2%	85.7%
	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.004$	$P < 0.001$	$P < 0.04$
48 months	42/50	21/23	18/20	8/17	13/19	6/6	22/23	5/5
$n = 50$	84%	91.3%	90%	47.1%	68.4%	100%	95/6%	100%
	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.01$	NS	NS	NS	NS
60 months	49/62	23/28	22/24	11/19	19/36	6/6	28/32	5/5
$n = 49$	79%	82%	91.7%	58%	52.8%	100%	87.5%	100%
	$P < 0.001$	$P < 0.001$	$P < 0.001$	$P < 0.003$	$P < 0.001$	$P < 0.04$	$P < 0.001$	NS

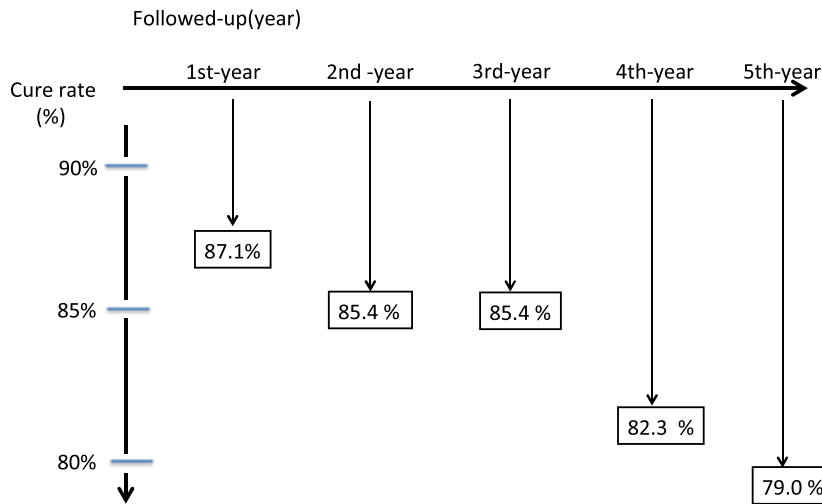NS, not significant; USI, urinary stress incontinence.

Figure 5 Anatomical cure rates after TFS: 1–5 years, surgical failure was defined as any compartment prolapse for that patient at or beyond stage 2, according to the Pelvic Organ Prolapse Quantification classification. The anatomical cure rate for pelvic organ prolapse was 49/62 (87.1%) at 12 months, 85.4% at 24 months, 85.4% at 36 months, 82.3% at 48 months, and 79.0% at 60 months.

Other than perineal body, the cumulative 5-year erosion rate varied between 0% and 1.7% for all ligaments: distal ATFP ligament TFS, 0/61 (0%); cardinal ligament TFS, 1/61 (1.7%); uterosacral ligament TFS, 1/59 (1.7%); and pubourethral ligament, 0/28 (0%). The cumulative erosion rate for TFS perineal body surgery over 5 years was 25.7% (9/35). This subsequently reduced to 2.6% following alteration of technique: care was taken to penetrate the deep transversus perinei ligament, which suspends the perineal body to the descending rami of the pubic bones. All erosions were trimmed as an office procedure. There was no prolapse recurrence related to trimming of the tape. There were two longer-term postoperative complications – ileus due to tape in the abdominal cavity and adhesion of the mesentery and USL mesh tape – 3 and 15 months after the operation, treated operatively by laparotomy and adhesiolysis, respectively. Omentum was dissected from the tape in case 1 and between the small bowel and the tape in case 2. Both patients recovered well without prolapse recurrence. These complications occurred in the first cohort of patients and were attributed to a faulty surgical technique in which the uterosacral ligament was penetrated from lateral to medial. The technique was changed, penetrating the uterosacral ligament from medial to lateral, ensuring the tape was extraperitoneal at all times. There have been no further complications of this type.

Discussion

This is the first long-term study of a minisling used for total ligament repair of major POP. This is also the first study to demonstrate that symptoms such as urgency, nocturia, chronic pelvic pain, dysuria, and fecal incontinence are potentially curable by repair of five suspensory ligaments and remain substantially cured at 5 years. The 5-year cure rates for urinary stress incontinence, urgency, nocturia, and frequency were 82%, 91.7%, 58%, and 52%, respectively. We consider this a major result of this study and one that is especially applicable to an ageing population such as exists in Japan today. One key finding of this study was that ligament repair with a TFS tape without any vaginal surgery whatsoever was sufficient to achieve a 79% anatomical cure rate for third- and fourth-degree POP over 5 years. Another key finding was that total repair was well tolerated with this system in this cohort of patients with a mean age of 70 years. We attribute this to the minimally invasive nature of the surgery: the use of tape to repair damaged ligaments and no excision of the vagina.

The biomechanics of this method when applied for repair of POP were described in 2006[8] as follows: A 7-mm-wide mesh tape is applied transversely and this supports the vagina, much like a ceiling plaster board is attached to a ceiling beam. Whereas a large mesh sheet may limit posterior stretching, a transverse tape does not. Furthermore, the mesh tape is attached superiorly by a soft tissue anchor, the TFS, which greatly diminishes the surfacing of the tape, a major cause of erosion.

Our data support the concept that ligaments are the prime factor in organs support.[7] The vagina is a weak membrane, with an estimated breaking strain of approximately 50 mg/mm^2,[20] whereas ligament-breaking strain is approximately 300 mg/mm^2.[20] It follows from this that it is the ligaments that attach the vagina and other organs to the skeleton, and that it is looseness in the ligaments that causes POP.[10] According to the

original theory,[10] the function of the vagina is to provide elastic support to the organs and to transmit the force of the muscle vectors. Thus, a loose PUL may cause urinary stress incontinence;[4] dislocation of the vagina from the ATFP and cardinal ligament/cervical ring explains bulging of the anterior vaginal wall (cystocele); elongation of CL and USL will cause uterine or apical prolapse; and separation of the two parts of the perineal body will allow the rectum to protrude (rectocele; Fig. 4). The TFS simultaneously shortens and strengthens the original ligaments, reattaches them to their original insertion points on the skeleton[6–8] (Figs 1–4) and creates an artificial collagenous neoligament. In the process, prolapse and symptoms are both cured.

Tape erosion

In the 2009 cohort, the anchors were inserted into the perineal body itself, not into the deep transversus perinei ligament as prescribed (Fig. 4).[16,17] When the tape penetrated the deep transversus perinei ligament (Fig. 4), the erosion rate fell to 2.6%. In contrast, the PUL, ATFP, CL, and USL tapes were correctly inserted and did not surface, hence the low erosion rate of 0–1.7%.

It is generally acknowledged that the larger and heavier the mesh, the more tissue reaction there will be and the more likely it is to erode. In this context, the low erosion rate for anterior wall ligament repair (1.7%) could be explained by the low volume of mesh implanted, the small narrow (7.5-mm wide) strips of mesh tape, and most importantly, suspension by the anchor.

This hypothesis excludes the florid immunological effect of tape observed both in the human and animal.[5,7]

Another related question that arises is: 'Why did we use mesh tapes as a primary repair?' The prevalence of re-operation after primary pelvic reconstructive surgery reported in some articles has been reported to vary between 43% and 58%.[21,22] Given the mean age of our patients (70 years), the poor quality of their aged tissues and previous poor results in our unit from native tissue repair, we felt that it was important to reinforce the tissues in the most minimally invasive way.

Because of its minimal nature, we have found the TFS method to be very suitable for the age group in which it was applied, women with a mean age of ≥70 years, often with comorbid conditions. Our results are consistent with those recently reported by Sekiguchi et al.,[23] though our surgery was not performed under local anesthesia.

It is our view that the wrong technique was the cause of implantation of the tape into the peritoneal cavity, causing ileus in two early cases. The technique has subsequently been modified. Greater care is now taken to dissect the enterocele more completely, so as to reveal the USL more clearly. Also, the channel is made through the ligament itself. This gives an extra layer of protection against entry to the peritoneum. There have been no such complications in more than 1000 subsequent implants. These two complications emphasize the fact that although this is minimally invasive surgery, major complications may occur. Like the major complications noted with TVT, the problem is almost invariably caused by incorrect surgical technique.

Shortening and strengthening the ligaments alone may be sufficient for the cure of third- and fourth-degree POP. The technique is minimal, suitable for elderly women and effective in the longer term.

Disclosure

The authors declare that they have no conflicts of interest.

SUPPORTING INFORMATION (VIDEO OF THE TFS SURGERY)

The video demonstrates the technique of the senior author, Hiromi Inoue, in performing the TFS surgery for major POP. The ligaments are identified, a tunnel is made along the track of the ligament. The anchor and tape are inserted with an applicator. The tape is tightened until resistance is encountered. The ends are cut and the vagina is sutured.

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Supporting information

Additional Supporting Information may be found online in the supporting information tab for this article.

Video S1. The tissue fixation system (TFS) for *arcus tendineus fasciae pelvis* ('U-Sling')

Video S2. The tissue fixation system (TFS) for perineal body sling