The Tissue Fixation System workshop was held in Yokohama as part of the annual meeting of the International Society for Pelviperineology (October 23rd 2012).

Introduction to the TFS Workshop ISPP 2012 Yokohama

PETER PETROS

Case Western Reserve University, Cleveland OH

The workshop began with brief presentation of pelvic floor anatomy, in particular, the role of connective tissue by Bernhard Liedl, and function and dysfunction by Peter Petros. This was followed by the reporting of results for the TFS by Drs Sekigichi, Inoue, Haverfield and Liedl. The presentations are in the form of abstracts.

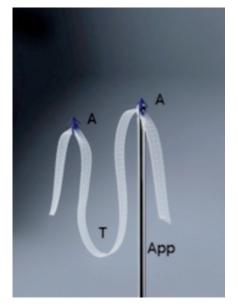


Figure 1. – The current Tissue Fixation System (TFS). Applicator (App) tape (T) and anchor (A). The tape is 7mm wide type 1 macropore polypropylene. There is a one way tensioning system at the base of the anchor.

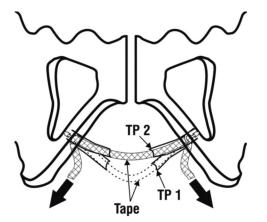


Figure 2. – Schematic view of repair of prolapsed and laterally separated perineal bodies. The perineal bodies are elevated and approximated by the one-way tensioning action of the Tissue Fixation System sling. TP1= prolapsed deep transverse perinei muscles attached to posterior surface of the descending ramus of the pubis. TP2 is the restored position of deep transverse perinei.

The Tissue Fixation System (TFS Surgical, Adelaide, Australia), is a universal minimally invasive single incision tensioned tape system designed to reinforce damaged pelvic ligaments/connective tissues (Figure 1). It reinforces the perineal body, (Figure 2), and 4 main suspensory ligaments, pubourethral, (Figure 3), ATFP, cardinal & uterosacral (Figure 4).

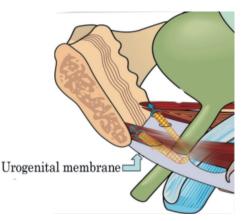


Figure 3. – The TFS midurethral sling. The anchors penetrate the urogenital membrane ("perineal membrane") and attach below the Space of Retzius into the insertion point of the pubourethral ligaments.

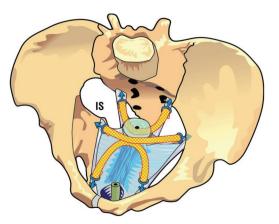


Figure 4. – Site and position of the slings. From front to back: TFS U-Sling tape for repair of central and lateral defects, TFS cardinal ligament tape for repair of transverse defect (high cystocele, uterine/apical prolapse) and TFS uterosacral ligament tape for repair of uterine/apical prolapse, enterocele and high rectocele. Perspective: Patient in standing position, looking into the pelvic brim. The U-Sling is inserted medial to the obturator fossa, and more cranially than a TOT sling. The cardinal ligament TFS penetrates the ATFP 2cm above and distal to the ischial spine (IS) and inserts into the muscles adjacent to the ATFP. The uterosacral ligament (USL) sling inserts into the USL approximately 2cm distal to its insertions into the sacrum.

Connective tissue of the pelvic floor: definitions and topografic anatomy

BERNARD LIEDL

Pelvic Floor Centre, Munich, Germany

INTRODUCTION

My lecture today aims to demonstrate the topografic anatomy on which the Integral System of pelvic floor repair is based.

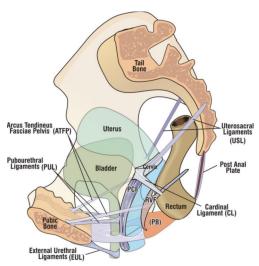


Figure 1. – The principal suspensory connective tissue structures of the vagina, sagittal view, standing position.

The principal suspensory connective tissue structures of the vagina structures are Extraurethral ligament (EUL); Pubourethral ligament (PUL); Arcus tendineus fasciae pelvis (ATFP) Cardinal ligament (CL)/Cervical ring; Uterosacral ligament (USL); perineal body (PB). In addition, we have the anterior vaginal wall represented by suburethral vagina (hammock), fibromuscular layer of upper wall (PCF) and posterior vaginal wall, whose fibromuscular layer is represented by RVF (Fascia of Denonvilliers).¹

The Pictorial Algorithm, (Figure 2), relates symptoms to damaged pelvic floor connective tissue structures. The 3 zones of the Algorithm are natural divisions of the ligament groupings and their causality of symptoms.

ANTERIOR ZONE (urethral meatus to bladder neck) Extraurethral ligament (EUL) Hammock Pubourethral ligament (PUL)

MIDDLE ZONE (bladder neck to cervix) Pubocervikal fascia (PCF) Arcus tendineus fasciae pelvis (ATFP) Cardinal ligament/Cervical ring (CX Ring)

POSTERIOR ZONE (cervix to anal canal) Uterosacral ligament (USL) Rectovaginal fascia (RVF) Perineal body

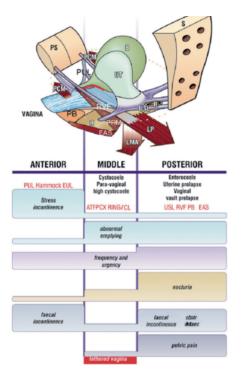


Figure 2. – Connective tissue alterations at pelvic floor which can be surgically cured as per the Integral Theory "laxity in the vagina or its supporting ligaments".¹ The "Hammock", Pubocervical fascia and Rectovaginal fascia represent the fibromuscular layer of the vagina.

ANTERIOR ZONE

The anterior zone extends from the urethral meatus to bladder neck. It comprises 3 main structures , all of which impact on the urethral closure mechanisms.

Extraurethral ligament (EUL) Suburethral Vaginal Hammock (H) Pubourethral ligament (PUL

PUL is the principal ligament for continence during effort. EUL and the suburethral vaginal hammock also assist in closure during effort, but their main function is sealing the urethra

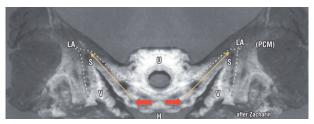


Figure 3. – Coronal section of the suburethral vaginal hammock S = sulcus - the attachment to the LA (anterior pubococcygeus muscle section "PCM"); U = urethra; V = vagina. The arrows indicate the dirctional movements of the muscle closure forces. From Robert Zacharin² by permission.

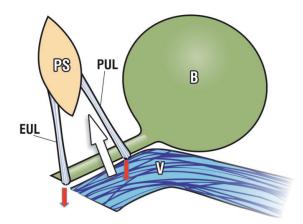


Figure 4. – The anterior zone structures sagittal view- sitting position EUL suspends the vaginal hammock to the anterior surface of pubic bone and PUL suspends the hammock to the posterior surface. The large arrow indicates how the PCM, figure 3, stretches the hammock forwards to close the distal urethra.³

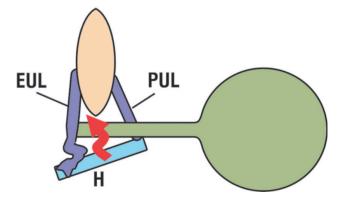


Figure 5. – A lax EUL prevents sealing of the urethra, so that even in patients who have been cured of urinary stress incontinence with a midurethral sling, urine can leak out insensibly. The hammock "H" falls open like a trapdoor. The classical symptom of EUL/hammock laxity is urine loss on sudden minor movement usually associated with a feeling of a"bubble" escaping.⁴

MIDDLE ZONE

The middle zone extends from bladder neck to cervix. It comprises 3 connective tissue structures.

Pubocervikal fascia* (PCF)

Arcus tendineus fasciae pelvis (ATFP)

Cardinal ligament/Cervical ring (CX Ring)

PCF is the musculofascial layer of the anterior vaginal wall. The vaginal epithelium has very little strength.

* The existence of RVF is controversial. Like the PCF, it can be viewed as the musculofascial layer of the posterior vaginal wall.

POSTERIOR ZONE

The posterior zone extends from the cervical ring to the perineal body. It comprises 3 structures.

Uterosacral ligaments

Rectovaginal fascia* "RVF" (Denonvilliers). Perineal body

CL = Cardinal ligament. This diagram is not quite correct as it does not show the important reflection of CL to the anterior surface of the cervix. The Uterosacral Ligaments are shown inserting between S2 and S4 and into the posterior ring of cervix.

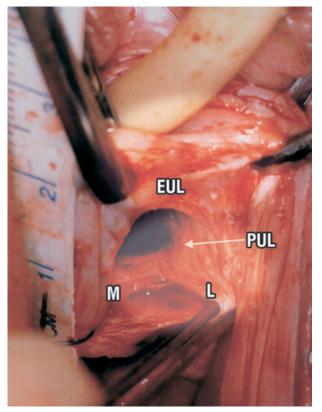


Figure 6. – Live anatomy of the anterior zone- paraurethral incision.⁵ The EUL is seen attaching the external urethral meatus to the anterior part of the pubic bone. PUL descends from behind the pubic symphysis to divide into 2 parts, medial, attaching to the midurethra and lateral attaching to m. puboccygeus.

Perineal body

The perineal body is 4-5 cm long. It separates the posterior vaginal wall from the anterior rectal wall and anus. It is composed of a central fibromuscular portion and two lateral portions attached to the central portion medially, and anterior and posterior parts of the descending pubic ramus laterally.

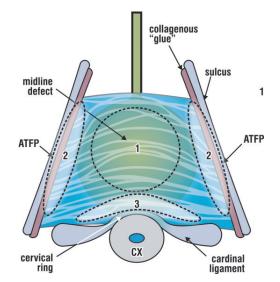


Figure 7. – The anatomy of the middle zone- schematic view into the anterior vaginal wall.⁶ The cardinal ligament is seen inserting into the anterior part of the cervical ring; The vagina is attached proximally to the cervical ring "3", and laterally attached to ATFP (sulcus) "2". CX = cervix. Broken pubcervical fascia causes a central or midline defect "1".

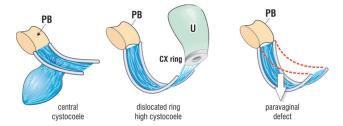


Figure 8. – The 3 types of cystocele. Schematic 3D sagittal view, from left to right, central defect, caused by overstretching of the PCF so that the bladder stretches the extended membrane downwards; dislocation of PCF and cardinal ligaments from the cx ring so that the vaginal wall dislocates downwards like a trapdoor "high" or "transverse" cystocele (transverse defect); damaged ATFP or more likely, lateral vaginal attachment to ATFP, "lateral defect". This is almost invariably associated with a central defect.

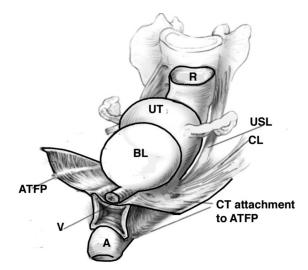


Figure 9. – Schematic 3D view of the middle zone pelvic connective tissues from in front and above. The paracolpium attaches the anterior vaginal wall to ATFP. Rupture causes the lateral defect. Also the attachments of cardinal (CL) and uterosacral (USL) ligaments are shown. V = vagina; R = rectum; A = anus; UT = uterus. (after Corton 2009)⁷

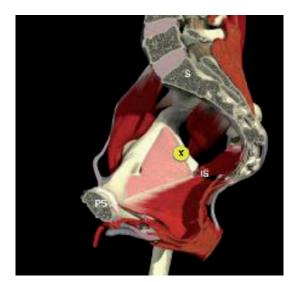
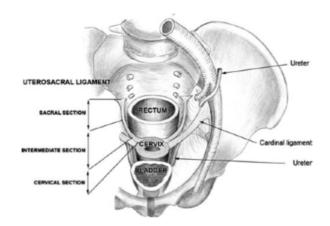


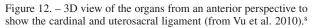
Figure 10. – The insertion point 'X' of cardinal ligament 2cm above the ischial spine 'IS'. Sagittal view into the left hemipelvis. The cardinal ligament is best felt rectally: stretch the cervix towards the introitus; identify the ischial spine with a finger tip; the cardinal ligament is felt 2cm above the ischial spine as a horizon-tal band extending from the lateral pelvic wall medially.



Figure 11. – Proof of causation of cystocele by dislocated cardinal ligaments by 'simulated operation'.⁶

Left 3rd degree cystocele, Allis forceps applied to dislocated cardinal ligaments (CL) which are identified as a "drooping" of the vagina on the lateral walls of the cervix. Right: Allis forceps brought to the midline, at the same time, reducing the cystocele. This maneuver demonstrates the essential role of the CL in supporting the proximal vagina as it inserts into the anterior cervical ring.





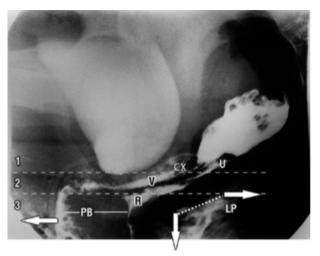


Figure 13. – Perineal body (PB) saggital perspective. Arrows represent directional striated muscle forces acting on the pelvic organs. V = vagina; R = rectum; U = insertion of USL. 1,2,3 represent levels of organ support.

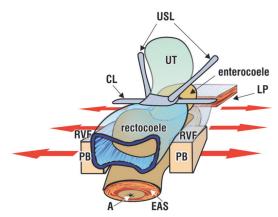


Figure 14. – Pathogenesis of rectocele Schematic 3D view of the vagina and perineal bodies from the introitus.⁶ The perineal bodies (PB) have been separated allowing the rectocele to protrude. The uterosacral ligaments have also been separated allowing protrusion of enterocele and high rectocele. The rectovaginal fascia (RVF) attached to PB, USL and levator plate muscles (LP). A = anus; EAS = external anal sphincter.

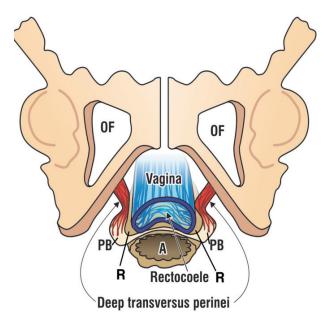


Figure 15. - The anatomy of low 3rd degree rectocele "perineo-cele".

The rectum "R" everts forward and spreads laterally to attach densely to the laterally displaced perineal bodies "PB". The arrows indicate the deep transversus perinei, the principal attachment of PB to the posterior surface of the descending ramus. In the surgical operation, anchors attached to an adjustable sling penetrated the "deep transversus perinei" muscle: one-way tensioning elevated both "PBs" and brought them closer to the midline, obliterating the rectocele herniation.

REFERENCES

- 1. Petros PE. The female pelvic floor. Chapter 3, diagnosis Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed , 2010; 77-117.
- 2. Zacharin RF (1963) A suspensory mechanism of the female urethra. J Anat 97:423-427.
- Petros PE, Ulmsten U. An inte-gral theory of female urinary incontinence. Acta Obstet Gynecol Scand 1990; 69 (Suppl 153):1-79.
- Petros PE, Richardson PA, Prepubic TFS sling in curing nonstress leakage following complete cure of stress incontinence by a midurethral sling, Pelviperineology 2007; 27:4.
- Petros PE. The pubourethral ligaments-an anatomical and histological study in the live patient, Int J Urogynecology 1998; 9: 154-157.
- Petros PE. Reconstructive Pelvic Floor Surgery According to the Integral Theory. The female pelvic floor. Chapter 4: Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed, 2010; 118-218.
- Corton MM. Anatomy of Pelvic Floor Dysfunction. Obstet Gynecol Clin N Am 2009; 36:401-419.
- Vu D, Haylen BT, Tse K, Farnsworth A. Surgical anatomy of the uterosacral ligament. Int Urogynecol J. 2010; 21:1123-1128.

Correspondence to: bernhard.liedl@t-online.de

Stress urinary incontinence, urgency, abnormal emptying and nocturia caused by connective tissue laxity

PETER PETROS

Case Western Reserve University, Cleveland OH

"Stress, urge and abnormal emptying are mainly caused by lax suspensory ligaments inactivating striated pelvic muscle forces".^{1,2}

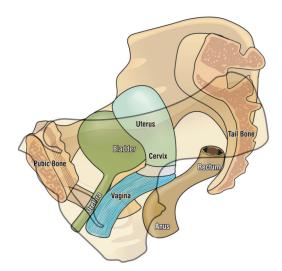


Figure 1. – Figure 1. Bladder, Uterus and Rectum function as storage containers.

•Urine •Foetus •Faeces

Their outlet tubes are •Urethra •Vagina •Anus

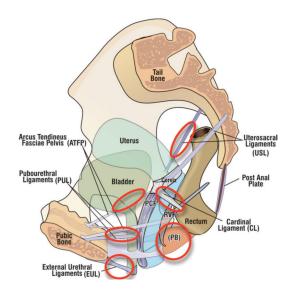


Figure 2. – Five Ligaments suspend the organs from above and perineal body supports them from below.³

External urethral ligaments attach external meatus to anterior surface of pubic bone. Pubourethral ligament attach midurethra and pubococcygeus muscles to pubic bone. ATFP supports the anterior vagina. Cardinal ligaments insert into the anterior cervix, also supporting anterior vaginal wall. Perineal body supports posterior vaginal wall, anterior rectal wall and external anal sphincter. The anterior vaginal wall which supports the bladder/urethra. The posterior vaginal wall which supports the anorectum.

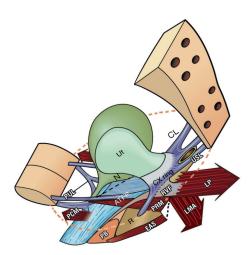


Figure 3. – Three Muscle forces pull against the suspensory ligaments.

External striated muscles (arrows) pull against the suspensory ligaments PUL and USL to close and open the urethral and anorectal tubes (broken lines). Any laxity in the ligaments translates to weaker closure forces⁴ (incontinence), or weaker opening forces (evacuation difficulties).

Suspensory ligaments PUL = pubourethral; ATFP = arcus tendineus fascia pelvis; <math>CL = cardinal; USL = uterosacral; PB = perineal body.

Striated muscles PCM = m. pubcoccygeus; LP = m. levator plate; LMA = conjoint longitudinal muscle of the anus. B = bladder; N = stretch receptors; Ut = uterus; R = rectum; RVF = rectovaginal fascia; cx = cervix.

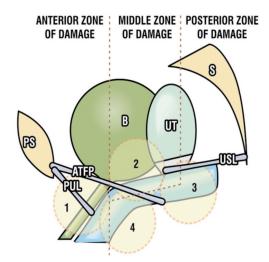


Figure 4. – Pathogenesis of pelvic organ prolapse.⁵ The circles represent the foetal head stretching the ligaments and perineal body as it descends down the birth canal.

1. PUL damage= stress incontinence; - 2. ATFP/CL damage = cystocele; 3. USL damag = uterine prolapse, enterocele; 4. perineal body damage= rectocele.

Multiple injuries may occur, some subclinical, explaining subsequent prolapses.

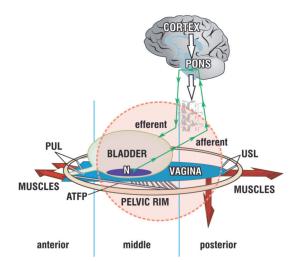


Figure 5. - Pathogenesis of bladder overactivity.

If the foetal head overstretches the vagina and ligaments, the ensuing laxity may not allow vagina to stretch and support stretch receptors "N". N fires off prematurely,⁶ activating the micturition reflex, resulting in urgency, frequency, nocturia.

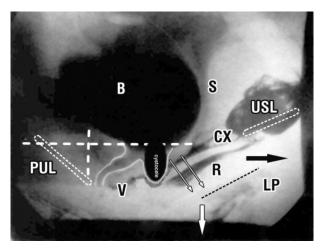


Figure 6. – Pathogenesis of bladder evacuation problems Cystocele and lax USLs inactivate the posterior vector forces (arrows) which open out the posterior urethra during micturition. As the internal resistance to flow is inversely proportional to the 4th power of the radius (5th power with non-laminar flow), even a minor laxity may cause significant evacuation problems.

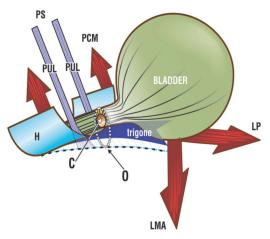


Figure 7. – Pathogenesis of urinary stress incontinence.⁷ A loose pubourethral ligament (PUL) means that PCM muscles cannot "grip" to immobilize the suburethral vaginal hammock "H". LP/LMA pull open the posterior urethral wall vastly decreasing the internal resistance to flow. Urine may leak with effortstress urinary incontinence.

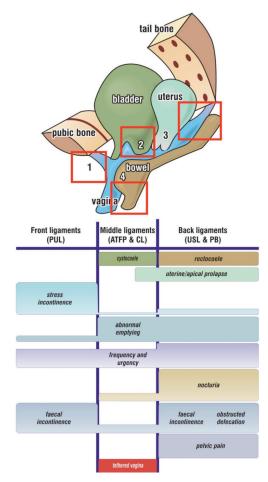


Figure 8. – Diagnosis-Simplified Pictorial Diagnostic Algorithm.⁵ Relates specific symptoms to lax (damaged) ligaments as seen in figure 4. Labelling as in figure 4.

Where there are multiple sources of abnormal symptoms, symptom grouping is used to assess site of ligament damage. All etiologies are laxity related except for the "tethered vagina syndrome", where excessive tightness in the bladder neck area of vagina (iatrogenically induced scar tissue) tethers the opposite muscle forces, so that the stronger posterior forces, overcome the anterior forces (PCM) to stretch open the urethra, much as occurs in USI, figure 7. The characteristic symptom is sudden massive urine loss immediately on getting out of bed in the morning.^{3,5}

REFERENCES

- Petros P., Ulmsten U. An integral theory of female urinary incontinence. Acta Obstet Gynecol Scand 69 1990; (Suppl 153):1-79.
- Petros P., Ulmsten U. An integral theory and its method for the diagnosis and management of fe-male urinary incontinence. Scand J Urol Nephrol Suppl. 1993; 153:1–93
- Petros P. Chapter 4: Reconstructive Pelvic Floor Surgery According to the Integral Theory. The female pelvic floor. Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed , 2010; pp. 118-218.
- 4. Gordon AM, Huxley AF, Julian FJ The variation in isometric tension with sarcomere length in vertebrate muscle fibres. J Physiol. 1966; 184:170-192.
- Petros P. Chapter 3, Diagnosis The female pelvic floor. Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed , 2010; pp 77-117
- 6. Petros P and Ulmsten U. Bladder instability in women: A premature activation of the micturition.
- reflex. Neurourology and Urodynamics 1993; 12, 235-239.
- Petros P, Von Konsky B, Anchoring the midurethra restores bladder neck anatomy and continence, Lancet 1999; 354: 9193: 997-998.

Correspondence to: pp@kvinno.com

Mid-urethral TFS sling operation for urodynamic SUI in an outpatient clinic: 3 year results

YUKI SEKIGUCHI,¹ YOKO AZEKOSHI,¹ MANAMI KINJYO,¹ YOSHIKO MAEDA,¹ YOSHIKO FUJISIMA,¹ KAORU KAWAJI,¹ HIROMI INOUE,² YOSHINOBU KUBOTA³

Yokohama Motomachi Women's Clinic LUNA

²Urogynaecology Center, Shonan Kamakura General Hospital ³Department of Urology, Yokohama City University Graduate School of Medicine

INTRODUCTION

The TFS (Tissue Fixation System) was reported in 2005 by Petros PE.

Like the TVT, the TFS works by creating a foreign body collagenous tissue reaction which reinforces weakened puburethal ligaments. However, TFS has very low risk of bladder or intestinal perforation and hematoma in the retropubic space.

The 4 pronged anchor has a mode of action like a grappling hook, while at the base, a one-way tensioning has the unique quality of restoring laterally displaced ligaments and fascia to the correct anatomical position.

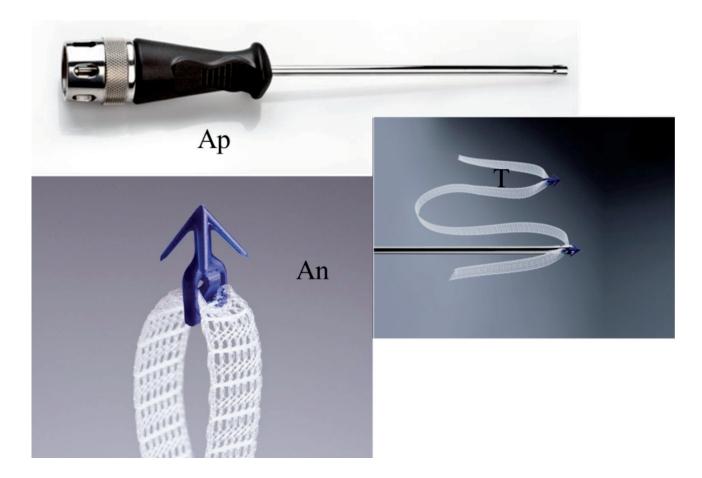


Figure 1. - The TFS (Tissue Fixation System): the applicator (Ap), anchor (An) and lightweight non-stretch TFS tape "T".

AIMS OF THE STUDY

To test the feasibility of using the TFS to perform a midurethral sling on a middle-term basis for urodynamic SUI in a free-standing outpatient facility.

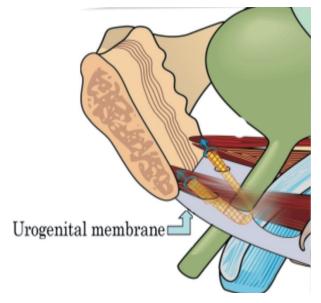


Figure 2. – The TFS midurethral sling. The anchors penetrate the urogenital membrane and attach below the Space of Retzius into the insertion point of the pubourethral ligaments immediately behind the perineal membrane.

MATERIAL AND METHODS

We performed 44 mid-urethral TFS sling operations between December 2006 and March 2008.

All patients had positive cough stress tests, and residual urines were less than 10 ml. We evaluated the patients at 1 year after the operations.

Pre-operative data

	Mean	± SD
Age	58.2	+/- 11.9
24 hr pad test	108 gm +/-	259 gm

- Average BMI is 23.57±12.03.
- Menopause rate is 61.4%.
- They had no previous urogynecologic surgery and no pelvic organ prolapse.

, CD

Pre-operative Urodynamic data

	Mean	$\pm 3D$
ALPP		
(abd leak pt pressure)	81.5 cm H ₂ C	$0 \pm 34.1 \text{ cm H}_2\text{O}$
MUCP (Maximum		
urethral closure pressure)	33.1 cm H ₂ C	$0 \pm 15.7 \text{ cm H}_2\text{O}$

 There was no detrusor overactivity recorded on urodynamic testing.

24.5 min ± 7.7 min

17.7 m l ± 21.7 ml

The definition of ISD : ALPP <65cmH2 0 or MUCP<20cmH2 0.

According to this definition, 15(34.1%) pts. were diagnosed as ISD out of 44 pts.

Operating data

Mean operating time include local anesthesia Mean blood loss

Mean staying time	5.56 hours ± 1
in the clinic	

Five patients discharged with indwelling catheter but voided with no difficulty within 2 days.

.06

RESULTS

Outcome after 1 year

Outcome after 3years

Success (84%) - 37/44 cases

Failure (16%) -	7/44 cases
In failure 4 cases at the	first year, we re-operated

In failure 4 cases at the first year, we re-operated on all 4 patients with another TFS midurethral sling.

- All 4 patients became continent after re-operation.
- Among 3 patients who were new failure cases, 1 patient had a re-operation and became continent after re-operation.

The change of operation (1)

- C3 We have changed volume of local anesthesia after an experience of anchor entry into bladder for enough liquid abruption.

⇒0.15% xylocaine 130 ml

The change of operation (2)

- CS Two failure cases were included in the first 5 cases. Therefore the learning curve of mid-urethral TFS operation may reach a sufficient level at about 5 cases.
- C3 After that, We met a failure case every $20 \sim 30$ cases.
- C3 Then we checked the length of urethra before operation and placed under the mid-urethra accurately.

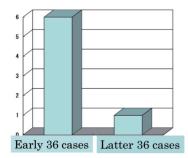


Figure 3. – The number of failure cases between the early and the latter phases: the success rate is improved from the early 36 cases to the latter 36 cases.

CONCLUSIONS

The 3 year success rate is almost as same as the TVT. The TFS mid-urethral sling operation is a simple, safe, and effective operation, and can be done without difficulty in a free standing clinic as an outpatient procedure.

REFERENCE

1. Yuki Sekiguchi et al.: Journal of Urology 2009;182, 2810-2813.

Correspondence to: Yuki Sekguchi, MD, phD Yokohama Motomachi Women_s clinic LUNA 3-115 Hyakudan-kan, Motomach, Nakaku, Yokohama 231-0861, JAPAN dumbo-ys@d9.dion.ne.jp

Tissue Fixation System (TFS) sling to repair pelvic organ prolapse: complications and outcome

HIROMI INOUE,¹ YUTAKA KOHATA, TUYOSHI KUSAKA,¹ TAKANORI FUKUDA,¹ MIKA MONNMA,¹ MIKI OOBAYASHI,¹TOMOYUKI ICHIDA,¹ YOSHIE UZAWA,¹ SIHO SUZUKI,¹ YUUNA TOYAMA,¹ YUKI SEKIGUCHI²

¹ Obstetric and Gynaecology Department and Urogynaecology Center, Shonan Kamakura General Hospital

² Yokohama Luna Ladys clinic

INTRODUCTION

There is rapid ageing of the Japanese female population. In September 2008, women age 65 and older accounted 16.35 million in Japan. In September 2012, women age 65 and older accounted 17.59 million, an increase of 7.6% in 4 years. Because of the ageing process, an increasing number of patients are developing pelvic floor laxity. Because of the presence of many collateral health problems, all of which vastly increase the risks of surgery, minimally inva-

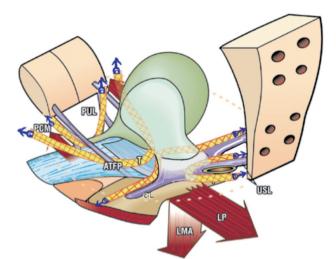


Figure 1. – TFS repair of 4 main suspensory ligaments, pubourethral (PUL) ATFP, cardinal (CL), uterosacral (USL) and perineal body (PB).

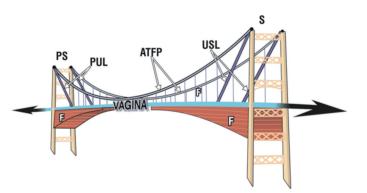


Figure 2. – The ligaments support the pelvic floor in the manner of a suspension bridge.

The muscle forces (arrows) stretch the vagina against the suspensory ligaments which attach to bone (PS = pubic symphysis; S = sacrum). The TFS strengthens the ligaments thereby restoring the muscle forces which support, open and close the organs.⁵

sive operations are required for safety and quality of life. In 2005, a new minimally invasive universal system for repair of pelvic organ prolapse (POP) and urinary stress incontinence (USI) was reported. For the first time, a high cure rate was reported for both POP and a wide range of pelvic floor symptoms by repairing 4 main suspensory ligaments, pubourethral (PUL) ATFP, cardinal, uterosacral and perineal body.¹⁴ The basis for these operations was the Integral Theory and its diagnostic and surgical applications.

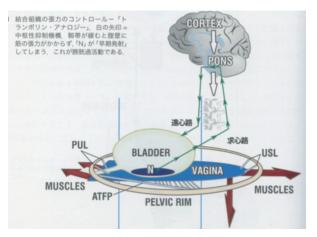


Figure 3. – The muscles stretch the vaginal membrane against competent ligaments to support the stretch receptors 'N', thereby controlling urgency. Lax suspensory ligaments may not allow the muscles to tension the membrane; 'N' fires off prematurely sending afferent impulses to the cortex which are perceived as urgency.⁵

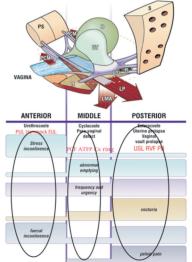


Figure 4. – The pictorial algorithm uses specific symptoms to indicate which ligaments/connective tissue structures have been damaged. 6

THE FIRST SURGERY OF TFS IN JAPAN

Professor Petros was invited to the 13th Annual Meeting of the Neurogenic Bladder Society of Japan in 2006. The first live surgery of TFS in Japan was performed in September 2006 under the aegis of the Japanese Society for Pelvic Floor Medicine.

Advantages of the TFS sling

- 1. Antero-posterior elasticity is largely maintained
- 2. Less risk of erosion, fistula, or organ adherence
- 3. The one-way sling allows lax ligaments and fascia to be tightened, an essential step for restoration of abnormal symptoms and function.

AIM OF THE STUDY

To evaluate the effectiveness ,complication and safety of Tissue Fixation System (TFS) surgery in

women with pelvic organ prolapse.

MATERIALS AND METHODS

Operations using the TFS anchor system were performed on 337 women aged between 36 to 85 year (average 68.3) for grade 3 or 4 pelvic organ prolapses (301 uterine prolapses and 37 vault prolapses) between October 2007 to July 2012 inclusive. In this operation, the TFS applicator® was used. This instrument has two polypropylene plastic anchors attached to an adjustable non-stretch multifilament (from October 2007 to December 2008) and monofilament (from January 2009) polypropylene mesh tape. The TFS sling operations, (since modified), were originally performed as reported by Petros & Richardson. The TFS sling was applied in 5 main sites, (U sling for ATFP, Cervical sling for cardinal ligament repair, USL-sling and Perineal body sling). In this operation, the TFS applicator® was used. This instrument has two polypropylene plastic anchors attached to an adjustable non-stretch multifilament (from October 2007 to December 2008) and monofilament (from January 2009) polypropylene mesh tape, Table 1.



Figure 5. – The TFS applicator (AP) and anchor (A). T = macropore monofilament tape. At the base of 'A' is a system which allows one-way directional tensioning of the tape.

TABLE 1. - TFS patients (337 persons): demographics.

Mean	Range
68.3.0	36-85
24.6	18.3-33.2
2.8	1-6
	68.3.0 24.6

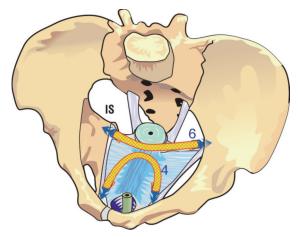


Figure 6. – Repair of cystocele with TFS Cardinal ligaments sling and U-Slings.

TFS Cardinal ligament sling. A tape is placed 1 cm above the fold of the bladder, and insert into the fibromuscular tissues beyond the sulcus 2cm above the ischial spine.

TFS U-Sling. A tape is placed approximately 3 cm above the fold of the bladder. The anchors penetrate the collagenous tissue near the insertion of ATFP.

In both, the tapes are tightened to support the anterior vaginal wall much in the manner of a ceiling joist.

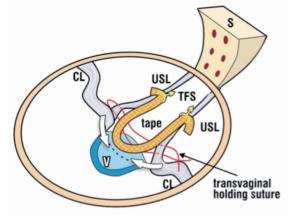




Figure 7. – Posterior USL sling. The anchors penetrate the USL approximately 2cm distal to the sacral bone insertion and tightened . This action shortens and reinforces USL and closes the enterocele.

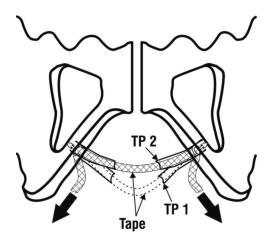


Figure 8. – Perineal body (PB) TFS sling. The anchors penetrate the deep transversus perinei which inserts exactly at the junction of the upper 2/3 and lower 1/3 and the tape is tightened. This action elevates the prolapsed perineal body from position TP1 to TP2.

RESULT

1156 tapes were used in all patients. 303 U slings for lateral/central anterior vaginal wall defects, 301 posterior slings (USL-sling) of the uterosacral ligaments, 314 Cervical sling for cervical ring defects, 234 perineal body slings for defect of the perineal body and 4 anterior slings for SUI (ISD) were performed. 1156 tapes were used in all patients.

TABLE 2. - 1156 tapes were used in all patients.

Variable	Value	Range
Mean operation time(min)	89.0	39-190
Mean estimated blood loss(ml)	71.2	7-378
Hospitalization after operation	0.7	0-3
Same day (42%)		
Mean days, Return to usual life	2.2	1-10

TABLE 3. – Cure rate of symptoms (337 patients) from 2007/10 to 2012/7). All patients had uterine prolapse with grade 3 or 4 according to the Pelvic Organ Prolapse Quantification (POPQ) standard scoring system.

Variable	no	cure rate
SUI	160/174	91.9%
Urgency	156/171	91.2%
nocturia	78/129	60.5%
Day time frequency	152/179	84.9%
Dragging pain	54/76	71.1%
Fecal continence	43/52	82.7%

All patients were followed up for a minimum of 3 months (3-57). There were no intraoperative complications and two post-operative complication: ileus due to tape in abdominal cavity and adhesion of the mesentery and USL mesh, 3 and 4 month after operation and treated operatively.

The average rate of rejection or erosions in 1156 tapes was 3.2%. 38 mesh tapes of 36 patients were rejected and partial excision of meshes was performed. However, this figure included a disproportionate number of perineal body slings. The rate of tape rejection or erosions was 0.7 (3 meshes)% in U slings, 1.0% (3 meshes) in Cervical sling, 1.0 (3 meshes) % in posterior slings (USL-sling), and 12.8 (30 meshes) % in perineal body slings, respectively. Rhere was no rejection in anterior (midurethral) slings. The rate of rejection or erosions in 1156 tapes was 3.2%.

TABLE 4. – Tape rejection or erosion. 337persons from 2007/10 to 2012/7; complications (FU 3-57months).

Variable	no	%
U-sling	2/303	0.7
Cervical sling	3/314	1.0
USL(posterior) sling	3/301	1.0
Perineal body sling	30/234	12.8
Total	37/1156	3.2

DISCUSSION

The rate of tape rejection or erosions in perineal body slings was better after improving the procedure. The first improvement was the the position of the anchors. We changed the position of the anchors from in the perineal body (not beyond) to beyond the posterior surface of the descending pubic ramus. And then, the rate of tape rejection or erosions in perineal body slings was improved after the changing from one layer closure to 2 layers closures and washing with sterile normal saline 100ml before closure, 20.5% in 2007 and 2008, 23.5% in 2009, 4.3% in 2010, 6.6% in 2011 and 2.6% in 2012, respectively. We hypothesize that the insertion of the anchor into the peritoneal cavity was caused by a fault in the method of insertion. Having located and grasped the uterosacral ligament (USL), the anchor was inserted from lateral to medial, instead of penetrating the USL and directing the anchor laterally, away from the rectum and Pouch of Douglas. We now penetrate lateral to the USL.

CONCLUSIONS

The TFS procedure delivers satisfactory results for pelvic organ prolapse (vault prolapse and uterine prolapse repair). The rate of mesh tape rejection and erosion was low, but we think that the rate will be lower because our operation techniques were improved.

REFERENCES

- Petros PE, Richardson PA: The TFS posterior sling for repair of uterine/vault prolapse-a preliminary report ANZJOG, 2005; 45: 376-379 incontinence- preliminary report ANZJOG, 2005; 45: 372-375.
- Petros PE, Richardson PA, The TFS posterior sling for repair of uterine/vault prolapse-a preliminary report ANZJOG, 2005; 45: 376-379.
- Petros PE, Richardson PA, Goeschen K and Abendstein B, The Tissue Fixation System (TFS) provides a new structural method for cystocoele repair- a preliminary report. ANZJOG, 2006; 46: 474-478.
- Inoue H, Sekiguchi Y, Kohata Y, Satono Y, Hishikawa K, Tominaga T and Oobayashi M. Tissue Fixation System (TFS) to repair uterovaginal prolapse with uterine preservation: A preliminary report 2009; J. Obstet. Gynaecol. Res. Vol. 35, No. 2: 346-353.
- Petros PE. Chapter 2: The Anatomy and Dynamics of Pelvic Floor Function and DysfunctionThe female pelvic floor. Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed, 2010; 17-77.
- Petros PE. Chapter 3, diagnosis The female pelvic floor. Function, dysfunction and management according to the integral theory. Springer, Heidelberg 3rd Ed, 2010; 77-117.

Correspondence to: HIROMI INOUE inoue@shonankamakura.or.jp

ERRATA CORRIGE

In the article "A simplified biomechanical perspective of the Integral Theory System", by F. Wagenlehner, B. Liedl and P. Petros (Pelviperineology 2012; 31 (4): 101-106), figures 9a and 9b the figures are erroneously the same.

Here and in the online version the correct sequence.

HOW A LAX LIGAMENT MAY CAUSE URINARY STRESS INCONTINENCE

The effective insertion point of the directional muscle forces (arrows, figure 6), is the pubourethral ligament (PUL). In figure 8, PUL is elongated (L) and so becomes loose. Because the insertion point PUL is loose, the PCM muscle forces (arrows) are weakened and cannot stabilize the suburethral vaginal hammock 'H' sufficiently for LP/LMA vectors to rotate and 'kink' the proximal urethra . Instead, the posterior urethral wall is pulled from closed 'C' to open 'O', ('funnelling') exactly as happens during micturition.

MICTURITION

During micturition in a normal patient, the geometry is exactly as depicted in figure 7, except that PCM relaxes, PUL lengthens and LP/LMA vectors open out the posterior urethral wall, vastly lowering urethral resistance; detrusor contracts and empties the bladder.

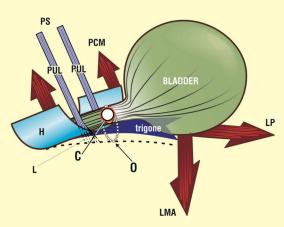
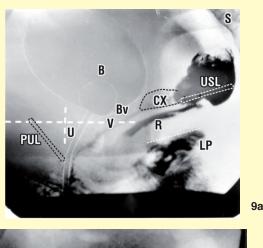


Figure 8. — How a lax ligament may cause urinary stress incontinence. O = open position of urethra; C = closed; L = excessive length of the pubourethral ligament (PUL). The contractile strengths of PCM, LP and LMA are weakened by a lax PUL.

ROLE OF THE UTEROSACRAL LIGAMENT IN MICTURITION

Once the forward PCM vector relaxes, LP vector stretches back the vagina and posterior urethral wall, while the downward LMA vector pulls down on the uterosacral ligament (USL) to open out the posterior urethra (figure 9b). According to Gordon's Law, a lax USL will weaken the muscle contraction (downward vector, figure 9b), so that the detrusor has to contract against a tube not fully opened out. The bladder has to work harder to expel the urine. This is interpreted by the patient as 'obstruction'.



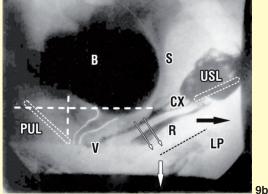


Figure 9a (resting) and 9b (micturition) in a nulliparous female in sitting position. The posterior urethral wall is opened out and pulled back behind the vertical co-ordinate by the posterior vectors (arrows) stretching the vagina'V' backwards/downwards below the horizontal co-ordinate. These vectors (arrows) pull against the uterosacral ligament 'USL'; B=bladder; PUL=pubourethral ligament; R=rectum; V=vagina; LP=levator plate (angulated downwards by the white arrow, the LMA force.

NEUROLOGICAL CONTROL MECHANISMS

These are akin to an electronic system, with peripheral sensors (bladder base stretch receptors, muscle spindles), central processors (cortical, subcortical) and intermediate relay stations (spinal cord). The peripheral sensors work via precise feedback mechanisms which co-ordinate contraction and selective relaxation of smooth and striated muscles, organ filling and emptying.

ROLE OF LIGAMENTS AND VAGINAL ELASTICITY

A central thesis of the Theory is that these peripheral sensors (bladder base stretch receptors, nerve endings) are