

TFS posterior sling improves overactive bladder, pelvic pain and abnormal emptying, even with minor prolapse.

A prospective urodynamic study

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Abstract: OBJECTIVE To prospectively challenge the Integral Theory's predictions that female patients with even with minor degrees of prolapse, and who have a symptomatic overactive bladder (urgency, nocturia and frequency), are surgically curable with uterosacral ligament repair. METHODS The study group comprised 67 patients with >2nd degree prolapse, with a subgroup of 27 symptomatic patients with only 1st degree prolapse. All patients were assessed pre and post-operatively by questionnaire, 24-hr urinary diary, transperineal ultrasound, urodynamics, cough stress and 24-hr pad test. Uterine/apical prolapse were repaired as a day case using the TFS. The TFS ('Tissue Fixation System') comprises an adjustable polypropylene 'mini sling' applied entirely per vagina, and which can be accurately tightened to reinforce loose or damaged pelvic ligaments. RESULTS: At median 9 months' review, the percentage improvement rate in pre-operative dysfunctions for the total group is expressed as a percentage, with 1st degree in parenthesis: urinary frequency >10/day 63% (63%); nocturia >2/night 83% (76%); urge-incontinence >2/day 78% (76%); abnormal emptying, 73% (73%); pelvic pain, 86%(82%) fecal incontinence, 87% (100%). CONCLUSIONS: The posterior TFS sling is a promising minisling technique which appears to address symptoms such as urgency, nocturia, frequency, abnormal bladder emptying, and fecal incontinence, even in patients with minimal uterovaginal prolapse.

Key words: TFS; Integral Theory; urge incontinence; overactive bladder; nocturia; pelvic pain; fecal incontinence.

INTRODUCTION

In the 1993 publication of the Integral Theory of Female Urinary Incontinence, the "posterior fornix syndrome"(posterior zone, figure 1) was described. It comprised symptoms of frequency, urgency, nocturia, pelvic pain, and abnormal bladder emptying.¹ Causation of this grouping of symptoms was attributed to laxity in the uterosacral ligaments (USL). According to this Theory,¹ the anatomical rationale for symptom causation was that lax posterior ligaments prevented the posterior muscle forces from stretching the vaginal membrane to support the bladder base stretch receptors, "trampoline analogy", fig. 1. Fundamental to this mechanism is the Theory's interpretation of "Overactive Bladder" (OAB) as a prematurely activated, but otherwise normal micturition reflex. This was urodynamically demonstrated in 1993.² Significant improvement in such "posterior fornix" symptoms in patients with 2nd degree or greater prolapse following reinforcement of USLs with a posterior sling operation has been reported previously.^{3,4} More recently, a less invasive posterior sling using the Tissue Fixation System (TFS) was described,⁵ fig. 2. The TFS allows precise tensioning of ligaments and fascia, consistent with the trampoline concept, fig. 1. There were 2 aims to this study. The primary aim was to challenge the theory's prediction¹ that even a 1st degree prolapse could cause major symptoms of urgency, nocturia and abnormal emptying. Twenty-eight patients fitted this description. A secondary aim was to test the efficacy of the new TFS sling in curing these conditions.

PATIENTS AND METHODS

Ethics Committee and Dept of Surgery Royal Perth Hospital approvals were obtained prior to the study.

Pre-operative assessment

All patients completed a 24 hour urinary diary, and a self-administered questionnaire which was completed at home in the patient's own time.⁶ A cough stress test, and 24 hour pad test⁶ were also administered. Symptoms derived from the questionnaire were ticked off in a diagnostic algorithm,

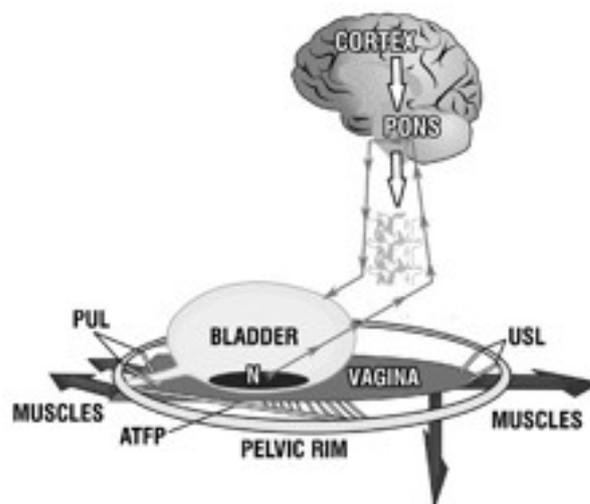


Fig. 1. – The Trampoline Analogy for OAB. Schematic representation. Muscle forces contract against the suspensory ligaments ("trampoline springs") to stretch the vaginal membrane. Even damage to one ligament may prevent the trampoline membrane from stretching. A lax vaginal membrane may not be able to support sensitive stretch receptors "N", so that these activate the micturition reflex prematurely. The patient senses this as urgency and frequency, and at night, nocturia. Minor damage may cause urgency, as this symptom is neurologically determined. Uterosacral ligaments (USL); pubourethral ligaments (PUL); Arcus Tendineus Fascia Pelvis (ATFP).

indicating the zone of connective tissue damage, anterior, middle, posterior. In this classification,⁷ the anterior zone extends from the external urethral meatus to bladder neck, the middle zone 4 from bladder neck to cervix or hysterectomy scar, and the posterior zone from apex to perineal body. Only patients with posterior zone defects were included in the study.

Inclusion/exclusion criteria

There were no exclusion criteria. The principal inclusion criterion for surgery was patients with 2 or more symptoms

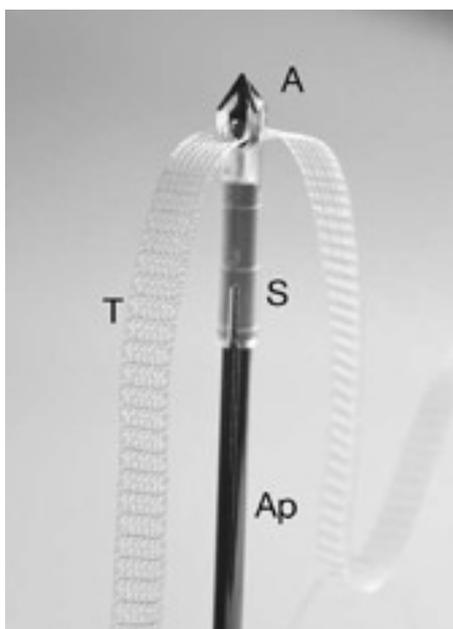


Fig. 2. – The Tissue Fixation System – a tensioned minisling. This is a photograph of the TFS anchor “A”, which sits in a saddle “S”, on an applicator “Ap”. T is a monofilament macropore polypropylene tape.

of urgency, frequency, nocturia, abnormal emptying or pelvic pain. Of the 67 patients who underwent surgery, 28 had only 1st degree prolapse, plus symptoms such as urgency, nocturia or pelvic pain. Without symptoms, none of these patients would normally have been considered for surgery. The criteria for symptomatic improvement post-operatively are detailed below: nocturia: change in patients having >2 episodes per night; abnormal emptying: self-assessed improvement >80%, using a 0-100 scale expressed as a percentage; urge incontinence: change in the number of times a patient wet per day (threshold 2/day); frequency: change in patients having >10 episodes per day; pelvic pain and fecal incontinence: self-assessed improvement >85%, using a 0-100 scale expressed as a percentage; otherwise objective measures such as pad weights and residual urine measured by catheter were used.

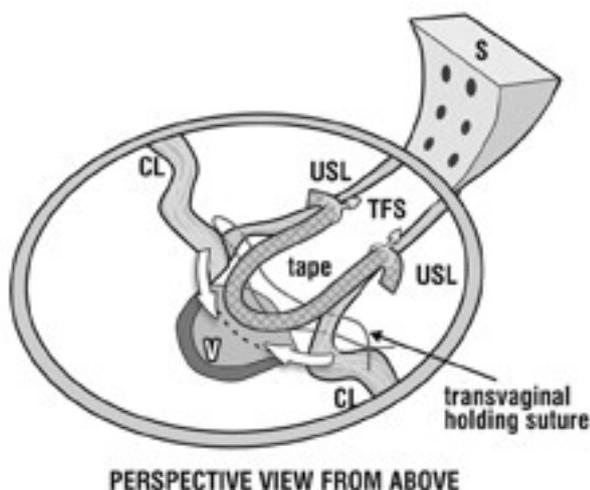


Fig. 3. – Posterior TFS sling. Perspective: View from above. The TFS anchors were inserted into the Uterosacral Ligaments (USL), and tightened to reduce apical or uterine prolapse. The arrows indicate that the remnants of USL and also the cardinal ligaments (CL) need to be approximated if the apex is wide, so as to prevent enterocele formation. Figure from Pelviperineology, by permission.

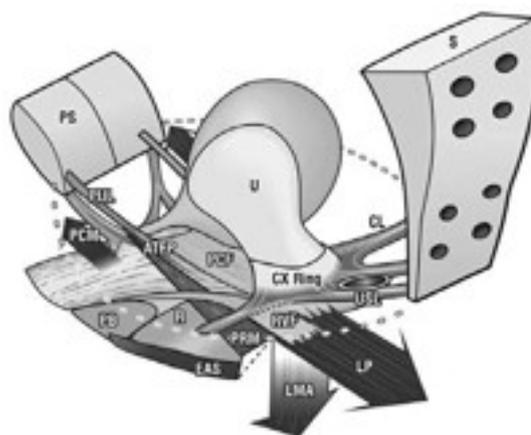


Fig. 4. – In its simplest form, anorectal closure occurs when the backward muscle forces LP (levator plate) and LMA (longitudinal muscle of the anus)¹⁵ stretch the rectum like a rubber tube, around an anus anchored by m.puborectalis (PRM) contraction. On relaxation of PRM, LP/LMA vectors open out the anal canal for evacuation to occur (broken lines). The vector forces, LP/LMA contract against the uterosacral ligaments (USL). If USLs are loose, the closure mechanism is invalidated, and fecal incontinence may result. Figure from Pelviperineology, by permission.

Objective assessment

Vaginal examination,⁷ involved inspection for damage to perineal body, posterior vaginal wall (rectovaginal fascia), and for the degree of prolapse of the vaginal vault or uterus. Transperineal ultrasound was performed by PP with a Toshiba 3.5 Mhz curvilinear probe to check organ position at rest and straining. Urodynamic testing was performed with a Neomedix System using Gaeltec microtransducers to assess for maximal urethral closure pressure, flow, residual urine, and ‘overactive bladder’. The patients were monitored at 6 weeks, and at 3 monthly intervals thereafter using a 24 hour urinary diary, structured self-administered questionnaire, cough stress test, 24 hour pad test, transperineal ultrasound, and urodynamic investigation. Residual urine was assessed by catheter after the patient had voided.

Surgical technique

The posterior TFS sling consists of two polypropylene soft tissue anchors through which is inserted an adjustable polypropylene tape, fig. 2. A transverse full thickness vaginal incision was made 1cm below the hysterectomy scar, or cervical ring. The uterosacral ligament was identified with Allis forceps. A 4-5 cm channel was dissected immediately lateral to the uterosacral ligaments. Using a special applicator, the TFS anchors were inserted into the uterosacral ligaments, fig. 3. The tape was tightened via a one-way system at the base to reduce apical or uterine prolapse, figure 3. Coexisting rectocele was repaired in 5 in 18 patients without vaginal tissue excision.

The halfay classification system of Baden & Walker was used to classify apical or uterine prolapse: first degree descent to halfway along the posterior vaginal wall ($n = 28$), second degree almost to the introitus ($n = 20$), third degree to 2 cm beyond the introitus ($n = 17$), and fourth degree total eversion ($n = 2$).

RESULTS

A total of 67 posterior TFS operations were performed. The median age of the women was 65 years (range 35–87). Median parity was 3 (range 0–8), and median weight was 71 kg (range 38–117 kg). Of the 67 patients, 28 had only 1st degree prolapse, and 39 had 2nd degree or greater prolapse.

TABLE 1. – Symptom Outcome - 67 patients.

	Symptom change with surgery			% cure in brackets	
	Frequency >10/Day	Nocturia >2/night	Urge incontinence >2/Day	Abnormal emptying	Pelvic pain
Fecal Incontinence	n=23 (87%)	n=47 (83%)	n=36 (78%)	n=53 (73%)	n=46 (86%)
	P<0.005	P<0.005	P<0.005	P<0.005	P<0.005

TABLE 2. – Symptom Outcome - 1st degree vault/uterine prolapse (n=28).

	Symptom change with surgery			% cure in brackets	
	Frequency >10/Day	Nocturia >2/night	Urge incontinence >2/Day	Abnormal emptying	Pelvic pain
Fecal Incontinence	n=8 (100%)	n=17 (76%)	n=17 (76%)	n=19 (73%)	n=18 (82%)

TABLE 3. – Pre-operative urodynamic “Overactive Bladder”

Patient	1	2	3	4	5	6	7	8
Pre-op 24 hr pad test (gm)	7	14.3	6.5	272	522	910	2100	644
Post-op 24 hr pad test (gm)	0	0	0	70	20	13	*1980	720

*asterisk indicates detrusor instability post-operatively also

The mean number of previous incontinence or vaginal repair operations was 1.6 per patient (range 0–6 operations). Only 15 patients had not had prior incontinence or vaginal surgery. Forty patients (56%) had undergone prior hysterectomy.

Mean hospital stay was 1.5 days (1–3 days). One patient was lost to follow-up.

The median post-operative review time was 9 months. The operation results are summarized in Tables I-III. Because the indication for surgery in the 28 patients with major symptoms but only 1st degree prolapse is likely to be highly controversial, the results are presented separately in Table II. For similar reasons, the surgical results for patients with pre-operative urodynamic ‘Overactive Bladder’ are presented separately in Table III. There was one recurrence of prolapse.

Severe urge incontinence

Seventeen patients had severe urge incontinence (UI), with a mean loss of 215gm/24 hour pad test (range 20 gm-644 gm). Post-operatively, 10 of these 17 patients stated they were >95% cured with a mean 24 hour loss of 6gm (range 0- 12gm). The results were significant (p<0.05, Student’s 2 tailed t test). In the other 7 patients from this group of 17 with OAB who were not considered cured of their symptoms, mean 24 hour loss reduced from 320 gm (range 25- 388gm.) to 223 gm (range 35-720 gm), 4 of these 7 patients were cured of nocturia, 3 of daytime frequency, and 6 of other symptoms such as fecal incontinence, pelvic pain and abnormal emptying.

Urodynamically diagnosed Overactive Bladder (OAB) with significant urine loss

Fifty eight patients underwent urodynamic testing pre-operatively, and 55 postoperatively. There were 8 cases of ‘overactive bladder’, ‘OAB’, as defined by the International Continence Society⁸ associated with significant urine loss, Table III. Five of these 8 patients considered themselves more than 95% cured, and a sixth more than 80% cured

(mean change from 288gm –17gm). Two reported no improvement at all.

Abnormal emptying and residual urine

A residual urine >50ml (50-600 ml) was seen in 6 out of 29 patients. In this group, the mean reduction of residual urine was from 271ml preoperatively to 53ml post-operatively (p<0.005). One patient who self-catheterized 4 times daily pre-operatively, was restored to normal emptying. Mean emptying time for this group (n=29) decreased from mean 41 seconds (12-130 secs) to 31 seconds. (7-130 secs) (p <0.005). There was no significant change in peak flow (41ml/sec pre-operatively to 37ml/sec post-operatively).

Prolapse repair

There was one failure of vault prolapse repair which required reoperation.

In another patient, one half of the sling was found in the vagina covered by a large granuloma, with no vault prolapse, and no posterior zone symptoms, figure 1. The prolapsed part of the sling was excised and the vagina sutured. Symptom cure was maintained.

DISCUSSION

At least in the short term, the posterior TFS sling appears to improve symptoms of urge-incontinence, frequency, nocturia, pelvic pain and voiding problems, similarly to previous methods, uterosacral ligament repair,¹ posterior IVS,^{3,4,9} sacrocolpopexy.¹⁰

Whereas all previous reports concerned patients with at least 2nd degree prolapse, 28 of our patients had only 1st degree prolapse. We attribute the effectiveness of the TFS in such 1st degree patients to its ability to tension the vaginal membrane through its one way tensioning system, supporting the stretch receptors according to the “Trampoline Analogy”. The stretch receptors “N” fig. 1 predicted by the theory,¹ and on which this explanation is based, are consistent with the recently described Transient Receptor Potential channels, “TRPs” which are found in the bladder epithelium.¹¹ These function as stretch, volume and pain receptors.¹¹

“Overactive Bladder”

Significant improvement in 10/17 patients with severe urge incontinence, and 6/8 patients with symptomatic “Overactive Bladder” in this study, accords with the explanation of OAB as a normal micturition reflex² prematurely activated by a lax vaginal membrane, fig1. Neuman⁹ also found that “overactive bladder” symptoms in non-neurological patient with uterine/apical prolapse may be potentially curable surgically. In a study of 140 patients who had a posterior sling operation (“Posterior IVS”-PIVS), Neuman et al⁹ reported troublesome bladder overactivity symptoms in 90 of the patients, reduced postoperatively to 9 patients, a 90% cure rate.

Pelvic pain

With regard to symptomatic improvement in pelvic pain, it is proposed that competent connective tissue in the uterosacral ligaments provides intrinsic support to the unmyelinated nerve endings which they contain.⁷ Lax ligaments “sag” due to the action of the force of gravity. The nerves are activated, and this is perceived as ‘dragging’ lower abdominal pain.⁷

Even patients considered as gross failures in one area (e.g., urge incontinence) had cures in other symptoms (e.g., fecal incontinence, stress incontinence, nocturia, frequency). This suggests a complex synergistic interaction of structures which we can describe, but not explain.

Fecal incontinence

Utilizing pre and postoperative evacuating proctograms, Abendstein¹² reported cure of fecal incontinence, obstructive defecation, pelvic pain, and xray proven anterior rectal wall intussusception. Abendstein proposed that the uterosacral ligament supports the anterior rectal wall much like the apex of a tent. The mechanism proposed for cure of fecal incontinence also involves the uterosacral ligaments.¹³ The longitudinal muscle of the anus (LMA) and levator plate (LP) vectors stretch the rectum around an anus anchored by forward contraction of the puborectalis muscle (PRM), figure 4. Laxity in the uterosacral ligaments (USL), the anchoring point of LMA, may inactivate this closure mechanism causing fecal incontinence.¹³ In a study similar to that of Abendstein, it was demonstrated that in patients with fecal incontinence, abnormal anorectal pressures, delayed pudendal nerve conduction times, and thinned internal anal sphincters had no negative impact on the results of surgery.¹⁴ Fecal incontinence was cured in 83% of patients by repair of the uterosacral and/or pubourethral ligaments.

CONCLUSIONS

The posterior TFS sling is a promising minisling technique which appears to address symptoms such as urgency, nocturia, frequency, abnormal emptying, and fecal incontinence, even in patients with minimal uterovaginal prolapse.

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