Review

A review of the Integral Theory of Pelvic Organ Prolapse and proposed concept of repair: part 2 – the TFS ligament repair

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Abstract: Aim: To demonstrate how TFS site specific repair of the 4 main damaged ligaments (Part 1) restores the anatomy of patients' with cystocoele, uterine/apical prolapse and high, mid and low rectocoele. *Surgery:* The surgery is based on the TVT neo-ligament principle, shortening and reinforcing the ligaments: arcus tendineus fascia pelvis (ATFP) and cardinal (CL) to cure cystocoele; CL and uterosacral (USL) to cure uterine/apical prolapse; USL and perineal body (PB) to cure rectocoele; PUL to cure urinary stress incontinence. There is no vaginal excision. Which ligament to repair is guided by the Pictorial Diagnostic Algorithm, which uses symptoms to identify which ligaments are damaged. *Results:* The application of TFS for repair of only 4 ligaments has been found to be sufficient for repair of all three prolapses, cystocoele, uterine/apical and rectocoele. The 5th ligament, PUL, is essential for repair of urinary stress incontinence. There seems to be minimal recurrence of the prolapses in the longer term. Data from patients having total repair (all prolapses) indicates there is only a minimal fall in cure rate, from 92% at 12 months to 84% at 48 months. *Conclusions:* Suturing damaged tissue to damaged tissue creates scar tissue and more damaged tissue. With reference to the suspension bridge analogy, if the tensioning cables (ligaments) have collagenous damage, the collagen must be strengthened by tissue reaction from precisely implanted tapes. The one-way system at the base of the anchors allows the tapes to both shorten and reinforce the damaged ligaments, thus restoring anatomy and function: the directional muscle forces require a firm insertion point (ligament) to contract efficiently, according to Gordon's Law.

Keywords: ATFP; Cardinal ligament; Uterosacral ligament; Perineal body; Pubourethral ligament; TFS surgery.

INTRODUCTION

This is the second of four related papers seeking to critically analyze the Integral Theory System and aims to introduce the TFS system of ligament repair.

The Integral Theory[1], states that pelvic organ prolapse, bladder and bowel dysfunction and some types of pelvic pain, mainly derive, for different reasons, from laxity in the vagina or its supporting ligaments, as a result of altered collagen/elastin.

Surgery with the TFS tool has a simple basis: it shortens and reinforces damage in the 5 suspensory ligaments using the TVT neo-ligament principle first applied in 1990[1]. The same surgical methods apply for major prolapse or significant symptoms with minimal prolapse.

Basic surgical principles

1. Ligaments provide suspensory strength[2]. They must be shortened and reinforced, preferably with a precisely located tape. This method is sufficient to restore all prolapses, apical, cystocoele, rectocoele and to restore the contractile force[3] of the pelvic muscles which control bladder and bowel function. Gordon's Law states that a striated muscle contracts efficiently over a small distance. Elongation of its insertion point also elongates the muscle and the muscle force decreases exponentially.

2. The uterus and vagina are conserved. The vagina has little structural strength[2]. Excision of vagina will shorten or narrow it and decrease its quantity of collagen and elasticity. The uterus functions like the keystone of an arch. All the suspensory ligaments directly or indirectly connect to the uterus. Hysterectomy, by division of the uterosacral and cardinal ligaments weakens the ligamentous insertions and predisposes to collapse of the vaginal walls as the patient ages. The effect of hysterectomy on structure and function becomes evident as collagen atrophies with age, especially after the menopause.

Which ligament to repair?

The surgery is guided by the diagnostic algorithm, Figure 1.

Symptoms indicate which ligaments cause a particular prolapse and which symptoms are associated with damage in particular ligaments. The aim of the repair is to shorten and strengthen the ligament.

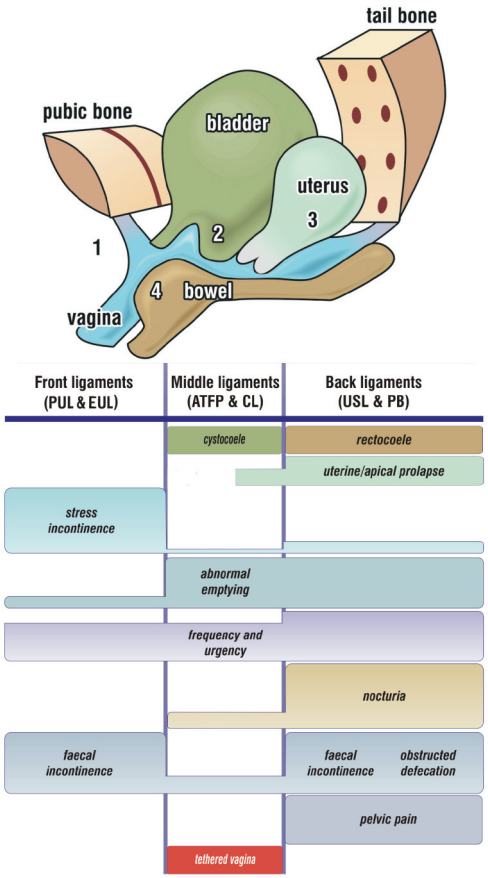

Figure 1. – Pictorial algorithm for diagnosis of pelvic organ prolapse. Symptoms indicate which ligaments cause a particular prolapse and which symptoms are associated with damage in particular ligaments.

The TFS tools

The TFS consists of an applicator, a non-stretch tape attached to two soft tissue anchors with a one-way adjustable mechanism for the tape which passes through the base. The tape is 7.5mm wide. It is a lightweight, non-stretch, individually knitted type I, lightweight, macropore, monofilament polypropylene mesh tape, Figure 2. At the base of the anchor is a system which allows one-way directional tensioning of the tape.

The anatomical fundamentals of how the TFS tools are applied are basically the same for each of the 5 ligaments. The vagina is incised. Bladder, rectum and enterocoele are dissected to access the ligaments as required. The ligament is identified. A tunnel is made through the ligament with Metzenbaum scissors, or similar. The applicator is inserted into the tunnel to the required length. The anchor is deployed. The operation is repeated on the contralateral side and the tape is adjusted until tape looseness is removed and a resistance is felt. This resistance indicates a reciprocal return of muscle tone in the muscles which act on that ligament. The tape is cut and the vagina is closed.

How the TFS works

The TFS shortens and strengthens all 5 ligament structures, Figure 2. The TFS has minimal contact with the vaginal wall as it is applied transversely. Unlike large mesh sheets applied to the vaginal wall, the tapes do not inhibit the forward and backward movements of the muscle forces which are essential for opening, closure and tensioning of the bladder and rectum.

Why is an adjustable tape necessary?

The ligaments against which the pelvic muscles contract need to be of a specific length for the muscles to contract efficiently against them, as the contractile force of a striated muscle falls off exponentially if its insertion point is loose[3]. Closure and opening of the urethral and to a lesser extent anal tubes (due to the ability of the rectum to contract independently) are also exponentially determined by the intraurethral resistance of the tube: only a small change in radius may cause the patient to leak or be unable to evacuate. Because the organ function is subject to such exponentially controlled mechanisms, symptom control has very fine tolerances. Therefore any shortening and strengthening of a damaged ligament with a tape must be precise if a high rate of symptom cure is to be achieved.

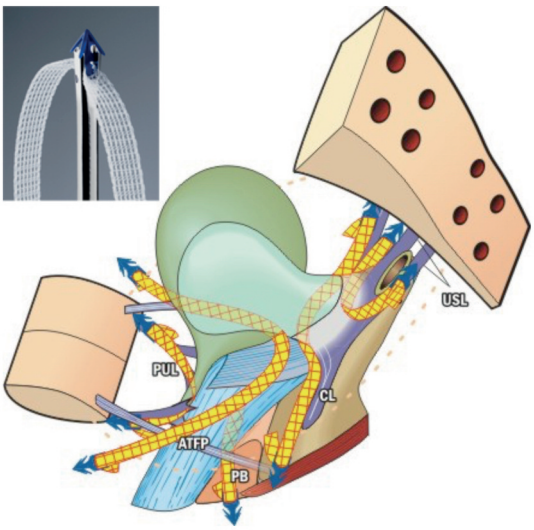

Figure 2. – TFS repair of 5 supporting ligaments - standing view. The tapes attach the organs transversely to the skeleton. The anterior vaginal wall is supported by ATFP and CL. The uterus is held up like the apex of a tent by USL and CL. The posterior vaginal wall is supported by USL cranially and PB distally.
Insert The TFS tool for creation of artificial collagenous neoligaments. The TFS consists of an applicator, a non-stretch macropore tape attached to two soft tissue anchors with a one-way adjustable mechanism for the tape which passes through the base.

How does the TFS adjust the tape to the correct length?

When the ligaments are loose, the striated muscles lengthen. As the tape is tightened, it removes the looseness in the ligament to the point where the striated muscle contractile force returns. The surgeon feels an increasing resistance to the tightening. At this point the tightening must stop there otherwise the anchor will pull out of the tissues. Each anchor has a pull out strength of 2.5 to 3kg.

How the TFS binds the organs to hiatus and skeleton.

The TFS tapes are inserted into the pubourethral, ATFP, cardinal (CL), uterosacral (USL), perineal body ligaments, Figure 2. The tapes create collagenous neoligaments which bind vagina, bladder, rectum to the hiatal muscles en route to the skeleton. The tapes limit the 'ballooning' of the hiatus so frequently seen in POP.

The feasibility of Total POP repair

The minimally invasive nature of the TFS allows all prolapses to be repaired at the same time. Essentially the same surgical technique is used to repair all 5 ligaments, PUL, ATFP, CL, USL, PB. The TFS sling is applied variously in up to 5 sites, Figure 2, depending on which ligaments are deemed to be damaged. The tape is applied into the body of the ligament, or directly adjacent to it. The tape creates a collagenous tissue reaction which strengthens the natural ligament[1].

Indicative structural results* for Total POP repair by TFS.

Inoue[4], performed total repair for POP, cystocoele, uterine/apical prolapse and rectocoele, repairing all 5 ligaments as required. At 12 months, he reported 92.1% anatomical cure for all prolapses (n=278) p <0.001 falling to 84% at 48 months (n=50). Tape rejections for Cardinal, USL, ATFP, PUL were 1.1%. Sekiguchi et al.[5] reported 90% cure rate with total ligament repair (n=62) at 12 months with <3% erosion rates. Table 1.

* Any protrusion from any compartment, 2nd degree POPQ or beyond, was considered an anatomical failure.

TABLE 1. Operative details CL/USL surgery 12 month data-1036 tapes in 278 patients, Inoue (4)

Variable		Value	Range
Mean operation time (min)		96.2	39-190
Mean estimated blood loss (ml)		75.1	7-280
Hospitalization after operation		0.7	0-7
Same day (38%)			
Mean days, Return to usual life		2.2	1-30
Mean tape per patient		3.5	1-5
Prolapse cure	92.1%	(n=278)	<0.001 falling to 84% at 48 months (n=50)

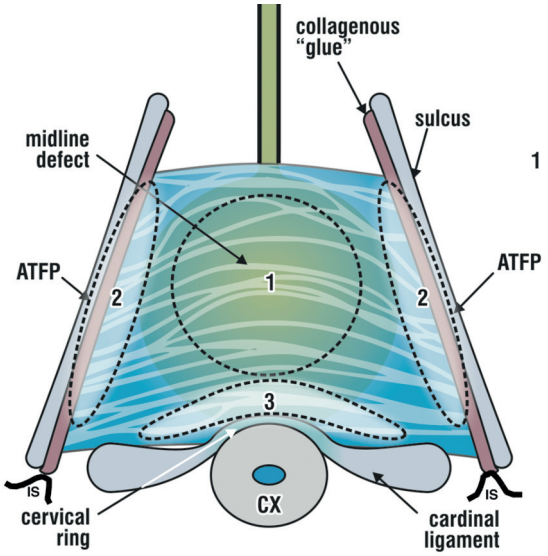

Figure 3. – Potential sites of anterior vagina damage. Schematic 2D view from below. Perspective: looking into the anterior wall of the vagina. 1. Midline defect (central part of PCF) caused by overstretching of vagina.
1. Central defect: overstretching of vagina usually part of defect 2.
2. Paravaginal or lateral defect: dislocation or stretching of the collagenous 'glue' attachment to ATFP.
3. High cystocoele or transverse defect is the most common cause of cystocoele, 80% in my estimate. *Causation*: dislocation of PCF attachment to the anterior cervical ring and cardinal ligament. Dislocation of the ATFP from its attachment to the ischial spines (IS) is usually seen; there is an associated shallow sulcus and downward rotation of the proximal vaginal wall on straining.

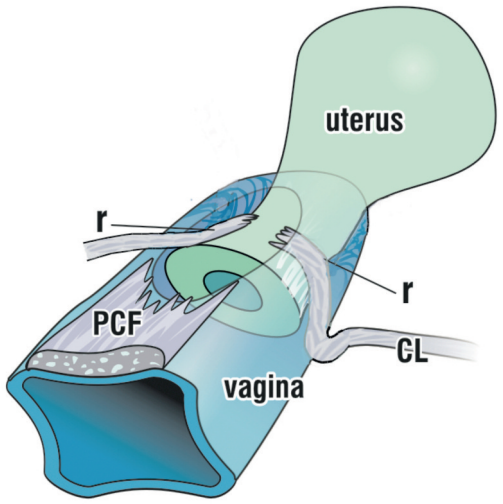

Figure 4. – The cardinal ligament (CL) extends anteriorly to fuse with the cervical ring (r) and the pubocervical fascia (PCF) of vagina. A break in CL and PCF attachments to the cervical ring during labour ring may cause the anterior vaginal wall to rotate downwards like a trapdoor to form a 'high cystocoele' or 'transverse defect'. In this situation, the cardinal ligaments also prolapse downwards lateral to the cervix to form the characteristic prolapse ('drooping') of vagina lateral to the cervix or hysterectomy scar.

TFS cystocoele repair

Surgical anatomy and preliminaries

Which operation, ATFP or cardinal? Correct diagnosis of which ligaments are damaged is an essential precondition for repair. The major cause of cystocoele is dislocation of the anterior vaginal wall (PCF) and cardinal ligament from the anterior cervical ring attachment, ('transverse defect' or 'high cystocoele')'3', Figure 3. Generally, vaginal rugae are present with such tears.

Dislocation from cervix.

The vagina prolapses downwards lateral to the cervix 'CX', usually on both sides, Figure 4. The presence of rugae indicates it is a pure CL dislocation. In patients with prior hysterectomy, the ligaments prolapse lateral to the hysterectomy scar. The CL TFS operation, Figure 5, is sufficient to restore even major cystocoeles. If the distal vagina continues to bulge after the CL TFS operation, the ATFP TFS ('U-Sling') is performed, Figure 5.

TFS cardinal ligament operation (Figure 5)

This tape 're-glues' PCF to cervix and re-suspends the cervix and ATFP (if dislocated from the spine) to the pelvic side wall.

Even with lateral/ central defects, the cardinal ligament is always repaired first. Under tension, a transverse incision is made at the vesico-cervical junction, usually 1-1.5 cm above the cervix or hysterectomy scar. Under tension, the bladder is dissected off the cervix or hysterectomy scar taking care to dissect it laterally off the vagina to the pelvic side wall. This is to protect against perforation during the application of the tape. Using a gently curved Mayo scissors, with tips always pressed towards the vaginal mucosa, a channel is made to the side wall. A finger is inserted to further define the channel. The TFS applicator is inserted into the channel until the fascia is perforated at the side wall. The anchor is released, tugged laterally to embed the prongs, then checked to ensure it has gripped. The procedure is repeated on the contralateral side. The tape is now tightened until a resistance is felt, an indication that reciprocal muscle activity has returned. The vagina is sutured. No

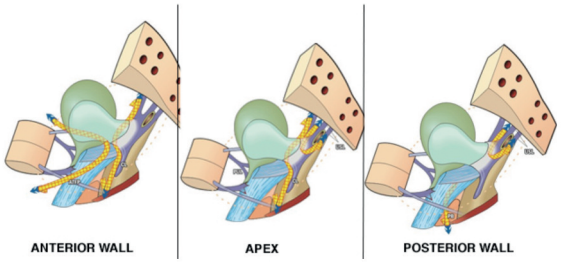

Figure 5. – Cardinal ligament and ATFP USL and PB TFS operations. Schematic view 3D view, patient in standing position. The tapes support the vagina in the manner of ceiling joists supporting a ceiling plaster board.
Anterior vaginal wall The (horizontal) cardinal (CL) tapes attach the proximal half of the anterior vaginal wall to the skeleton, recreate the cervical ring and re-attach a detached anterior vaginal wall to the cervical ring. The distal tape (TFS U-sling) reinforces the existing ATFP structure. It provides structural support to the distal half of the vagina, supports the central defect and re-attaches a dislocated PCM to the symphysis.
Apex The cardinal TFS tape re-attaches the dislocated CLs 2cm above and forward of the ischial spine. This automatically re-attaches an ATFP torn from the ischial spine (IS) to the side wall. The tape reglues the dislocated PCF attachments to the cervical ring. The USL tape shortens and reinforces elongated or damaged USLs and "reglues" the USL ligaments to cervix posteriorly.
Posterior vaginal wall The posterior vaginal wall is re-attached cranially by the TFS USL operation and distally by the TFS PB (perineal body) operation.

attempt is made to excise any vaginal mucosa however lax it may appear.

Cystoscopy is performed at the end, taking care to observe ureteric function.

TFS ATFP repair, U-Sling operation (Figure 5)

In the 20% of patients where a bulging persists after CL TFS surgery, the TFS ATFP (U-Sling) operation is performed.

The ATFP tapes support the vagina in the manner of ceiling joists supporting a ceiling plaster board (vagina). Like a ceiling plaster board, a damaged vagina has little structural strength. The U-Sling pulls the distal vagina forwards to re-attach it to the origin of ATFP at the symphysis. Because the pubococcygeus muscle inserts into the distal vagina, it, too, is re-attached to the symphysis.

A separate full thickness vertical incision about 5 cm long is made, beginning 1cm behind the bladder neck. The bladder is dissected off the vagina as per a standard native tissue repair sufficiently to create a channel for the tape. A channel is made with dissecting scissors behind the descending ramus, ascending towards the insertion of ATFP at the pubic bone. The applicator is inserted into the channel, the anchor released and checked for grip. This procedure is repeated on the contralateral side and the tape is tightened until a resistance is felt. The vagina is sutured. No attempt is made to excise any vaginal mucosa however lax it may appear.

Cystoscopy is performed at the end, taking care to observe ureteric function.

TFS Uterosacral ligament (USL) operation (Figure 5)

Surgical anatomy and preliminaries

The uterosacral and cardinal ligaments are related. It is evident that with any degree of uterine or apical prolapse, the cardinal ligaments are also elongated, so they should always be repaired at the same time as the USL. In the standing position, the USL is some 3cm higher than the sacrospinous ligament. The TFS uterosacral ligament (USL) operation is therefore more anatomically accurate than insertion in the sacrospinous ligament and will result in a longer vagina. Furthermore, it does not cause any unilateral deviation of the vagina maintaining a normal anatomical axis.

The CL/US Ligament complex is the insertion point of the LP/LMA muscle vectors: accurate tightening is critical for relief of posterior zone symptoms, Figure 1. The USL's attach to the lateral wall of rectum. A lax USL will predispose to intussusception and with straining produce anal mucosal prolapse and haemorrhoids. If the USL tape is too loose, the result of the procedure for all posterior zone symptoms, Figure 1, will be suboptimal.

TFS Surgery for USL repair

Under tension, a full thickness transverse incision 5cm wide is made approximately 3-4 cm below the cervix or hysterectomy scar. If the prolapse is 3rd or 4th degree, the incision is made 1-2cm below the cervix, as the tape will need to shorten a longer length of USL. Any enterocoele is dissected to allow access to the USLs. The vagina is stretched to tension the USLs so they can be more easily located. Look for them at 2 and 10 o'clock. These are grasped with Moynihan/Littlewood forceps. The direction of the USL's is determined an important aspect for creation of the tunnel and tape insertion. A small bleb of local anesthetic is injected into the ligament to enlarge it. A vertical incision is made in the superior border of the USL. Still under tension, a fine Metzenbaum scissors or similar, is inserted into USL to create a tunnel for the TFS which extends to 1cm short of the sacrum. Direct palpation of the ligament (rectally or vaginally) during this manoeuvre can be helpful. The procedure is repeated on the contralateral side. Traction on the vaginal apex is relaxed by removal of the forceps to allow shortening and the tape is tightened and checked to ensure the anchor has gripped. The vagina is closed.

For apical prolapse Petros at al. reported symptomatic cure by 30 patients (86%), and improvement in two (6%). Three patients were classified as failures. There were two tape rejections, one associated with operative failure. The cure/improvement rate in the examination group was 87%[7].

TFS surgery for perineal body (PB)

Surgical anatomy and preliminaries

There are two perineal bodies connected by a central tendon. The PBs are attached behind the descending ramus at the junction of the upper 2/3 and lower 1/3, Figure 3, by the deep transversus perinei 'muscle' (DTP) * (Figures 6a, 6b). During childbirth, the tendon is stretched and the two PBs are displaced laterally, allowing protrusion of a rectocoele. Diagnosis of laterally separated perineal bodies can only be made definitively by rectal examination.

* The DTP is whitish in colour and except for the presence of some striated muscle fibres, it has the classical histological appearance of a ligament, collagen, smooth muscle, elastin, nerves, blood vessels.

Surgical principle: For a correct anatomical restoration, the perineal bodies need to be re-attached to the posterior surface of the descending pubic ramus, at the junction of the upper 2/3 and lower 1/3 by penetration of the deep transversus perinei ligament by the TFS tape. The model in figures 6a, 6b represent TFS repair of the descending perineal syndrome. It shows how the TFS shortens, reinforces, elevates and centrally restores loose, elongated, laterally displaced ligaments, in this instance, perineal bodies. The deep transversus perinei ligaments attach the perineal bodies to the descending ramus.

Indications for PB repair: Rectocoele with assisted defecation, descending perineal syndrome, anterior rectal wall intussusception, obstructed defaecation, faecal incontinence. The perineal body functions as a unit with the uterosacral/cardinal ligaments. It is therefore standard practice to repair USLs at the same time as PB repair.

Surgery

Under tension, a posterior vaginal transverse incision 5cm wide is made just behind the hymen. The vagina is dissected off the rectum and the laterally displaced PBs are identified. The PB is whitish in appearance. On stretching, it is important to confirm that it inserts into the descending ramus*. Using a strong curved needle on a No1 vicryl suture, the PB is 'dug out": the needle is placed into the PB and it is lifted up and grasped with a strong forceps. Using Metzenbaum scissors, a tunnel is made into each PB, through the deep transversus perineus, penetrating its insertion to just behind the descending ramus. The scissors needs to be horizontal. Any downward angulation may injure the pudendal nerve as it exits Alcock's Canal. The applicator is inserted, the anchor is released, checked and the procedure is repeated on the contralateral side, stopping when a resistance is felt. The incision is closed.

The pubococcygeus is situated close by the DTP. It is a deep red colour. On pulling it can be confirmed that it inserts just behind the inferior border of the pubic bone.

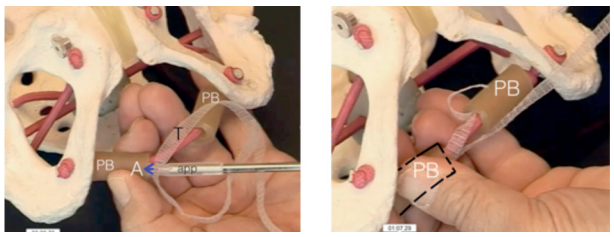

Figure 6. – TFS PB operation for descending perineal syndrome.
Left figure The laterally displaced perineal bodies (PB) are attached behind the upper 2/3 and lower 1/3 of the descending ramus by the deep transversus perineus ligament. A tunnel 'is made through PB and the ligament penetrating behind the ramus. The TFS anchor 'A' is inserted bilaterally. Note downward angulation of the PBs.
Right figure Tightening of the tape The PBs are elevated as the tape is tensioned. This, reverses the 'descending perineal syndrome' anatomy; a 1.5-2cm gap is left between the PBs. This fibroses in time to form a new central ligament.

TFS PB operation for descending perineal syndrome (Figure 6)

Results of TFS PB surgery for descending perineal syndrome

Thirty patients with 3rd degree rectocoele, symptoms of obstructive defecation and manually assisted defecation underwent TFS USL and TFS PB surgery. At 12 months follow-up, cure of symptoms of manually assisted defecation and prolapse was achieved in 27 patients (90%) of patients[8].

TFS repair of pubourethral ligaments

Surgical anatomy and preliminaries

There may not be significant distal vaginal prolapse with PUL laxity. The main symptom is urinary stress incontinence, (USI), but also, urgency when associated with USI and fecal incontinence when associated with USI. A midurethral sling is applied to shorten and reinforce damaged pubourethral ligaments. The technique is retropubic. Like the TVT, the TFS creates a neoligament in the exact position of the pubourethral ligament.

TFS Surgery for repair of PUL

The first part of the TFS mid-urethral sling is almost identical to that of the TVT

Under tension, a full thickness incision approximately 2cm long is made between mid-urethra to within 0.5cm of the external meatus. Under tension, pointing towards ipsilateral shoulder, dissecting scissors create a tunnel until a resistance is encountered, the perineal membrane. The scissors is guarded with a forefinger, and a 1.5-2cm perforation is made. The applicator is guarded, inserted, the anchor released and checked for grip. The procedure is repeated on the contralateral side. A No. 8 Hegar dilator is inserted into the urethra during tightening of the tape to prevent urethral constriction by the tape. The tape is then tightened until a resistance is felt. The bladder is filled and cystoscopy performed to ensure there is no perforation of the bladder. If urine continues to leak after removal of the cystoscope, it indicates that the tape is too loose. The Hegar is inserted and the tape is tightened. The tape should never be tightened without a Hegar in the urethra.

*Repair of distal closure mechanism**

The hammock/external urethral ligament (EUL) are now repaired. With a Foley No. 18 catheter in-situ, a continuous suture is inserted: first into one EUL, fascial layer of the vaginal hammock, first on one side, then the other and the suture ends by insertion into the contralateral EUL. The suture is gently tightened over a No. 18 Foley catheter. The vaginal epithelium is now closed with interrupted sutures.

* The external urethral ligament attaches the external meatus to the anterior surface of the pubic bone. The vaginal 'hammock' is densely adherent to the distal half of the urethra and therefore to PUL. Laterally it is attached to the forward vectors pubococcygeus muscle, ('pubovaginalis').

Rationale for EUL and distal vaginal repair- the urethral sealing mechanism.

The main function of the distal mechanism (hammock and EUL) is sealing of the urethral mucosa rather than closure during effort. The vagina is pulled forwards towards the bone by the anterior portion of pubococcygeus muscle pulling against the external urethral ligament (EUL) and the pubourethral ligament (PUL). Laxity in EUL, PUL or vagina may invalidate the closure force by the muscle. Symptoms are insensible urine loss, often accompanied by "a feeling of a bubble of air escaping".

Results -TFS repair of PUL

Using a local anesthetic technique, Sekiguchi et al.[9] reported 91% cure of USI including the 40% of patients who had ISD. Petros et al reported 80% cure at 3 years, plus another 6.5% with a > 70% improvement[10]. In a 5 year RCT, Sivaslioglu[11] reported 89% cure for TFS and 78% for TOT. Urinary retention (n=2/40), groin pain (n=12/40) and mesh extrusion (n=1/40) were noted in the TOT group, but not in the TFS group. In the TFS group there was no urinary retention or significant postoperative pain. There was one anchor displacement (left side) in 1 patient. The anchor was removed. The patient remained continent.

CONCLUSIONS

Suturing damaged tissue to damaged tissue equates to more damaged tissue. Damaged ligaments have to be reinforced with precisely placed tapes. The one-way system at the base of the anchors allows the tapes to both shorten and reinforce the damaged ligaments, thereby restoring anatomy and function: the directional muscle forces require a firm insertion point (ligament) to contract efficiently (Gordon's Law). The neo-ligaments created appear to have longevity. Four year data in patients having total repair (all prolapses) shows mild deterioration with the TFS for POP, from 92% cure rate at 12 months to 84% at 48 months.

CONFLICTS

There are no financial conflicts.

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