

Tissue Fixation System posterior sling for repair of uterine/vault prolapse – A preliminary report

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Abstract

Aims: To assess the posterior Tissue Fixation System (TFS) sling for repair of uterine/vault prolapse.

Patients and methods: The TFS comprises of two small polypropylene soft tissue anchors connected to an adjustable polypropylene tape. The posterior TFS sling works much like a McCall procedure. The anchors are inserted just lateral to the uterosacral ligaments. Tightening the sling elevates the prolapsed uterus/vaginal vault. The study group comprised 67 patients who were assessed with a 24-h urinary diary, structured questionnaire, transperineal ultrasound, urodynamics, cough stress test, and 24-h pad test, pre and postoperatively.

Results: Sixty-seven patients, mean age 65 years (35–87), mean weight 71 kg (38–117 kg), mean 1.6 previous pelvic operations, underwent posterior sling (level 1) repair for uterine/vault prolapse (fourth degree: $n = 2$; third degree: $n = 17$; second degree: $n = 20$; symptomatic first degree: $n = 28$). Level 2 ($n = 18$) and level 3 repairs ($n = 18$) were also performed as required. One patient was lost to the study. At mean 9 months' review (3–15 months), the prolapse repair had been successful in all but one patient. There were however, 14 de novo herniations postoperatively (20%), cystocele 12, enterocele 1, rectocele 1. Operating time for the sling only was 5–10 min, and mean hospital stay was 1.5 days. Minimal analgesia was required.

Conclusions: The preliminary results indicate that the TFS posterior sling appears to work well in patients with uterine/vault prolapse. Longer term follow up and studies by other surgeons are required to fully evaluate this procedure.

Key words: mesh, pelvic floor surgery, posterior sling, TFS, uterine prolapse, vault prolapse.

Introduction

The uterosacral ligaments are a principal support of the uterus and vaginal vault.¹ Attached to these is the rectovaginal fascia ('Denonvillier's fascia') which inserts distally into the perineal body, and proximally into the cervical ring and levator plate muscles¹ (Fig. 1). In a previous radiological study,² it was demonstrated that the above structures function interactively as a subsystem.²

Loose fascial attachments between organs and the tensioning muscles may not allow the organs to be stretched downwards and backwards sufficiently, and that this may predispose to rectocele, cystocele and vault prolapse.² In his guidelines for reconstructive surgery, Nichols¹ emphasised the importance of restoring the axis of the vagina. Nichols stated that axial restoration is only possible with abdominal or laparoscopic sacropexy, or with the McCall procedure. Abdominal sacropexy operations are major procedures which may last up to 2–4 h, and they are not exactly anatomical as they generally attach mesh to the sacral promontory and the vaginal vault. Also, these are often at least in

part, intraperitoneal operations, and are subject to the normal complications of intra-abdominal procedures, thrombosis, haematoma, infection, adhesions, and mesh erosion.³ In a large series ($n = 245$), Culligan⁴ reported a mesh erosion rate of up to 2.4%, with a mean estimated blood loss per patient of 328 mL, with two patients requiring blood transfusions.

Sacrospinous fixation attaches the vagina to the sacrospinous ligament, incurring the risk of pudendal nerve and vessel damage, and also, bleeding from the peri-rectal venous plexus during the dissection of rectum away from the attachment site.¹ Furthermore, sacrospinous fixation pulls

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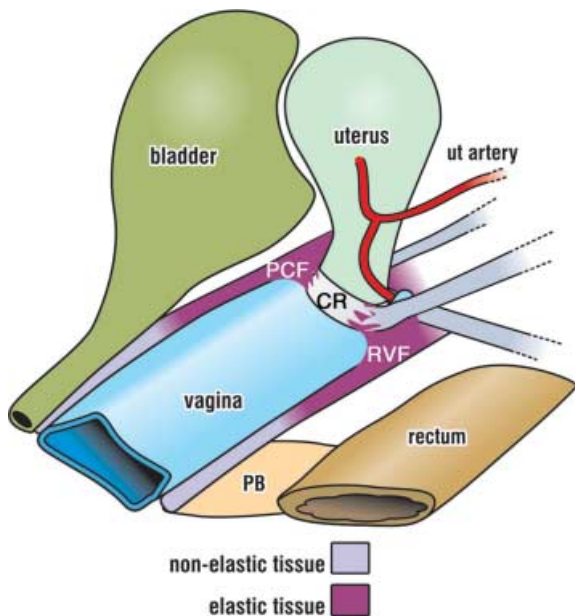


Figure 1 Fibromuscular supports of the vagina. CR, cervical ring; PCF, pubocervical fascia; RVF, rectovaginal fascia.

the vagina across at an angle, and this may cause dyspareunia or subsequent enterocele.⁵

The McCall operation attaches the vault to the uterosacral ligament remnants. As these are very close to the ureter, ureteric ligation may occur.¹ The operation may fail if the uterosacral ligaments are atrophic, or if the sutures are misplaced.

The posterior IVS operation ('infracoccygeal sacropexy' or 'PIVS') was specifically developed to avoid such complications.⁶ It is a minimally invasive axial procedure which works by connecting the vaginal vault to the posterior pelvic muscles with a woven plastic polypropylene tape. The tape is inserted via the ischioanal fossa, and it is attached to the posterior wall of the vagina. The tape works by creating an artificial collagenous neoligament, so that when the muscles contract, the vault is pulled backwards.² There is negligible bleeding from the PIVS itself. Any bleeding recorded came from the accompanying vaginal repair.⁶

A genuine day-care procedure, the PIVS operation does require sound anatomical knowledge and some technical skill. Though ischioanal haematoma, abscess and rectal perforations are all possible complications from this procedure, they are uncommon. The most common complication has been tape erosion into the vagina.⁶ This is rarely infected and is generally a 'surfacing' of the tape due to slippage, or a result of a foreign body reaction.⁷

The posterior TFS (tissue fixation system) operation uses the TFS applicator (TFS Manufacturing). This operation is a direct evolution of the posterior IVS operation. Its modus operandi, however, is more like the McCall procedure (Fig. 2). It uses two polypropylene plastic anchors attached to an adjustable non-stretch multifilament polypropylene mesh tape. The anchors are inserted into the tissues around

the uterosacral ligaments, and the tape tightened. This action pulls up the vaginal vault to its normal anatomical position. This study was performed following approval of the TFS device by the Australian and European Government regulatory bodies, and clinical approval by the Ethics Committee and Department of Surgery Royal Perth Hospital. The aim of this study was limited only to testing the posterior TFS sling for its effectiveness in restoring vaginal prolapse.

Patients and methods

Sixty-seven patients, mean age 65 years (range 35–87), parity 2.7 (range 0–8) weight 71 kg (range 38–117 kg) underwent a posterior TFS sling. 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. A cephalosporin antibiotic and metronidazole were given intravenously on induction of anaesthesia in all operations. In 10 patients, the operations were performed under local anaesthesia/sedation.

Inclusion criteria

Patients with at least second degree prolapse complaining of a 'lump' in the vagina, or prolapse to the middle part of the posterior vaginal wall (first degree) who complained of dragging pain, or other symptoms (such as emptying difficulty) related to prolapse of the posterior fornix.⁸

Pre-operative assessment

All patients completed a 24-h urinary diary, structured questionnaire, cough stress test and 24-h pad test. The halfway classification system of Baden Walker⁹ 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 ($n = 2$). Transperineal ultrasound (for bladder descent and urethral opening during straining), urodynamic testing (for urethral pressure, flow, residual urine, and 'detrusor instability') were also performed.

The patients were monitored at 6 weeks, and at 3-monthly intervals thereafter using a 24-h urinary diary, structured questionnaire, examination, cough stress test, 24-h pad test, transperineal ultrasound, and urodynamic investigation.

The posterior TFS sling

Primary uterosacral ligament repair was undertaken in 67 patients. The posterior TFS sling is similar to the McCall operation insofar as it anchors the apical fascia into the uterosacral ligaments (USL) (Fig. 2). A full thickness, 2.5-cm transverse incision was made in the vaginal apex, 2 cm below the cervix, or just below the hysterectomy scar. The uterosacral ligaments or their remnants were identified and

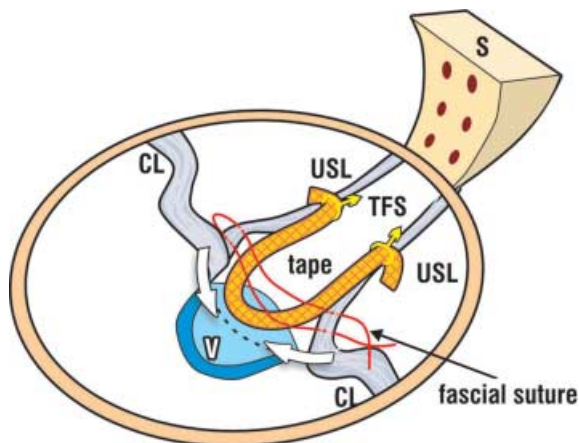
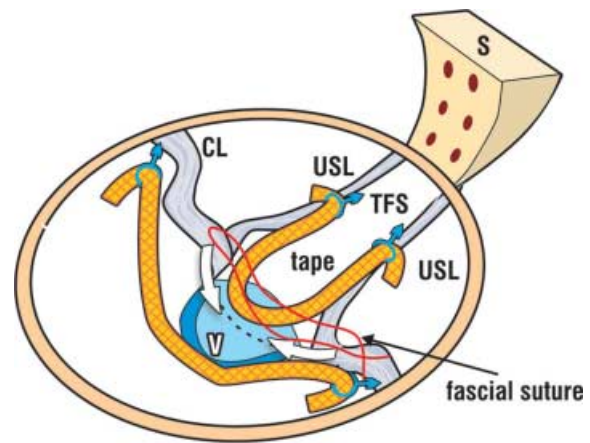


Figure 2 Posterior Tissue Fixation System (TFS) sling. Tape is inserted along the line of the uterosacral ligaments 'USL' between USL and vagina and tightened to elevate the vaginal vault. CL, cardinal ligament.



PERSPECTIVE VIEW FROM ABOVE

Figure 3 Posterior Tissue Fixation System (TFS) sling. A second tape brings together the displaced rectovaginal fascia.

grasped with Allis forceps. If an enterocele was present it was dissected clear of the fascia and reduced. Fine dissecting scissors angled at 30 degrees created a 4–5 cm space between the ligamentous remnants and the vaginal skin just below the insertion point of the uterosacral ligaments, just sufficient to accommodate the TFS delivery instrument. At the required depth, the instrument was triggered, and the anchor dislodged. The instrument was removed, and 30 s allowed to elapse so as to allow for restoration of the tissues. The anchor was 'set' by pulling on the tape. The insertion was repeated on the contralateral side. Maintaining the instrument to support the anchor base, the tape was tightened along the instrument axis, and inspected for adequate tightening. The free end of the tape was cut 1 cm from the anchor. The lax uterosacral ligaments and adjoining fascia above the tape were approximated as an extra layer of support for the TFS. Operating time for the sling was 5–10 min.

Repair of levels 2 and 3¹⁰ (rectovaginal fascia and perineal body repair), was carried out without any tissue excision. The fascial remnants of the rectocele were repaired directly ($n = 6$), with a TFS transverse tape ($n = 9$) (Fig. 3), or with a tape and mesh ($n = 3$). The mesh was trimmed and sutured laterally and to the perineal body.

Results

General

Sixty-seven posterior TFS operations were performed in patients with symptomatic prolapse. Mean hospital stay was 1.5 days (1–3 days). One patient was entirely lost to follow-up. Mean post-operative review time was 9 months (range 3–15).

In patients who had not undergone perineal body repair, only two required opiates postoperatively. Most patients were

managed simply with paracetamol. Six patients (8.6%) developed urinary tract infection within 4 weeks of discharge and these were treated with antibiotics.

De novo herniations ($n = 14$). De novo cystocele at least to second degree occurred in 12 patients (18%) with minimal preoperative cystocele. Six patients from this group had de novo symptoms of urgency and eight de novo emptying difficulties. Another (13th) patient developed a third degree enterocele. She remained cured of her preoperative symptoms of nocturia, urgency and pelvic pain. A posterior TFS with mesh was successfully performed. Another (14th) patient developed a third degree rectocele with accompanying evacuation disorder. A transverse TFS was successfully applied to a high rectocele, and lax perineal body.

There was one failure of vault prolapse repair which required re-operation with mesh. 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 fornix symptoms. The prolapsed part of the sling was excised and the vagina sutured. It was not possible to insert a TFS in one patient who had previously undergone pelvic clearance for extensive endometriosis. A posterior IVS operation was successfully performed instead. There was one vaginal infection following a standard rectocele repair (no tape or mesh was used) which cleared with antibiotic treatment. One patient reported with severe de novo urgency immediately after surgery. Transperineal ultrasound demonstrated a 2-cm diameter haematoma at bladder base. The symptoms settled in 6 weeks, once the haematoma was absorbed.

Discussion

The posterior TFS sling operation is a direct evolution of the posterior IVS procedure.⁶

It is a simpler operation than the posterior IVS, as it is performed entirely via the vagina, and it does not require suturing of the tape to the posterior vaginal wall. Its action, approximating and elevating the uterosacral ligaments (Fig. 2), also closes any enterocele which may be present, lengthens the vagina and restores the vaginal axis.

Cure rates for prolapse repair are at this stage equivalent to those reported previously for posterior sling surgery,^{6,11} but with a significantly reduced operating time.

Although the study group consisted of older patients (mean 65 years), with poor tissues (mean 1.6 pelvic surgeries), the TFS appeared to work adequately in all but two cases. Failure of the surgeon to check for adequate anchoring may lead to failure, as may inadequate tissue for the anchor to grip into. Prolapse of half a tape was attributed to the former, and failure to grip in a patient with previous pelvic clearance to the latter.

Our rate of de novo cystocele herniations (18%) is higher than the 17% reported by Shull¹² following sacrospinous colpopexy, and after posterior IVS surgery (16%).⁶ The higher rate of prolapse may be explained by an older cohort (65 vs. 54 years) with poorer tissues (mean 1.6 previous operations). De novo herniations may be explained by the pelvic forces impacting on subclinically weakened (but as yet unherniated areas of the vagina).

Our review period was limited to 9 months. Our study gains some perspective when viewed against the data of Culligan *et al.*⁴ who reported a 15% recurrence rate of vault prolapse after sacrocolpopexy ($n = 245$). They demonstrated that 70% of vault prolapse recurrences were likely to occur at 6 months, 81% at 12 months, and 95% at 24 months.

Conclusions

The preliminary results indicate that the TFS posterior sling appears to work well in patients with uterine/vault prolapse. Longer term follow up and studies by other surgeons are required to more fully evaluate this procedure.

Declaration of interest

The first author has a financial interest in the TFS instrument.

Acknowledgement

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