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Original Article

Midurethral Tissue Fixation System sling – a 'micromethod' for cure of stress incontinence – preliminary report

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Abstract

Aims: To assess the effectiveness of the Tissue Fixation System (TFS) in patients with stress incontinence. The TFS uses two small plastic anchors to fix an (adjustable) midurethral polypropylene mesh sling into the soft tissues below the pubic bone.

Patients and methods: Thirty-six patients with stress incontinence, mean age 55 (35–87), mean weight 76 kg (33–117 kg), mean 0.8 previous operations for stress incontinence, underwent a TFS midurethral sling operation. The patients were preoperatively assessed with a structured questionnaire, 24-h urinary diary, cough stress test, transperineal ultrasound, and urodynamics. Using the TFS delivery system, a midurethral mesh tape was attached to the fibromuscular tissues behind the perineal membrane. The suburethral vaginal fascia was also tightened. Post-operatively. the patients were reviewed at 6 weeks, and at 3-monthly intervals with ultrasound, and cough stress tests.

Results: Primary symptomatic cure rate at mean 9 months (3–15 months) was 83.4% ($n = 36$). Pad test loss decreased from a mean 12.7 g to a mean of 0.2 g; mean operating time was 5 min, and mean hospital stay was 24 h (12–48 h). There were no cases of obstructed micturition, and minimal analgesia only was required postoperatively.

Conclusion: The TFS is a promising new method. The results at this stage are similar to those achieved previously with the 'tension-free' tape operations, but with greater safety and shorter operating time. Testing by other surgeons will be required to evaluate this method further.

Key words: integral theory, midurethral sling, stress incontinence surgery, stress incontinence, TFS

Introduction

The past 10 years has seen an explosion in the use of 'tension-free' midurethral slings for cure of stress incontinence. These are all based on a connective tissue theory of urethral closure which emphasises the importance a firm pubourethral ligament (PUL) anchoring point for three directional muscle forces.[1] The sling creates a collagenous reaction to reinforce the pubourethral ligament.[2] 'Tension-free' midurethral slings give an equivalent cure rate to colposuspension operations, but with less operating time and shorter hospital stay.

Though minimal morbidity is the norm, major complications such as small bowel and bladder injury, obturator nerve and major vessel injury, haemorrhage and even death may occur[3] as a result of these operations. These complications are attributed to the blind nature of these procedures.[3] Though the simplicity and efficacy of 'tension-free tape' operations has led to their widespread acceptance, the growing list of serious complications such as those reported[3] was the motivating factor behind the development of a safer delivery instrument, the TFS 'Tissue Fixation System' (TFS Manufacturing) (Fig. 1). Two polypropylene soft tissue anchors provide a one-way directional system for adjusting a non-stretch multifilament polypropylene tape. A non-stretch tape was chosen because it does not retract to constrict the urethra post operatively.[4]

During the development period, the TFS prototypes were rigorously tested for mode of action, fragmentation and maximal load at the bioengineering laboratories of Royal Perth Hospital. A series of histological tests in rats carried out at 2, 4, 6 and 8 weeks showed a continuous veil of collagenous tissue covering the anchor points, the base and the tape, even at 2 weeks, with many macrophages surrounding the polypropylene microfibrils, in spaces as small as five microns (Petros, unpublished data).

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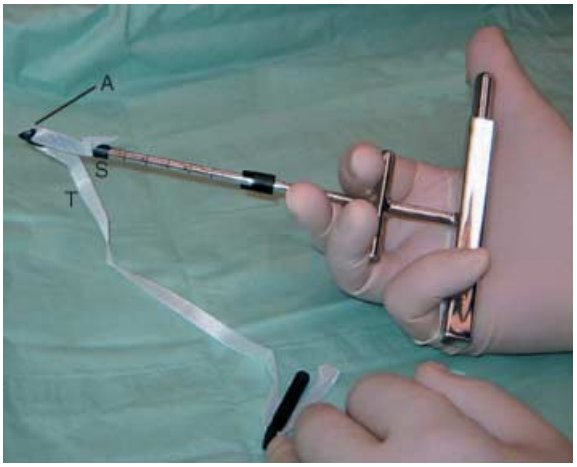

Figure 1 Tissue Fixation System (TFS) consists of a polypropylene mesh tape 'T', attached to two anchors: 'A', sitting inside a saddle 'S'. The anchors are applied by a stainless steel applicator.

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 midurethral TFS sling for safety and effectiveness in curing urinary stress incontinence.

Patients and methods

Thirty-six patients, mean age 55 years (range 33–86), parity 2.7 (range 0–6) weight 76 kg (range 38–116 kg) underwent a subpubic midurethral sling using the TFS as a delivery instrument. 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.

Pre-operative assessment

All patients completed a 24-h urinary diary, structured questionnaire, and cough stress test. Vaginal examination,[5] was in all cases performed with a full bladder so as to directly confirm urine loss during coughing, and control thereof using the technique of 'simulated operations': anchoring the anterior and midurethral ligamentous supports of the urethra, and also the suburethral vaginal hammock. A haemostat placed gently against the urethral meatus, then, in turn, placed lateral to the midpoint of urethra, then taking a fold of the suburethral vagina (all during coughing), directly confirms the contribution of these structures to the continence control mechanism by observing diminution (or not) in the quantum of urine loss.[5] The anatomical rationale for this testing is that all these three structures may play a part in the continence control mechanism,[6] and all three were repaired as part of the TFS sling operation.

Pad testing

Urine loss was measured during 10 coughs performed in the upright position with a full bladder before and after surgery.[1] A 24-h urinary diary was completed by all patients.

Transperineal ultrasound was performed with a full bladder in all cases to test for bladder descent and urethral opening during straining. Urodynamic testing (for urethral pressure, flow, residual urine, and 'detrusor instability')[5] was also performed. In 6 patients, using a 5.5 Mhz probe, it was possible to locate the position of the anchor postoperatively.

The patients were monitored at 6 weeks, and at 3-monthly intervals thereafter using a 24-h urinary diary, structured questionnaire, cough stress test, and transperineal ultrasound. Three criteria needed to be fulfilled for the patients to be classified as 'cured' postoperatively: self-assessed symptomatic improvement of > 90%, absence of urine loss on coughing in the supine position with a full bladder, and a measured pad loss of less than 0.5 g with 10 coughs in the standing position.

The anterior TFS sling operation is identical to the first part of a midline 'tension-free tape' operation. A full thickness midline incision was made into the vagina from just below the urethral meatus to midurethra. The vagina was dissected off the urethra with dissecting scissors, and the dissection was carried a few millimeters beyond the perineal membrane, the space created being just sufficient for the passage of the applicator. The applicator was placed into the dissected space, pushed firmly against the membrane, and triggered to release the TFS anchor. The tape was pulled with a short sharp movement to 'set' the prongs of the anchor into the tissues. Adequate 'gripping' of the anchor was tested by pulling on the free end of the tape. The procedure was repeated on the contralateral side. Taking care to pull in the axis of the anchor's base, the tape was tensioned over a urethra distended by an 18G Foley catheter just sufficiently without indenting it, and the free end cut. The vaginal hammock fascia and the external ligamentous attachment of the external urethral meatus were now tightened with 2–0 Dexon sutures. No cystoscopy was required. Mean operating time was 5 min. In four patients with previous failed 'tension-free tape' surgery and very loose external urethral ligaments, a vertical incision was made into the ligaments almost to the pubic bone. A 0.5×0.8 cm length of tape was inserted into the incision which was then sutured to close it off.

Results

Thirty-six patients had a TFS midurethral sling operations, 10 under local anaesthesia.

The results of all operations are presented, no allowance having been made for a 'learning curve'. The mean number

of previous stress incontinence operations was 0.8 per patient (range 0–3). Thirty-five patients underwent preoperative urodynamic testing preoperatively, and all had the 'simulated operations' test. Total control of urine loss was as follows: midurethral anchoring in 29 patients; hammock tightening in 11 patients, pressing against the external meatus in three patients.

Mean post-operative review time was 9 months (range 3–15). Mean hospital stay was 24 h (12–48 h). One patient was entirely lost to follow-up. She was classified as an operative failure.

At mean 9 months, 30/36 patients (83.4%) remained cured, including one patient with stress incontinence and cough activated detrusor instability. Mean urine loss on preoperative cough stress pad testing (10 coughs in the upright position with a full bladder) was 12.7 g (range 2–35 g), and postoperatively 0.2 g (0–0.5 g) ($P < 0.005$). Mean pre-op bladder volume for this test was 414 mL. The mean postoperative bladder volume was 331 mL. Three patients with stress incontinence also had detrusor instability (DI) (as defined by the International Continence Society),[8] and all were cured of their stress incontinence.

In the failed group of five patients, the mean postoperative urine loss was 5.2 g (range 1–26 g), and no patient had preoperative DI. Repeat anterior TFS sling surgery in four of the failed patients has cured three patients to date (minimum 3 months). The fifth patient states she was satisfied by her improvement. All five failures occurred in the first half of the study.

One failure was caused by total slippage of the tape on one side, presenting as a large vaginal granuloma. This was attributed to surgeon error in the placement of the anchor, given that the TFS operation was successfully performed on another occasion. It was not possible to position the anchor subpubically in one patient because of dense scarring from a previous Burch Colposuspension. The anchor was successfully positioned laterally. Ten patients had Intrinsic Sphincter Defect (ISD, mean urethral closure pressure < 20 cm H_2O). With regard to involuntary urine loss, nine patients were cured, and one stated she was 80% improved. There was no significant change in mean urethral closure pressure. Though her cough pad test loss decreased from 5.2 g to 1 g, she was classified as a surgical failure. There were no cases of haematoma or infection, or postoperative urinary retention, all patients passing urine spontaneously within 24 h. Postoperative pain was minimal, the patients requiring only paracetamol postoperatively.

Using postoperative transperineal ultrasound, the anchor was located just behind the lower part of the posterior surface of the pubic bone, in a position which accords with Robert Zacharin's description of the origin of the pubourethral ligament.[7]

Discussion

The preliminary results indicate that the TFS may give equivalent results to existing blind 'tension-free tape' procedures,[9,10] while at the same time avoiding viscus, nerve and major vessel injuries. Because it is fixed into the subpubic tissues under direct vision and does not penetrate into the retropubic space, the TFS is inherently far safer than existing 'blind' procedures. It requires no cystoscopy. Because the operation was successfully repeated on another occasion, we explain the 'prolapse' of half the tape as surgeon error. This complication highlights a potential problem with this method – it will only work if the anchor can grip into competent tissues, and it may not work in very poor tissues. Furthermore, in order to minimise surgeon error, the surgeon needs to ensure the channel dissected is not too large. A large channel makes it more difficult for the anchors to grip into the tissues. Also, the surgeon needs to test that both anchors have 'gripped' sufficiently before the tape is trimmed. We now wait 20–30 s before testing. This gives time for the elasticity inherent in these tissues to narrow the dissected channel.

Cure of three out of four failed operations by repeating the TFS technique was most encouraging. It indicated that whatever the cause of failure, surgeon error, or patient mishap, the technique itself appeared to be sound.

Though the numbers were small ($n = 36$), we were surprised that there was not even one instance of postoperative urinary retention. We explain this as follows: the anchors grip into reasonably elastic subpubic tissues, so there is inevitably some 'give' at the insertion point of the tapes when the outflow tract is actively 'opened out' during micturition.[1] In contrast, a conventional midurethral sling may constrict the urethra when the rectus abdominis contracts. This may explain why some of those patients sometimes need to bend forward so as to facilitate micturition.

Though the number of patients with Intrinsic Sphincter Defect (ISD) was small ($n = 10$), the high cure rate is attributed to repairing all three components of the urethral closure mechanism. This usually involved only one extra suture, incorporating the lower end of the external urethral ligament and the fascial layer of the suburethral vaginal hammock, a step which takes only 30 s to perform. It is recommended therefore that this extra step be incorporated into every midurethral sling, whatever the technique or delivery instrument used.

The rationale for inserting a small piece of tape into the external urethral ligament in four cases is identical to that for using a midurethral tape:[2] the tape elicits a foreign body reaction. The scar tissue created reinforces the weakened ligament and provides a distal anchoring point for closure of the distal urethra by the forward closure muscles (arrows, Fig. 2).

'Simulated operations'[5] work in exactly the same way as the surgery, by providing a temporary anchoring point for the three directional muscle forces (arrows, Fig. 2). As such, they are a direct test for the theory[1] underlying the TFS operations. In fact, the only way to test for a damaged pubourethral ligament is by unilateral midurethral support during coughing. Performed under video-ultrasound control, this technique has been shown to instantaneously restore not only continence, but normal anatomy.[11]

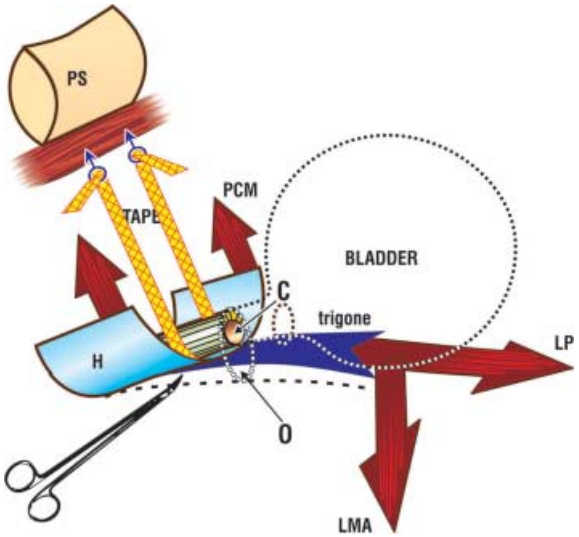

Figure 2 Mechanism of action of the anterior Tissue Fixation System (TFS) sling (3D sagittal view). A polypropylene mesh tape sited at midurethra and attached below pubic symphysis (PS) reinforces the pubourethral ligament allowing the three directional closure muscle (arrows) to restore the urethra from an open position 'O' to a closed position 'C'. H, hammock; LMA, longitudinal muscle of the anus; LP, levator plate; PCM, pubococcygeus muscle. Haemostat 'simulated operation' controls urine loss on coughing by providing a temporary anchoring point.

Conclusions

The TFS is a promising new method. The results are similar to those achieved previously with the 'tension-free' tape operations, but with much more safety and a much shorter operating time. Longer term studies and testing by other surgeons will be required to evaluate this method further.

Declaration of interest

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

Acknowledgement

The TFS system is manufactured by TFS Manufacturing, (Adelaide, Australia). Therapeutic Goods Administration (TGA) CE certificate 0805.

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