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ORIGINAL ARTICLE

Midurethral tissue fixation system (TFS) sling for cure of stress incontinence—3 year results

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Abstract We have previously reported preliminary (9 month) results using the tissue fixation system (TFS) in patients with stress incontinence. The aim of the study was to assess the effectiveness of the TFS in patients with genuine stress incontinence at 3 years. The TFS uses two small plastic anchors to fix a (adjustable) midurethral polypropylene mesh sling into the pelvic muscles and tissues below the retropubic space. 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 between 2003 and 2004. The suburethral vaginal fascia was also tightened. The patients were contacted by telephone independently by a nurse. The critical question was "Do you leak when you cough?" A negative answer was taken as a cure. If she said "sometimes", she was asked on a scale of 1 to 100 what her improvement was. Of the 31 patients contacted, total symptomatic cure was reported by 25 patients (80%) and >70% cure in a further two patients (6.5%). Five patients could not be contacted. There was a slight deterioration in cure rate for stress incontinence between 9 months and 3 years, similar to that seen with retropubic midurethral sling surgery.

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Introduction

The tissue fixation system (TFS) was designed as a safer simpler alternative to existing retropubic and transobturator midurethral sling procedures [1]. Like these operations, the tape is inserted at midurethra. The TFS uses two small plastic anchors to fix a (adjustable) midurethral polypropylene mesh sling into the pelvic muscles below the retropubic space.

Two polypropylene soft tissue anchors provide a one-way directional system for precise tightening of a non-stretch polypropylene tape (Fig. 1). During this operation [1], the suburethral vaginal fascia and external urethral ligament were also tightened. In the original report [1], ten operations were performed entirely under local anesthesia (LA)/sedation. The LA method allowed easy and precise intra-operative tightening of the tape while the patient coughed. No major complications were noted [1]. There was no requirement for cystoscopy, and only paracetamol was required post-operatively for analgesia [1]. Initial results were consistent with those reported for retropubic midurethral slings [2, 3].

Although the anatomical basis of the TFS is similar to that of the retropubic methods [2, 3], it is not identical. The TFS is subpubic, and it attaches the tape to the undersurface of the muscles and fascia of the pelvic floor [1] (Fig. 1). The retropubic "tension-free" tape method [2, 3] attaches the tape not only to the anterior abdominal muscles [2, 3] but also to the posterior surface of the pubic bone, as demonstrated on the canine animal model in 1990 [4]. Although post-operative ultrasound studies [1] demonstrat-

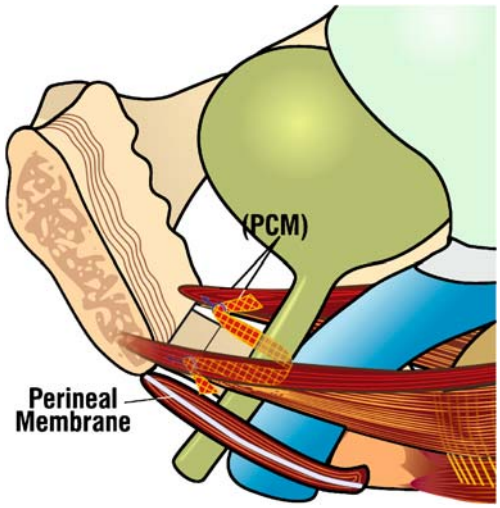

Fig. 1 Anatomical position of the TFS anchor. The tape is anchored into the inferior surface of the pelvic floor muscles. *PCM* pubococcygeus muscle

ed that the TFS anchor was sited in the approximate position of the origin of the posterior pubourethral ligament (PUL), behind the lower part of the pubic bone as specified by Zacharin [5], parity with long-term results with the retropubic operations [2, 3] could not be assumed. Our aim was to assess the long-term results of the midurethral TFS.

Materials and methods

Thirty-six patients with stress incontinence (SI), mean age 55 (35–87), mean weight 76 kg (33–117 kg), mean 0.8 previous operations for SI, underwent a TFS midurethral sling operation between 2003 and 2004 [1]. The patients were independently contacted by a nurse 3 years after surgery by telephone. The critical question was "Do you leak when you cough?" A negative answer was taken as a cure. If the patient said "sometimes", she was asked on a scale of 1 to 100, what her improvement was. A response of less than 70% was the cut-off point for "improvement".

Results

Of the 31 patients contacted, total symptomatic cure was reported by 25 patients (80%), and >70% cure in a further two patients (6.5%). Five patients could not be contacted. Symptomatic cure at 9 months was 87%. [1]. There were no long-term tape rejections.

Discussion

The initial cure rate reported [1] was inferior to that of other colleagues who reported 94% cure rates for the midurethral TFS sling during the same period [6, 7]. Nevertheless, the cure rate initially observed [1] was largely maintained, consistent with observations for the retropubic midurethral tension-free sling procedure at 3 years [8].

The retropubic midurethral tension-free sling procedure [2, 3] was designed to create an artificial pubourethral neoligament attaching the midurethra to the posterior surface of the pubic bone [4]. The TFS attaches the tape to the undersurface of the pelvic muscles and related tissues (Fig. 1). Under video ultrasound control, digitally anchoring the anterior vaginal wall at its midurethral point ("simulated operation") not only controlled urine loss on coughing but also restored the urethrovesical geometry [9]. The finger was not approximated to the posterior pubic bone during this maneuver, suggesting that a firm anchoring point, not attachment to the pubic bone, is the essential element in continence control. This has been borne out by results from the transobturator tape midurethral sling. From a purely mechanical perspective, forward contraction of pubococcygeus muscle (PCM; Fig. 1) would be sufficient to immobilize the urethra. The anatomical work of Zacharin supports this contention. Zacharin described insertion of the PUL not only into the lateral side of the urethra but also into the PCM, the insertion point of the TFS anchor. In a subsequent study of Chinese women [10], Zacharin demonstrated that strong muscle fascia, even in the presence of a weak PUL, seemed sufficient to maintain continence.

A frequent critique of the TFS (Petros and Richardson, unpublished data) concerns the potential use of a non-biodegradable anchor. Our rationale for a non-degradable polypropylene anchor is set out below. The TFS animal experiments [1] showed an encapsulation of the anchor extending across both surfaces of the tape. This meant that the tape was actually attached into the muscle, something we felt was critical for the restoration of the urethral and bladder neck closure mechanisms. We were concerned that after dissolution of the anchor, the fibrous attachment to muscle would, in turn, dissolve, weakening the sling attachment points. In experiments with female Wistar rats in 1973, Bailey et al. demonstrated that only a plastic sponge created a permanent deposition of collagen [11]. Although substances which were ultimately absorbed also produced human collagen in response to an initial foreign body inflammatory reaction, this collagen was also ultimately absorbed. In contrast, a plastic sponge continued to produce collagen on an ongoing basis, as would a polypropylene tape.

In the majority of patients, continence is maintained with retropubic midurethral sling operations in the long term [12]. However, at a 7-year review [12], 5% of patients reported improvement in their SI, whereas 8% reported deterioration. These data can be explained with reference to

the properties of connective tissue. Urethral closure relies on an adequately firm PUL, and also a tight suburethral vaginal hammock [9]. Collagen contracts with age [13]. Therefore, patients with a slightly lax PUL would report improvement in their symptoms with time. However, the vaginal tissue becomes lax with age [14], weakening the musculoelastic closure mechanism [9], with worsening of their SI with time. Depending on individual circumstance, a patient may report maintenance, improvement, or worsening of their continence state.

Conclusion

There was a slight deterioration in cure rate for SI between 9 months and 3 years, similar to that seen with retropubic midurethral sling surgery.

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

Declaration of interest The first author has a financial interest in the TFS patent, whereas the second author does not.

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