A Prospective Randomized Controlled Trial of the Transobturator Tape and Tissue Fixation Mini-Sling in Patients with Stress Urinary Incontinence: 5-Year Results

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Abbreviations and Acronyms

CSPT = cough stress pad test

ISD = intrinsic sphincter deficiency

QoL = quality of life

RCT = randomized controlled trial

SUI = stress urinary incontinence

TFS = tissue fixation system

TOT = transobturator tape

TVT® = tension-free vaginal tape

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Study received local ethics committee approval.

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Purpose: We present the 5-year results of a randomized controlled trial comparing the efficacy of a transobturator tape operation with an adjustable mini-sling (tissue fixation system) for the treatment of stress urinary incontinence.

Materials and Methods: This prospective randomized controlled trial comprised 80 female patients with only urodynamically proven stress urinary incontinence. The participants were randomly allocated to the transobturator tape group or the tissue fixation system group according to a computer program at a maternity research hospital. The patients were reassessed 5 years after surgery. Primary outcome measures were objective and subjective cure rates as well as total failure rate.

Results: Total followup was 64 months (range 58 to 70). The objective cure, subjective cure and failure rates in the tissue fixation system group were 83% (30 cases), 6% (2) and 11% (4), respectively. The objective cure, subjective cure and failure rates in the transobturator tape group were 75% (27 cases), 3% (1) and 22% (8), respectively. The difference in objective cure rates was statistically significant in favor of the tissue fixation system ($p = 0.029$). The difference in decreased cure rates between 5 and 3 years was 7% (90% to 83%) for the tissue fixation system vs 9% (84% to 75%) for the transobturator tape. The relative decrease in cure rates between the 2 groups was not statistically significant ($p = 0.16$).

Conclusions: Contrary to reports in the literature of poor results with mini-slings, the tissue fixation system mini-sling demonstrated a higher cure rate and lower complication rate than the transobturator tape.

Key Words: suburethral slings, surgical fixation devices

FROM 1990 to the present there has been an exponential change in surgical treatments offered for SUI, which in some way can be attributed to the concepts inherent in the integral theory of Petros and Ulmsten.[1] They described a prototype intravaginal suburethral slingplasty operation (TVT), a minimally invasive same day operation with minimal pain, no significant postoperative urinary retention and a high success rate. However, reports of small bowel and external iliac artery perforations, albeit infrequent, were major causes of concern, inviting calls for zero tolerance of such surgery.[2] Delorme's transobturator mid urethral sling significantly decreased such complications with an equivalent cure rate.[3] However, the TOT

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was not as effective in curing ISD, and was subject to complications such as obturator nerve and artery damage, groin pain, and even bladder perforation.

A more recent development is the single incision mini-sling for SUI, inserted below the mid urethra without entry to the retropubic or obturator space. Our interest in the TFS, the first mini-sling procedure for the treatment of SUI, began in 2005 after review of the initial results of the TFS.[4] These appeared to show a cure rate equivalent to that of the TVT and TOT slings, without the need for cystoscopy and with minimal postoperative pain.

When we commenced the RCT to our knowledge there were no other data available for mini-slings. We assessed the efficacy of the TFS in the treatment of SUI in women. We chose the TOT for the other arm of the RCT rather than the TVT because of its safety, lesser invasiveness and equivalent cure rate.

MATERIALS AND METHODS

This single blind, prospective RCT was conducted in the urogynecology clinic of Ankara Etlik Zubeyde Hanim Women's and Maternity Research Hospital, Turkey. All operations were performed between September 2005 and September 2006. The study comprised 80 female patients with urodynamic SUI, randomly allocated by computer program for a TOT or TFS operation. Each group included 40 patients.

The patients were evaluated with a full clinical history, pelvic examination, pelvic ultrasound, validated incontinence impact questionnaire,[5] quality of life scoring system (a simplified QoL score with grades from 1 to 5 to describe the limitation of normal activities by incontinence, with higher scores indicating problems)[6] and CSPT (preweighed pad placed on vulva, patient with full bladder coughs 10 times, urine leakage assessed as positive—greater than 1 gm urine loss and negative—less than 1 gm loss). Urodynamics were performed before and after the initial operations but not at the 5-year review. Patients with overflow incontinence, those with overactive bladder and those who underwent previous anti-incontinence surgery were not included in the study (fig. 1).

Informed consent was obtained by all patients and the local ethics committee of the hospital accepted the study. All operations were performed by the same physician (AAS). The postoperative assessment was performed by a senior surgeon at the urogynecology clinic who did not participate in the operations. The operating physician was not involved in the followup reviews. All operations were performed with the patient under spinal anesthesia in the lithotomy position with legs in stirrups. TFS (TFS Surgical, Adelaide, South Australia, Australia) and I-STOP® (CL Medical, France) are kit based procedures. The mesh tapes are similar in that they consist of nonstretch polypropylene monofilament tapes.

The standard outside-in method was used for the TOT, with the monofilament tape (I-STOP) inserted at the level of the clitoris. The TFS mid urethral sling was performed as previously described.[4] Two anchors attached to an adjustable sling were inserted into the inferior surface of the pubovaginalis/pubourethral ligament/muscle complex, immediately behind the urogenital diaphragm (perineal membrane). The tape was tightened over an 18-gauge rigid Foley catheter until it touched, but did not indent, the urethra.

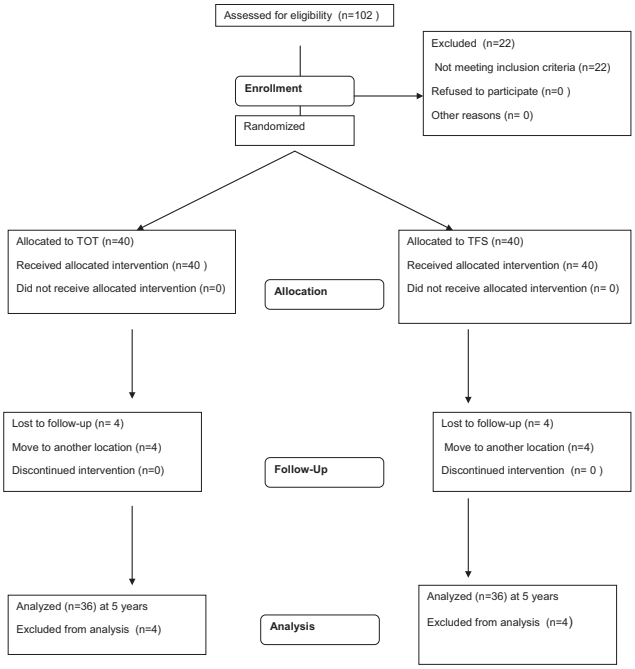

Figure 1. CONSORT diagram

The patients were reevaluated 1, 3 and 6 months, and annually thereafter. At the beginning of the study we planned to report the results of the RCT at 3 and 5 years (long period) of followup. In terms of the criteria for the 5-year assessment, if the supine CSPT was negative after the operation and the patient reported the restoration of urinary continence, then the procedure was regarded as an objective cure. If the patient reported restoration of urinary continence but the supine CSPT was positive, then treatment was regarded as a subjective cure. If there was no change in incontinence after the operation it was regarded as failure.

Our primary outcome measures were rates of objective cure, subjective cure and failure 5 years after anti-incontinence surgery. Secondary outcome measures were procedure duration, postoperative groin pain, postoperative urinary retention and mesh extrusion. The total followup period was 64 months (range 58 to 70). When the study began there were no published long-term data on the TOT or TFS to use for a formal power analysis. Based on our expectations and on practical considerations we decided to enroll 80 patients (40 in each arm).

All data were recorded using standard forms and we used SPSS® 11.5 for Windows for statistical analysis. The Student t test, Mann-Whitney U test, paired sample t test and Fisher exact test were used in the analysis of data. For all comparisons $p < 0.05$ was considered statistically significant.

Table 1. *Patient characteristics*

	TOT Group	TFS Group	p Value
Mean ± SD pt age	52 ± 11.7	50 ± 9.8	0.83
Mean ± SD kg/m^2 body mass index	28.1 ± 1.4	28.6 ± 2.3	0.98
Mean ± SD parity	2.4 ± 1.6	2.5 ± 1.1	0.84
No. postmenopausal (%)	25 (69)	26 (72)	0.69
Mean ± SD yrs SUI	4.5 ± 2.4	4.9 ± 0.2	0.74

RESULTS

We were able to test 36 of the original 40 patients in each arm. The groups were similar in terms of age, body mass index, parity, menopausal status and duration of SUI (table 1). The operating time was statistically significantly shorter in the TFS group (6 ± 1 minutes) than in the TOT group (12 ± 2 minutes, p = 0.007, table 2). No intraoperative complications were seen in either group. Urinary retention, groin pain and mesh extrusion were noted in 2, 12 and 1 patient, respectively, in the TOT group. In the TFS group there was no urinary retention or significant postoperative pain, but anchor displacement (left side) was found in 1 patient. There were no statistically significant differences between the groups in terms of preoperative and postoperative CSPT values, whereas there were statistically significant differences within the groups in CSPT values before and after surgery (table 3).

The objective cure, subjective cure and failure rates in the TFS group were 83% (30 cases), 6% (2 cases) and 11% (4 cases), respectively. The objective cure, subjective cure and failure rates in the TOT group were 75% (27 cases), 3% (1 case) and 22% (8 cases), respectively (table 4). There were statistically significant differences between the groups in terms of objective cure rates (p = 0.029) and failure rates (p = 0.04). The decrease in cure rate from 5 to 3 years was 7% (from 90% to 83%) for the TFS group and 9% (from 84% to 75%) for the TOT group (fig. 2). The difference in decreased cure rates between the 2 groups was not statistically significant (p = 0.16).

There were 4 patients in whom treatment failed in the TFS group, including 2 who did not want any further intervention and 2 who elected oral antimuscarinic treatment. There were 8 patients in whom treatment failed in the TOT group, including 3 who did not want any further intervention, 3 who opted to receive oral antimuscarinic treatment, 1 who underwent abdominal hysterectomy plus bilateral salpingo-oophorectomy (uterine bleeding unresponsive to hormonal treatment) plus Burch colposuspension (the patient fared well) and 1 who had suburethral mesh cutting plus retropubic TVT insertion (for urgency). QoL scores improved after both operations (table 5).

Table 2. *Operating time, and intraoperative and postoperative complications*

	TOT Group	TFS Group	p Value
Mean ± SD mins procedure	12 ± 2	6 ± 1	0.007
No. bladder injury	0	0	Not applicable
No. bleeding exceeding 100 ml	0	0	Not applicable
No. urinary retention (%)	2 (5.5)	0	0.4
No. postop groin pain (%)	12 (33)	0	0.03
No. mesh extrusion (%)	1 (3)	0	0.7
No. anchor displacement (%)	0	1 (2.5)	Not applicable

Table 3. *Assessment of CSPT before and after surgery*

	TOT Group	TFS Group	p Value
Mean ± SD gm preop CSPT	73 ± 27	71 ± 18	0.8
Mean ± SD gm postop CSPT	0.41 ± 0.4	0.66 ± 0.8	0.5
p Value	0.0002	0.0001	

TOT Group Complications

Urinary retention was resolved with 3-day catheterization. Postoperative groin pain lasted for 2 weeks in 9 patients. Two patients needed anti-inflammatory medications and the pain stopped within 1 month. One patient refused any intervention for groin pain and at the 3-year followup reported pain at times (particularly during long distance walking) but did not want any intervention. This patient had persistent groin pain at 5-year followup but also reported becoming accustomed to it. Mesh extrusion (2C/T4/S1) was seen in 1 patient at the 5-year followup visit, and the extruded mesh was trimmed without full surgery and anesthesia.

TFS Group Complications

Anchor displacement in the left side was observed in 1 patient at the first year followup visit. The anchor was removed with the patient under local anesthesia and the patient remained continent. Abnormal urination was noticed by 1 patient at the 4-year followup visit. Poor stream and staying in toilet for longer durations (approximately 20 minutes) were noted, and uroflowmetry revealed outflow obstruction. The suburethral mini-sling was cut lateral to the urethra and symptoms persisted through the early postoperative period. However, 6 months after urethrolysis the symptoms subsided and the patient remained continent.

DISCUSSION

The introduction of mini-slings is another chapter in the ongoing revolution which began in the early

Table 4. *Cure rates at year 5*

	TOT Group	TFS Group	p Value
% Objective cure (No.)	75 (27)	83 (30)	0.029
% Subjective cure (No.)	3 (1)	6 (2)	0.80
% Failure (No.)	22 (8)	11 (4)	0.04

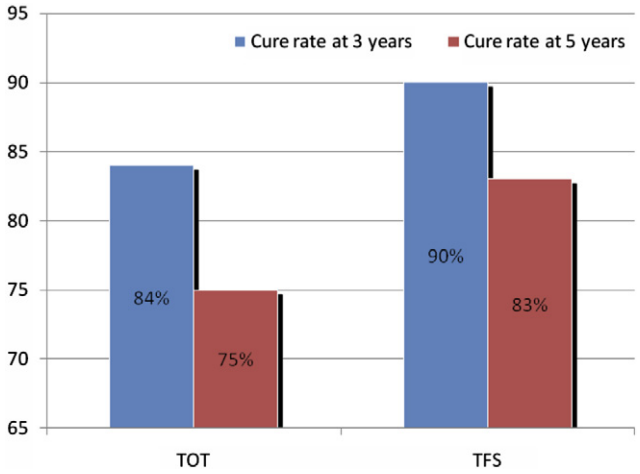

Figure 2. Decreases in cure rates

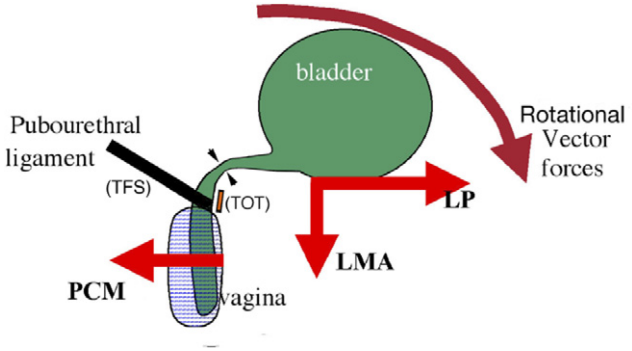

Figure 3. Proximal and distal urethral closure mechanisms. Distal—pubococcygeus muscle force (*PCM*, forward arrow) stretches suburethral vagina against pubourethral ligament to close it from behind. Proximal—backward/downward muscle forces (arrows), levator plate (*LP*) and longitudinal muscle of anus (*LMA*) stretch proximal urethra around pubourethral ligament to narrow (small arrows) and kink tube. TFS tape grips sides and inferior part of urethra. TOT tape merely provides inferior fulcrum point. Reprinted with permission from Petros.

1990s,[1] offering potentially equivalent cure rates, but with shorter hospital stays, significantly less morbidity and lower costs to the health system. The size of the study population is the significant limitation of this first long-term RCT of a mini-sling compared to an established mid urethral sling operation.

The results of this study indicate that the TFS has a cure rate superior to that of the TOT at 83% vs 75% at 5-year followup ($p = 0.029$), a slightly larger differential than at the 3-year followup (90% TFS cure vs 84% TOT cure).[7] If subjective cure is added, the differential at 5 years is even larger at 89% vs 78%. We believe the superior results are mainly due to the unique design of the system, the strong grip of the anchors (up to 3 kg pullout for each) and the precise 1-way tensioning system.

When we began the RCT in 2005 no results were available for any other type of mini-sling. Since then there has been a profusion of mini-slings, the 2 most common being the TVT SECUR™ System and the MiniArc®. Neither has achieved the results achieved by the TVT and TOT operations. In a recent publication on the TVT SECUR Lim et al reported the premature cessation of study recruitment due to the high number of early failures.[8] Commenting on the 6-month results of a RCT comparing the TVT SECUR and MiniArc, Basu and Duckett stated that the mini-sling was associated with a higher failure rate than retropubic TVT.[9] However, this has not been the experience for the TFS mini-sling, which appears to have results at least equivalent to those of the TVT/TOT for stress urinary incontinence, and a high cure rate in patients with ISD.[4,10] Sekiguchi et al reported a 91% cure rate for the TFS.[10] Our 5-year study appears to confirm other reports at 3 years of minimal decrease in continence with time with the TFS operation.[7,11]

We agree with Basu and Duckett, who attributed the inferior cure rates of the TVT SECUR and MiniArc mini-slings[9] compared to TVT to the extra grip exerted by the TVT on the urethra. The TVT SECUR and MiniArc mini-slings work by being pushed upward alongside the middle part of the urethra. Whether the operation works depends on whether the tape and anchor have a sufficient grip to withstand the restorative force generated by the inherent elasticity of the compressed tissue, as a loose anchoring point will invalidate the urethral closure mechanisms (fig. 3).[12] The TFS works differently than the TVT SECUR and MiniArc mini-slings. A tunnel is made on each side to the perineal membrane. The anchors penetrate the membrane and a 1-way tightening system at the anchor base precisely tightens the tape to the tension required. Each anchor has a grip of up to 3 kg, which is more than sufficient to withstand the restorative elastic forces.

Although the TOT seems to have a cure rate equivalent to that of TVT in nonISD cases, in those with ISD the results of the TOT are considered inferior.[13,14] In the first study of the TFS mid urethral

Table 5. *QoL before and after surgery*

	TOT Group	TFS Group
Mean ± SD preop QoL score	16 ± 5	15 ± 4
Mean ± SD postop QoL score	3 ± 2	4 ± 1
p Value	0.002	0.003

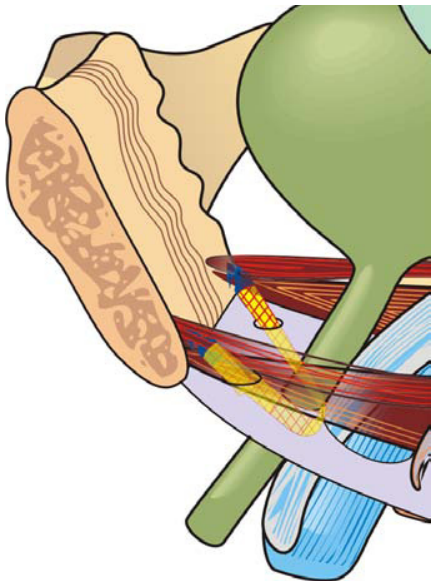

Figure 4. TFS is inserted retropubically in exact same axis as TVT. Reprinted with permission from Petros.

sling, 30% of the original group of patients had ISD.[4] Similarly Sekiguchi et al reported that 34.5% of their patients had ISD and, again, the cure rate was equivalent to that of those without ISD.[10]

The anatomical restoration of the TFS is almost identical to that of the TVT (fig. 4). The TFS is inserted retropubically in exactly the same axis as the TVT. However, unlike the TVT, the TFS remains at all times below the space of Retzius. Postoperative ultrasound studies indicate that it is close to the origin of the pubourethral ligament, which it seeks to reinforce.[4]

Schierlitz et al explained this difference in results in a trial of TVT vs TOT by urethral wall compression by the TVT tape.[15] We agree that the lateral position of the tape is central to explaining the superior cure rates of the TVT and TFS relative to the TOT, but not by compression. There is no mechanism that could cause the tape to compress the urethra laterally during stress.

It is possible to explain the difference in the TFS and TOT results by applying the integral theory, on which both of these operations are based. The theory describes 2 distinct urethral closure mechanisms, distal and proximal, the latter being the more important (fig. 3). These closure mechanisms have been demonstrated by ultrasound[12,16] as well as radiologically.[17] Distal urethral closure is achieved by a forward movement of the vaginal hammock, and proximal urethral closure by a backward and downward stretching of the proximal urethra around a competent pubourethral ligament. Both require a competent pubourethral ligament.

Zacharin described the pubourethral ligament as descending almost vertically.[18] It diverges into 2 parts, medially to attach to the lateral wall of the urethra, and laterally into the pubococcygeus muscle. The TVT and TFS mimic the urethral insertion precisely. The TOT does not attach to the lateral wall. It simply provides an inferior fulcrum point around which the proximal urethra can rotate (fig. 3). This rotation is driven solely by the downward muscle force.

In contrast, the TFS (and TVT) provide a firm grip on the lateral urethral walls to provide a lateral and inferior fulcrum point. The urethra can now be stretched backward and rotated. Backward stretching would narrow the urethra more than is possible with TOT. According to Poisseuille's Law, any narrowing of the urethra increases the resistance to flow from the bladder (for example, during coughing) exponentially, by the 4th power.[19] The other physical mechanism quoted to explain continence is the Law of Laplace (pressure = tension/radius). Stretching increases the tension of the urethral wall and also narrows it, increasing the intraurethral pressure.

It is evident on examining figure 3 that Laplace's Law would apply to the TVT and TFS slings, but not to the TOT. At a more fundamental physical level this may sufficiently explain not only the higher cure rate obtained for the TFS in our study, but also why the TVT and TFS seem to cure stress urinary incontinence (with ISD) more consistently than the TOT.

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