An in-house Composix™-based pubovaginal sling trial for female stress urinary incontinence: Five-year comparative followup to tension-free and transobturator vaginal tapes

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Cite as: *Can Urol Assoc J* 2017;11(8):275-80. http://dx.doi.org/10.5489/cuaj.4243

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Abstract

Introduction: We compared the efficacy of three slings in the long-term treatment of stress urinary incontinence (SUI): tension-free vaginal tape (TVT), vaginal tape-obturator (TVT-O), and an in-house two-layered polypropylene mesh with a submicronic polytetrafluoroethylene (Composix™). Our primary endpoint was the objective measurement of continence (24-hour pad test). Secondarily, we measured the satisfaction and complication rates.

Methods: This prospective, non-randomized study included 128 patients with SUI. Preoperative evaluation included medical history, physical exam, 24-hour pad test, Urinary Incontinence Quality of Life Scale (IQOL), FPSUND, and global satisfaction questionnaires. Patients were followed at one month postoperative, biannually for two years, and then annually for a total of five years. Followup visits included a focused questionnaire, physical exam, satisfaction questionnaire, 24-hour pad test, IQOL, and FPSUND questionnaires.

Results: Composix, TVT, and TVT-O groups included 60, 34, and 34 patients, respectively. No significant differences were found in baseline characteristics except for the pad test. Length of catheterization was the only immediate operative significant parameter (Composix 4.7 days vs. TVT 1.1 days vs. TVT-O 2.6 days; p=0.03). The entire cohort had significant improvements in their IQOL, FPSUND, and pad test at one and four years (p<0.01). The cohort-wide 24-hour pad test average weight was 30.4 g preoperatively vs. 5 g at 12 months (p<0.00001) (Composix 37 to 5 g, TVT 83 to 4 g, and TVT-O 55 to 5 g). The Composix group had a higher number of minor complications (Clavien I, II) and secondary procedures.

Conclusions: This single-surgeon cohort with five-year followup demonstrated a large improvement and maintenance of continence in all three surgical groups. The Composix-based sling provided comparable continence outcomes at a fraction of the cost; however, its increased morbidity and higher complication rate raise concerns over future use

Introduction

It is estimated that up to 50% of women will suffer from urinary incontinence, with 50–80% of them suffering from stress urinary incontinence (SUI).[1-4] Midurethral slings (MUS) are currently the most performed incontinence procedure in North America, with an estimated 4–10% of women in the U.S. undergoing surgery to restore continence.[5]

Several brands and techniques for MUS are available to surgeons. Among them, retropubic MUS, including tension-free vaginal tapes (TVT), transobturator vaginal tapes (TVT-O), and single-incision mini-sling systems, are frequently performed. While they provide good results, potential complications include urinary tract infections, urgency urinary incontinence, bladder perforation, chronic pain, and mesh-related problems, including potential urethral erosions, among others.[6]

In this article, we report our prospective, single-surgeon series in which three different SUI surgical options were performed and compared: TVT, TVT-O (Gynecare TVT Obturator System, Ethicon, Johnson-Johnson), and an in-house alternative retropubic sling. In 2002, our institution began exploring the possibility of a less expensive synthetic sling alternative to current pre-made kits. A Composix™ (Bard, Davol)[7]-based sling (10 X 1.5 cm) was cut out from a large ventral hernia repair sheet. The Composix sling was attached with resorbable sutures over the lower abdominal rectus fascia and suspended tension-free suburethrally, similar to a pubovaginal fascial sling (Raz procedure).

Methods

This prospective, single-surgeon study included three different MUS implanted between April 2002 and May 2010. The choice of sling was based on the surgeon's preference at the time of consultation and product availability. Inclusion criteria were women with SUI confirmed through cough test

or urodynamic evaluations. Patients were selected if they had failed conservative treatment options and were advised on the possible necessity for postoperative clean intermittent catheterization. Subjects were excluded if they were unfit for surgery, had active urinary tract infection, pelvic organ prolapse, acontractile bladder, overactive bladder, a neurogenic underlying condition, or were unable to attend followup.

A preoperative medical history and physical examination were completed, along with a 24-hour pad weight test (considered positive if >2 g lost urine/day). Relevant information collected included age, parity, and previous hysterectomy or incontinence surgery. A cough stress test was performed at the time of physical examination. If equivocal, urodynamic studies were performed. FPSUND classification,[8,9] Urinary Incontinence Quality of Life Scale (IQOL),[10,11] and an overall satisfaction scale (0–10) questionnaires were administered.

The Composix mesh is a two-layered monofilament polyprolene mesh (pore sizes 800–1000 μm) with a submicronic polytetrafluoroethylene (PTFE) layer (pore sizes 1 μm) touted to minimize mesh adhesions and the risk of fistula or mesh erosion.[7,12] Composix was withdrawn from the market in 2007 for reasons unrelated to its chemical composition. TVT^{T} and TVT-0 polypropylene meshes were implanted thereafter, with average pore sizes of 1379 μm.[13]

All three techniques were performed in the operating room under general or spinal anesthesia. All patients received intravenous prophylactic antibiotics at anesthetic induction. A first-generation cephalosporin was administered or an aminoglycoside if the patient reported penicillin or cephalosporin allergies.

Composix sling implantation involved bilateral dissection of the paraurethral tissue up through Retzius space and two 2 cm paramedial suprapubic incisions with dissection down to the rectus fascia. A Raz needle was used to pierce and pass the polyglyconate (Maxon) sutures through the fascia. The sutures were secured over the rectus fascia after the humidified Composix sling was positioned flat and tension-free under the urethra, with the PTFE-coated layer facing the urethra.

The TVT uses a similar midline transvaginal incision at the midurethra level to develop paraurethral spaces and pass the synthetic meshed tape retropubically, with the needle curvature designed to maintain contact with the posterior aspect of the pubic bone.[14-16] The TVT-O approach also proceeds through a midurethral dissection, however the synthetic tape is passed transvaginally through the obturator foramen rather than the retropubic space using a safety-winged guide.[15,17] Both techniques use an "in/out" approach.

Once the mesh was in place, subsequent steps were identical in all three groups: running absorbable sutures were used for the vaginal mucosa and the skin incisions suprapubically or at the tape exit sites. A control cystoscopy was done before the insertion of a urinary catheter. It was removed by a home care nurse on a full bladder, checking the ability to void adequately; if voiding was incomplete (i.e., the residual urine was >100 ml), the catheter was put back for another 48 hours. If voiding remained problematic, self-catheterization was instituted. Time for catheter dependence was noted. Patients underwent a focused physical exam one month post-surgery.

Surgical and postoperative complications were noted and recorded for all patients. Postoperative complications were recorded and graded according to the Clavien-Dindo classification of surgical complications.[18] Followup visits were scheduled six, 12, 18, 24 months, and yearly thereafter for a total of five years. All visits included a focused history and physical exam, along with FPSUND, IQOL, overall satisfaction questionnaires, and a 24-hour pad test.

Primary efficacy endpoints included objective changes in SUI (postoperative 24-hour pad test). Secondary outcomes were subjective changes in SUI reported by the standardized questionnaires, along with postoperative complications (Clavien-Dindo surgical complications grade)[18] and multivariate analyses.

Statistical analysis was completed using R 3.2.0 and SAS® 9.3 software for Mac. Kruskal-Wallis one-way analysis of variance (ANOVA) was used to demonstrate equivalence related to preoperative factors for the three surgical groups. Factors analyzed included previous hysterectomy, previous urethropexy, age, gravida, and duration of postoperative urinary catheterization. Means were calculated for IQOL, FPSUND, and pad test results for each visit. Primary and secondary outcomes were evaluated preoperatively vs. 12-month and 12- vs. 48-month postoperatively. Data needed to be available at both time points in the same patient for the analysis. Paired Wilcoxon test was used for testing the efficacy of treatment for primary and secondary outcomes. One-way ANOVA was used for treatment arm comparisons. Univariate and multivariate models were conducted to isolate significant predictive factors for sling outcomes based on FPSUND, IQOL, and 24-hour pad test results.

Results

This study included 128 patients with 60, 34, and 34 patients in the Composix, TVT, and TVT-O groups, respectively. All three surgical groups did not differ significantly in their baseline characteristics, including previous incontinence surgery, with the exception of the 24-hour pad tests (Table 1). The mean 24-hour preoperative pad test was significantly higher in the TVT group (Composix 37.4 g/24 hours, TVT 83.2 g/24 hours, TVT-O 55.2g/24 hours; p=0.0005). The Composix subgroup had the longest average postoperative catheterization at 4.6 days (p=0.03), whereas the TVT and TVT-O patients averaged 1.1 and 2.6 days, respectively.

Significant improvements in 24-hour pad test at 12 months were noted for each subgroup of the cohort (Composix 5

Table 1. Baseline patients characteristics

	Composix	TVT	TVT-O	Total	p
Patients, n (%)	60 (46.9%)	34 (26.5%)	34 (26.5%)	128	
Age, years (SD)	57.6 (12.1)	57.3 (11.5)	61.4 (11.2)	58.5 (12.2)	0.21
Previous hysterectomy, n (%)	29 (52.7%)	10 (18.8%)	16 (29%)	42.9%	0.18
History of previous urethropexy, n (%)	1 (18.3%)	4 (11.7%)	3 (8.8%)	14%	0.46
Gravida mean	2.9	2.5	2.3	2.6	0.72
FPSUND score, mean (SD)	12.2 (2.5)	11.6 (2.2)	11.3 (2.2)	11.8	0.19
I-QOL score, mean (SD)	58.2 (22.3)	51.8 (18.4)	56.3 (21.6)	55.7	0.44
Pad test, g/24 hr, mean (SD)	37.4 (35.1)	83.2 (58.2)	55.2 (56)	52.1	0.0005
Satisfaction,* mean (SD)	2.4 (2.4)	2.4 (2.5)	2.9 (2.1)	2.5	0.54
Postoperative catheterization, days (SD)	4.7 (10.1)	1.1 (0.6)	2.6 (4.3)	3.6 (8.3)	0.03

*Overall urinary satisfaction (0–10). Kruskal-Wallis, Univariate ANOVA analyses. I-QOL: Incontinence Quality of Life; SD: standard deviation; TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

g/24 hours, TVT 4 g/24 hours, TVT-O 5 g/24 hours). This was maintained over the next 48 months (Table 2, Fig. 1). One-way ANOVA analyses did not identify a difference between the three surgical groups and the 0–12-month and 12–48-month followup results (24-hour pad test, $p< 0.001$).

Secondary outcomes demonstrated a significant improvement post-surgery. Symptomatic improvements were maintained throughout the five-year followup period. FPSUND values significantly improved postoperatively (all groups $p<0.005$; Table 3, Fig. 2) except for the TVT-O group between 12 and 48 months. IQOL showed similar significant improvements for all three groups ($p<0.01$) postoperatively; these were maintained over time (Table 4, Fig. 3). This trend was mirrored in the overall satisfaction questionnaire, which increased substantially postoperatively and was maintained throughout followup (Fig. 4).

Univariate and multivariate analyses were conducted to isolate predictive factors for the 24-hour pad test and the FPSUND and IQOL questionnaires. No factors were predictive of the IQOL and 24-hour pad tests.

The Composix group experienced a much higher number of minor (Clavien I, II) postoperative complications with bladder traumas, hematomas, seromas, and wound infections , among others (Table 5). Additionally, these women experienced a higher rate of erosions/extrusions and a more important rate of secondary procedures, which included sling loosening and anchoring suture or tape removal. TVT-Os had the highest rate of surgical removal required (11.7%). It should be noted that several of the TVT and TVT-O patients who were re-operated were patients undergoing their second or third SUI surgery.

Discussion

With the increasing numbers of female SUI procedures being performed in North America, alternatives and new models are constantly rising to the forefront. The rise of MUS has virtually eliminated the practice of Burch colposuspension, which until recently was considered the gold standard.[19] Series have demonstrated similar long-term complications and cure rates between colposuspensions and MUS.[20-22] The use of autologous fascial slings, as studied by Albo et al, was reported to have an increased cure rate compared to Burch colposuspensions.[23] Khan et al's randomized, controlled trial of TVT vs. autologous vs. xenograft slings demonstrated superior (yet non-significant) dry rates in autologous slings

Table 2. Pad test

	Preoperative	12 months	p	12 months	48 months	p
Composix, g	30.2 (41)	2	<0.001	4.5 (19)	3.0	<0.001
TVT, g	36.1 (19)	7	<0.001	3.9 (11)	6.0	<0.001
TVT-O, g	26.9 (22)	7	<0.001	4.6 (15)	8.0	<0.001

Mean values listed. Numbers in parentheses are the number of patients present at both time points. Wilcoxon matched-pairs signed-ranks test. TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

Table 3. FPSUND

	Preoperative	12 months	p	12 months	48 months	p
Composix, g	12 (41)	3	<0.001	4.2 (19)	5	0.36
TVT, g	15.9 (9)	3	<0.002	8.3 (11)	3	0.18
TVT-O, g	11.4 (22)	2.5	<0.01	3.7 (15)	2	0.03

Mean values listed. Numbers in parentheses are the number of patients present at both time points. Wilcoxon matched-pairs signed-ranks test. TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

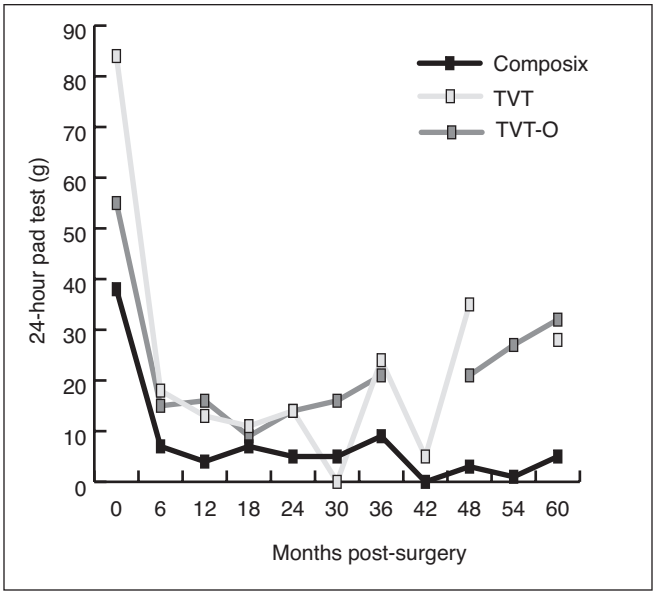

Fig. 1. Postoperative **24-hour pad test** for each subgroup. TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

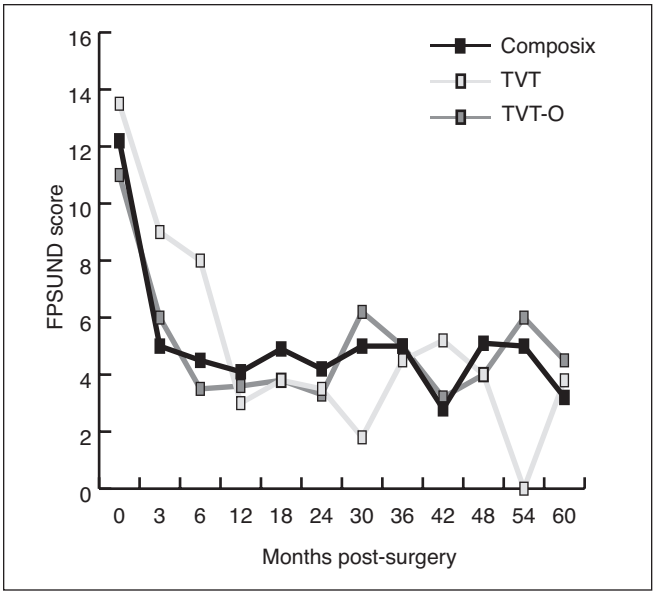

Fig. 2. Postoperative **FPSUND** values for each subgroup. TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

as compared to TVTs;[24] however the synthetic MUS had a higher five-year re-operative rate. Combined with the inferior results provided by the xenograft slings (Pelvicol™),[24] this paved the way for the trial of a synthetic pubovaginal sling in the treatment of SUI. Along with the lowered cost of an in-house sling, this surgery would have a potentially decreased surgical morbidity to autologous fascial slings, as no fascia is harvested.

In-house slings have been reported previously in the literature. Ciftici et al published a series of commercial vs. in-house polypropylene monofilament TOT slings.[25] While both groups reported similar efficacy, the custom group reported a longer operating time and a higher vaginal extrusion rate (p=0.016).

As expected, 24-hour pad tests were significantly improved at 12 months in all groups. This positive effect was maintained for the ensuing four years. Between the surgical groups, no significant difference was demonstrated in objective results with a one-way ANOVA. Subjective measures reported similar and persistent satisfaction rates with all three slings.

The Composix-based slings were last installed in this series in 2007 due to two factors. Firstly, the recall of the

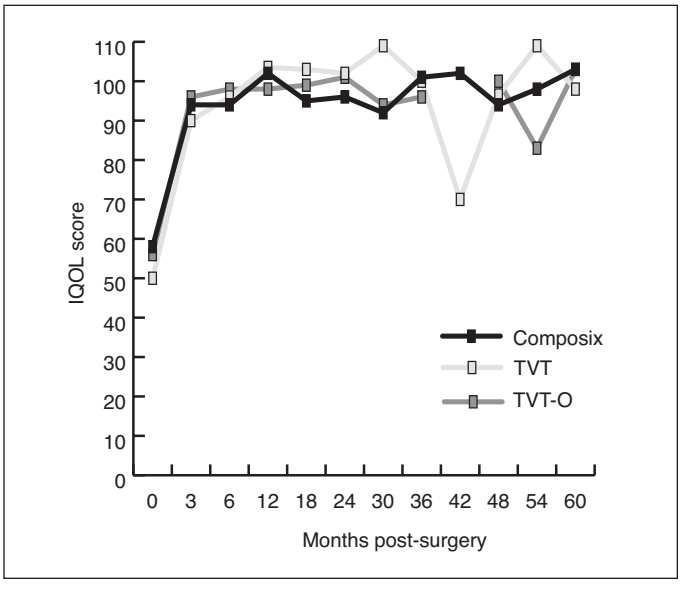

Fig. 3. Postoperative **I-QOL scores** for each subgroup. I-QOL: Incontinence Quality of Life; TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

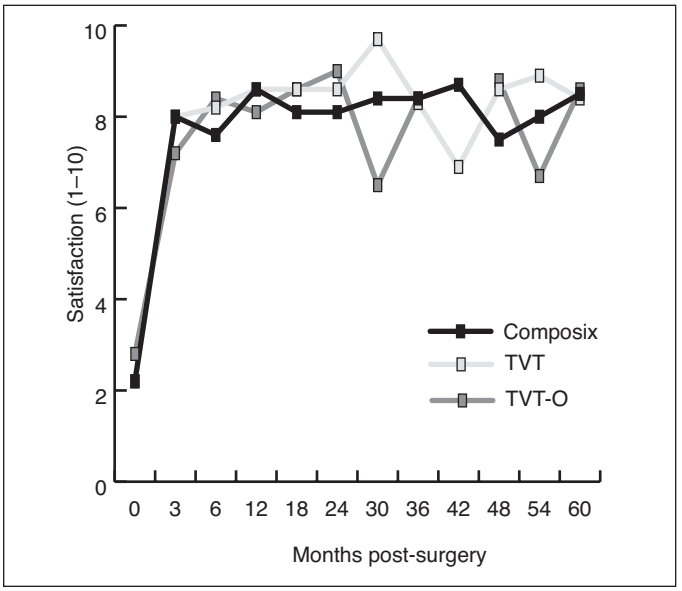

Fig. 4. Results of the **overall satisfaction** questionnaire. TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

Table 4. I-QOL

	Preoperative	12 months	p	12 months	48 months	p
Composix, g	66.8 (41)	92.3	<0.001	100 (19)	91.5	0.45
TVT, g	40.8 (19)	100.2	0.001	103.7 (11)	95.9	0.31
TVT-O, g	50 (22)	99.5	<0.001	99.4 (15)	98	0.93

Mean values listed. Numbers in parentheses are the number of patients present at both time points. Wilcoxon matched-pairs signed-ranks test. I-QOL: Incontinence Quality of Life; TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

Composix ventral hernia repair system due to a defect in the laparoscopic release mechanism decreased availability. Secondly, the evidence towards macroporous (>75 µm) synthetic sling materials discouraged further use of the Composix-based slings.[26] The more important combined erosion rate was reported in the Composix group (4/60, 6.6% vs. TVT 1/34, 2.9% vs. TVT-O 1/34, 2.9%). The erosion may be caused by the weave of the Composix mesh. In addition, a recent systematic review and meta-analysis did not find a higher rate of return to operating room for erosions/extrusions in (autologous) pubovaginal slings as compared to MUS; however, there are limited studies in this area.[22] The more important erosion/extrusion rate with the Composix sling could be attributed to the synthetic mesh in this series, yet we refrain from drawing any conclusions due to the limited patient numbers.

The major limitation in this analysis is the high attrition rate. The descriptive nature of this cohort of 128 consecutive patients operated with the available product at time of surgery and non-exclusion of previously operated patients prevents us from drawing conclusions on the MUS complication and re-operative rate. Moreover, the three sling types were not used concomitantly. Therefore, the later patients in this series may have benefited from the experience gathered from previous surgical procedures.

Globally, all three options produced similar satisfaction and dry rate that sustained the test of time. This novel in-house sling proof of concept provided comparable results with a fraction of the price; however, its increased morbidity puts in doubt its place in the surgical armamentarium of SUI treatments.

Table 5. Complications

	Composix (60)	TVT (34)	TVT-O (34)
Urethral trauma	1 (1.6%)	0	0
Bladder perforation	4 (6.6%)	1 (2.9%)	0
Hematoma	2 (3.3%)	0	0
Seroma	2 (3.3%)	0	1 (2.9%)
Wound bleeding	1 (1.6%)	0	0
Cystitis	4 (6.6%)	0	0
Wound infection	3 (5%)	0	0
De novo urgency	3 (5%)	0	1 (2.9%)
Urinary retention	2 (3.3%)	1 (2.9%)	1 (2.9%)
Persistent postoperative pain	0	0	1 (2.9%)
Secondary procedures			
Sling loosening	2 (3.3%)	0	0
Sling infection	0	1	0
Anchoring suture removed	3 (5%)	0	0
Extrusion	2 (3.3%)	0	1 (2.9%)
Erosion	2 (3.3%)	1 (2.9%)	1 (2.9%)
Sling removed	2 (3.3%)	1 (2.9%)	4 (11.7%)
Clavien complications			
I	14	2	5
II	6	0	0
IIIa	0	0	0
IIIb	10	2	2

TVT: tension-free vaginal tapes; TVT-O: transobturator vaginal tapes.

Conclusions

This five-year cohort demonstrated similar outcomes on quality of life, satisfaction, and maintenance of continence with TVT, TVT-O, and our in-house Composix-based sling. All three techniques are effective in correcting SUI and improvements were sustained over time; however, data concerning the ideal mesh size for a suburethral sling indicate that the Composix material is suboptimal, and therefore cannot be recommended.

Competing interests: Dr. Moore has been an advisor for Astellas and Pfizer; and has participated in clinical trials supported by Astellas, Ipsen, and Pfizer. Dr. Haider has been a speaker for Astellas, Eli Lilly, and Pfizer. The remaining authors report no competing personal or financial interests.

This paper has been peer-reviewed.

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