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Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women

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Abstract This study was a 1-year follow-up of a cohort of 52 women who underwent trans-obturator tape (TOT) procedures using Obtape. Follow-up information was available for 45/52 (87%) women. The rate of erosions was 8/52 (15%). Among 34 women examined, 26% experienced tenderness on palpation of operative site, and 72% were objectively cured on pad test. Forty women completed questionnaires (median Incontinence Impact Questionnaire-7, 0; median Urogenital Distress Inventory-6, 17) and of those, 93% would recommend TOT to a friend. We found a high rate of erosions among our cohort. Our high rate of erosions may be a result of our review of the majority of the cohort, and it is likely related to the specific device used (Obtape). The majority of women were satisfied with the outcome. Before introducing new procedures into widespread clinical practice, it is important to rigorously investigate their outcomes.

Keywords Trans-obturator surgery (Obtape) · Urinary incontinence · Cohort study · 1-year follow-up · Complications

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Introduction

The trans-obturator tape (TOT) procedure was developed by Delorme [1] in 2001 as a new, minimally invasive sling procedure for urinary stress incontinence. Its proposed advantage over the transvaginal tape (TVT) procedure is that, by avoiding the transpelvic introduction, there would be a decrease in significant complications such as bladder, bowel, and vascular injury [1]. It is also a midurethral placement; therefore, the TOT would theoretically have the same continence outcomes as the TVT.

Before introducing the TOT procedure into general use in our practice, four surgeons undertook 52 TOT procedures as part of the surgical quality assurance program. All 52 women had stress incontinence diagnosed by examination and urodynamic studies.

Five unexpected cases of tape erosion, one complicated by a groin abscess, were observed among our 52 cases [2]. Because there were no previously reported cases of tape erosions in the literature, we decided to carry out a detailed evaluation of the remaining women from our cohort to determine the overall rate of tape erosions and other complications, as well as objective and subjective cure rates.

Materials and methods

Surgical technique

After training in a cadaver laboratory and appropriate preceptorship, four surgeons undertook 52 TOT procedures as part of the surgical quality assurance program. All 52 women had stress incontinence diagnosed by examination and urodynamic studies. All surgeries were performed between December 2003 and April 2004. The TOT procedure was undertaken with an "outside-in" approach using a nonwoven polypropylene mesh with an average pore size of 50 μm (Obtape, Mentor-Porges) [1]. Procedures were performed under local anesthesia, with sedation or general anesthesia according to patient preference. All patients received antibiotics intraoperatively.

Follow-up

Ethics approval was obtained from the Conjoint Health Research Ethics Board of the Calgary Health Region and University of Calgary to invite all eligible women to attend a follow-up appointment, at least 52 weeks after their original surgery. All women who agreed to take part signed a consent form.

Follow-up was carried out at the Calgary Health Region Pelvic Floor Disorders Clinic. All physical exams were performed by the same physician, who had not been involved in the initial surgery or clinical care of the patients (AD). All women were asked to complete Urogenital Distress Inventory (UDI)-6, a six-item measure of urogenital distress, and Incontinence Impact Questionnaire (IIQ)-7, a seven-item measure of incontinence impact [3]. Speculum and bimanual examinations were performed. Inspection and palpation were used to determine position of the tape and presence and degree of erosion and tenderness. Women then undertook a standardized pad test (Table 1), based on the schedule recommended by the International Continence Society [4]. At the end of the pad test, each woman voided on a uroflow toilet and her peak flow, volume, mean flow, and flow pattern were recorded [5]. Finally, each woman was asked questions about satisfaction with the procedure: whether the procedure had met her expectations, whether she would have the same surgery again, and whether she would recommend the surgery to a friend.

Women who were unable or unwilling to attend for follow-up were asked to complete UDI-6, IIQ-7, and satisfaction questions.

Analysis

Simple descriptive statistics were calculated to describe the population, the incidence of the primary outcome (tape erosion), and the prevalence of other outcomes. All

Table 1 Description of the pad test

The patient voided on arrival at the clinic.
Retrograde filling of bladder with 300 ml saline was performed.
Preweighed ^a collecting device (pad) was put on and the 15-min test period began.
The subject performed the following activities:
Climb and descend one flight of stairs
Standing up from sitting, ten times
Coughing vigorously, ten times
Running on the spot for 1 min
Bending to pick up small object from floor, five times
Washing hands in running water for 1 min
At the end of the test, the collecting device was removed and weighed ^a .
Subject voided and the volume was recorded.
No leakage was defined as less than 1 g.

^aAll pad weighing was carried out by one investigator (CS)

analyses were carried out using SPSS for Windows (version 12.0).

Results

Operative details of the 52 patients included in the original cohort are given in Table 2. Of the 52 patients who originally had a TOT procedure, five presented with tape erosion (one with a groin abscess), all of whom required additional procedures [2]. Of the remaining 47 patients, 40 (85%) completed questionnaire items, and 34/40 attended the Pelvic Floor Clinic for physical examination and objective measures of incontinence. Seven (13%) were lost to follow-up (four were unavailable at their initial contact address, and three reported being well but declined participation). Thus, information on erosions and/or questionnaire information was available for 45/52 (87%) women (Fig. 1).

Follow-up appointments with the 40 women ranged from 52 to 74 weeks (mean 62 weeks). The mean age of these 40 women was 53 years (range 33 to 79), and 33 (83%) were Caucasian. The mean number of deliveries was

Table 2 Operative details

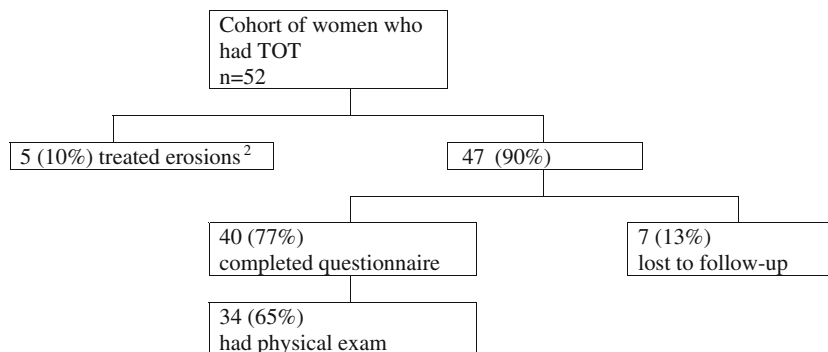
Detail	Occurrence (n=52)
Patient age (years)	Mean 53, SD 10 (range 33 to 79)
OR time, min	Mean 49, SD 20 (range 31 to 147; two missing)
Anesthesia ^a	
General	22 (42%)
Local	28 (54%)
Regional	3 (6%)
Cystoscopy	
No	10 (19%)
Yes	41 (79%)
Missing	1 (2%)
Blood loss	
None/min	34 (65%)
<100 ml	15 (29%)
≥100 ml	3 (6%)
Complications	
None	49 (94%)
Complications ^b	3 (6%)
Admission	
No admission	38 (73%)
Planned hospital admission	11 (21%)
Unplanned hospital admission ^c	3 (6%)

^aOne patient started with local anesthesia then had general anesthesia

^bComplications: (1) three tried to pass tape on left (L) side, blood loss approximately 150 ml; (2) perforated vaginal wall with L introducer; (3) oozing noted and vaginal packing placed

^cReasons for unplanned admission: (1) O₂ desaturation on room air in recovery room, (2) high postvoid residuals (procedure late in day), (3) severe headache

Fig. 1 Patient flow in the study



2.6, SD 1.5 (range: 0–8). Thirty-six women (92%) had at least one vaginal delivery. Twenty-three (58%) had never smoked, and 18 (45%) reported a family history of urinary incontinence. Mean BMI was 28.2 kg/m² (SD 5.4, range 18.8 to 42.2).

Clinical examinations were carried out on 34 women (Table 3). Among those women, the tape was visible along its vaginal course, indicating erosion, in three (9%) women (all were referred back to their primary surgeon for review). The additional three erosions found were small (3–5 mm) and easily located by directing the physical examination to the area of most tenderness. Palpation along the vaginal course of the tape elicited tenderness in five women (15%). The tape was palpable without tenderness in 24 (71%). Pain with palpation along the lateral sites was experienced by six (18%) and was severe for one woman (3%). Overall, nine women (26%) experienced tenderness on palpation of either groin or urethral sites. Thirty-two women carried out a pad test: 23 (72%) had no leakage. Urine flow pattern was normal or slightly prolonged [5] for 23 (72%) women.

For the 40 women who completed a questionnaire, the median IIQ-7 score was 0 (ranging from 0 to 90), and UDI-6 was 17 (ranging from 0 to 100) (Table 4; the lower the score, the lesser the impact). For the individual UDI-6 items, frequent urination was either moderately or greatly bothersome for seven (18%) women. In nine (23%) women, urine leakage related to urgency; urine leakage with activity was reported in five (13%) women; small drops of leakage was reported in eight (21%); difficulty emptying the bladder was reported in five (13%); and pain in the lower abdomen or groin was reported in six (15%). For 31 women (78%), the operation met their expectations (mainly to be continent again). If women were having the same symptoms, 36 (90%) would elect to have a TOT procedure, and 37 (93%) would recommend the TOT procedure to a friend.

Discussion

Our study is the first to describe a North American cohort of women who had a TOT procedure and to report on their systematic follow-up 1 year after surgery. We report that 15% of the 52 women had erosions; 38% of the women who attended for review had some tenderness with palpation (one woman with severe pain), and 18% reported

urge incontinence. Despite these problems, we found a 72% cure rate (defined as <1 g increase in pad weight after the standardized test), and 93% of the women would recommend the TOT to their friends.

Table 3 Clinical examination and objective measures of incontinence at follow-up

Findings at follow-up	Occurrence
Clinical examination	n=34
Groin incision palpation	
Normal	30 (88%)
Tape palpable, not tender	1 (3%)
Tape palpable, tender	1 (3%)
Tender, not palpable	2 (6%)
Vaginal palpation	
Normal	2 (6%)
Tape palpable, not tender	24 (71%)
Tape palpable, tender	5 (15%)
Tape visible and tender	3 (9%)
Pain along adductors	
No pain	28 (82%)
Mild/moderate pain	5 (15%)
Severe pain	1 (3%)
Measures of incontinence	n=32 ^a
Pad test	
Cure Rate	
<1 g leakage	23 (72%)
≥1 g leakage	9 (28%)
Leakage (g)	Median 0, IQR 0 to 1, maximum 104
Uroflow	
Peak flow rate (ml/s)	Mean 25, SD 8
Volume (ml)	Mean 322, SD 59
Mean flow rate (ml/s)	Mean 13, SD 5
Flow pattern [5]	
Normal	12 (38%)
Pushing	2 (6%)
Slightly prolonged	11 (34%)
Dysfunction	4 (12%)
Obstructed	3 (9%)

^aOne woman refused to do the pad test; one was unable to do the test because the retrograde filling with 300 ml caused her to have urge

Table 4 Follow-up patient questionnaires

Questionnaire findings	Occurrence (<i>n</i> =40)
UDI-6	Median 17.0, IQR 5.6 to 33.3 (one missing)
IIQ-7	Median 0.0, IQR 0 to 4.7 (one missing)
Met expectations	
Yes	31 (78%)
No	9 (12%)
Would repeat surgery	
Yes	36 (90%)
No	4 (10%)
Recommend to a friend	
Yes	37 (93%)
No	3 (7%)

A number of European [6–12] and Australian [13] investigators have reported follow-up of patients who had a TOT procedure: the results from these studies are presented in a summarized form (Table 5). We discuss our results in the context of the other published TOT reports.

Tape erosion

The primary reason for conducting our study was to determine the rate of tape erosions in our cohort. We found that eight of the 52 women (15%) had tape erosions. We have already reported the first five cases that led us to follow the remaining women: of the five women, all have had additional surgical procedures, and three remain incontinent [2]. Our overall erosion rate of 15% is higher than that reported for other TOT case series (0–2.7%) [6, 8, 9, 11–13], but it is consistent with the rate of 14% recently reported by Domingo et al. [10]. Our high erosion rate can partly be explained by our systematic review of the patients with digital exam (rather than waiting for erosions to be discovered opportunistically), as our follow-up identified another three cases that may have remained undiscovered for some time. The three patients were referred back to their operating surgeons and have gone on to further investigation.

The tape erosions may be the result of a number of explanations [2]. The most likely explanation, as suggested by other authors, is that the characteristics of the tape used contribute to the success (or otherwise) of surgical procedures [10, 14]. In one study using Obtape, the nonwoven polypropylene tape was suggested as a factor predisposing the procedure to later erosion or abscess [10].

Table 5 Other studies reporting TOT follow-up

Author	No. of women in TOT series, no. followed	Device used	Length of follow-up	Outcome
Cindolo et al. (2003) [6]	86 in series, 80 followed up (7% loss to follow-up)	Uratape	1 to 8 months (mean 4)	One vaginal erosion with inguinal abscess at 6 months, two de novo urge incontinence, 80% objectively cured (resolution of symptoms, no leak on cough stress test), 82% subjectively cured
Mellier et al. (2004) [7]	94 in series, 61 followed up (35% not contacted)	American Medical Systems device	Telephone follow-up at 2 to 20 months (mean 12.8 months)	95% reported being cured, 92% were very satisfied with the surgical results
Costa et al. (2004) [8]	183 in series, 130 followed up at >6 months	Uratape	1 to 21 months (mean 7 months)	Four (2%) perioperative complications, three vaginal extrusions, two urethral erosions; At >6 months, 83% were cured (cough stress test).
Krauth et al. (2005) [9]	604 in series, 131 followed at 1 year (6% loss at 1 year)	I-STOP	1 year	86% of patients were satisfied; 2% had urinary urgency and dysuria. No clinical evaluation done. No report of serious complication due to surgical route.
Domingo et al. (2005) [10]	65 in series, information on nine	43 Uratape, 21 Obtape	2 to 19 months	Only information on nine (14%) erosions (five had Uratape, four had Obtape), no information on the remaining women.
Spinosa and Dubuis (2005) [11]	117 patients (no reported loss to follow-up)	Obtape	7 to 22 months (median 16.3 months)	Three tape erosions (3%) at 13, 15, and 18 months. 92% of patients were completely satisfied.
Roumeguère et al. (2005) [12]	120 in series, all reviewed at 12 months	60 Uratape, 60 Obtape	12 months	17 perioperative complications, three vaginal erosions at >6 months, 80% objectively cured (no leak on cough stress test, no need for pad during past month), 78% very satisfied/satisfied
Barry et al. (2005) [13]	96 in series, 83 women in main analysis (no reported loss to follow-up)	Monarc	6 to 12 weeks (7 weeks)	81% were satisfied, and 81% were cured objectively on urodynamic assessment

This could be due to the nonknitted, nonwoven mesh with small pore size (<50 µm), which theoretically may restrict the passage of macrophages and fibroblasts [15]. From our review of the literature, we found that erosions were reported more frequently after the use of Obtape and Uratape (Table 5).

Two additional theoretical explanations for erosions are possible. There may be an inherent susceptibility of the trans-obturator approach to erosion due to the “hammock” positioning, which allows more tape to be in close apposition to the vaginal wall, thus making the tape susceptible to disruption during sexual activity. A further explanation may also be possible: the positioning through the obturator foramen places the tape in close proximity to the adductor muscle insertions [16]. Theoretically, thigh adduction could cause tension on the tape, which would increase friction between the tape and the vaginal mucosa. These two possible explanations require further study. It is interesting that reports of adverse outcomes following trans-obturator procedures using devices with other types of tape than Obtape and Uratape are now appearing in the literature (Table 5) [9, 13, 17].

Erosions after TOT predispose patients to secondary complications, such as infection (including perineal cellulitis [18], infected hematoma [17, 18], abscesses [6, 8–20], and sinus formation [20]) and severe groin pain [21]. Our study reinforces the observation that tape erosion is a late complication that can arise at any time postoperatively from 6 weeks, [22] to 19 months [10].

Pain and tenderness

We found that 26% of our cohort expressed moderate or severe tenderness with palpation either along the course of the tape in the vagina or at the adductor tendons insertion points, the majority in the absence of an erosion. One woman reported severe pain along the adductors. This complication has seldom been mentioned in the literature. Krauth et al. [9] reported a 2.3% transient perineal pain rate after surgery, and 0.3% dyspareunia and 0.2% perineal pain at 1 to 3 months follow-up. A recent report describes a tape erosion with severe groin pain 10 days after a TOT procedure [21]. We suggest that adductor motion might increase the tension of the tape as a result of constant movement of the adductors. In addition to causing pain, this increase in tension may predispose the TOT to erosions.

Cure rate

Our objective cure rate of 72% is somewhat lower than that reported in the literature [6, 8, 13]. However, one of the other papers used a cough stress test and a lack of symptoms of stress urinary incontinence as their definition of objective cure [6], one used stress test alone [8], and one used urodynamic assessment [13], while our a priori

definition of cure is more stringent: <1 g increase in pad weight after the standardized pad test.

Quality of life and satisfaction

Our median score of 0/100 for the IIQ-7 score appears to demonstrate that our patients have achieved excellent quality of life a year after operation. This may be true, but perhaps, it reflects a “ceiling” effect in IIQ-7 scores similar to that found in other incontinence-specific quality of life measures [23]. Our median score of 17/100 on the UDI-6 indicates that the TOT did not fully alleviate all incontinence symptoms.

Although only 78% of women stated that their surgery met their expectation of regaining urinary continence, 90% said that if they went back in time knowing what they now know, they would opt to have this surgery again. This suggests that, although 12% were not perfectly satisfied with their results, there was sufficient improvement to make the surgery worthwhile. Our satisfaction rate of 78 to 90% is consistent with that presented in the literature [6–8, 10–13].

Strengths and weaknesses of our study

Our study prospectively identified a series of women having a TOT and followed them systematically at least 12 months after surgery. Our loss to follow-up of 13% is reasonable compared to other studies (6% loss for a 1-year telephone interview [8], 7% loss at 1 to 4 months [6], 35% not contacted at 2 to 20 months [7]). In addition, all physical examinations were carried out by an independent clinician (AD) not involved in the clinical care of the women.

The main weakness of our study is that we do not have ideal baseline data (for example lack of information on urge incontinence or quality of life at baseline) or complete follow-up on all 52 women. The first five cases of tape erosion were responsible for the systematic follow-up of the cohort of women, and these cases were not recalled for review after their subsequent procedures because all five women have received further surgical intervention. We have added their data to the erosion rate. Seven cases were lost to follow-up, and six were unwilling or unable to return for physical examination, although they completed the questionnaires. It is possible that these additional women could have erosions; therefore, it is possible that our study has underestimated the rate of adverse events.

Conclusion

Our 15% erosion rate after the TOT procedure (using Obtape) was unexpected because no reports of this complication were published before the start of our recruitment. It is important to be cautious with the introduction of new surgical procedures into widespread

clinical practice. We suggest that studies be carried out on all new procedures, with systematic review of all cases. Unless patients are rigorously examined over extended follow-up, many complications and their true incidences will remain unknown because unsatisfied patients may go to alternative surgeons and new symptoms may fail to be attributed to their original surgical procedure.

We believe that the high erosion rate found in our study is at least partly due to the characteristics of the particular tape we used. To investigate the TOT further, we are recruiting women with stress urinary incontinence to a randomized trial which compares the outcome at 1 year of TOT vs TVT. We are using a tape with mesh pore size greater than 75 μm .

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