

Long-term follow-up of trans-obturator vaginal tape for stress urinary incontinence: a single-center retrospective study

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Abstract

Among surgical options for stress urinary incontinence, the trans-obturator tape (TOT) procedure is preferred for its effectiveness and safety, but long follow-up data on its outcomes remain limited. This study evaluates the long-term efficacy and safety of the “out-in” TOT procedure using the InGyneS Dipromed device (Dipromed s.r.l, San Mauro T.se, Turin, Italy). A total of 43 patients who underwent the TOT procedure at S. Croce Hospital in Moncalieri between 2011 and 2023 were included. Medical history, pelvic examination, stress test, and urodynamic tests were considered, along with the Patient Global Impression of Improvement scale, a patient satisfaction scale, and the Incontinence-Quality of Life questionnaire. The patients were grouped by follow-up duration: group 1 (<5 years of follow-up) and group 2 (>5 years of follow-up). Objective and subjective cure rates and complications were recorded. The objective cure rate was 62.5% in group 1 and 63.2% in group 2, while the subjective success rates were 83.3% and 73.7%, respectively. Complications were rare and the differences between the two groups were not statistically significant. The “out-in” TOT procedure is effective and well-tolerated, with favorable long-term outcomes and low complication rates.

Key words: stress urinary incontinence, incontinence surgery, urethral sling, trans-obturator tape.

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Introduction

Urinary incontinence is defined by the International Continence Society (ICS) as any complaint of involuntary urine leak reported by the patient.¹ Classification of urinary incontinence includes stress urinary incontinence (SUI), urgency urinary incontinence (UUI), and mixed urinary incontinence (MUI).

Initial management of SUI includes weight reduction, behavioral modifications, pelvic floor muscle training and biofeedback.² The surgical treatment of SUI is chosen only after conservative treatments have failed. One of the different approaches involves the use of mid-urethral slings (MUS) to restore the normal functions of the urethra, representing a less invasive procedure compared to other previous surgical treatments, with reduced operating time and recovery time.³ The first MUS approach was introduced in the late 90s,⁴ and consisted of a transvaginal tape (TVT), in which the sling is inserted through the retropubic space. To reduce the risk associated with this procedure (namely, bladder perforation and vascular injury), the trans-obturator tape (TOT), in which the sling is placed *via* the obturator fossa, was introduced by Delorme in 2001.⁵ Meta-analyses of trials comparing TVT and TOT did not reveal any difference in effectiveness between the two approaches,^{6,7} although the risk of bladder perforation and pelvic

hematoma is less frequent in patients undergoing surgery with the TOT approach.⁷

The TOT procedure can be carried out following two approaches, the “outside to inside” (out-in) approach and the “inside to outside” one (in-out). In the former approach the sling is placed using a helicoidal needle inserted in the groin’s incision to the vagina, passing through the obturator foramen, while in the latter approach the sling is inserted with a helical needle *via* a vaginal incision and exits through the groin. Both procedures are considered effective, despite the in-out approach appearing to be more painful.⁸ In 2008, the FDA issued a Public Health Notification to alert the community about some serious complications related to the use of surgical meshes for the treatment of pelvic organ prolapse (POP). This raised attention on the efficacy and safety of mesh devices also used for the treatment of SUI and abdominal wall hernia; as a consequence, the European Commission up-classified these devices as class III devices (rule 8 of Annex VIII of the medical device regulation).⁹ Hence, the necessity to obtain more long-term data to confirm the safety and the performance of these devices. The success of the surgical procedure is generally defined by a combination of objective and subjective outcome measures. However, the great majority of current studies report follow-up data in the short period (up to 12 months).⁵ The aim of this retrospective observational study is therefore to analyze if subjective

and objective cure rates and complication rate on the use of a TOT “out in” (InGyne S, Dipromed s.r.l, San Mauro T.se, Turin, Italy) are stable over time, on patients with long follow-up (greater or equal to 5 years) and patients with shorter follow-up (less than 5 years).

Materials and Methods

An observational retrospective monocentric study has been carried out at Santa Croce Hospital, Moncalieri (TO), Italy. The study was approved by the Ethics Committee of our institute. The study enrolled patients with pure SUI or MUI who underwent the TOT procedure with an out-in approach (InGyne S polypropylene sub-urethral slings, Dipromed s.r.l, San Mauro T.se, Turin, Italy) between January 2011 and June 2023.

Women with previous radical surgery, neurological diseases, postvoiding residue >100 mL and anterior prolapse grade ≥ 2 according to the Baden-Walker (BW) grade were not considered eligible patients for the study.¹⁰

To avoid mixing recent results on the effectiveness of the device with older data, the population has been divided into two groups, based on the follow-up length: group 1 comprises patients with a follow-up of less than 5 years, while the other includes patients with a follow-up greater than 5 years.

The preoperative assessment considered demographic details and pertinent medical history, including comorbidities and any significant prior pelvic surgeries. A physical examination was also carried out to objectively assess the grade of the anterior prolapse according to the BW grade.

All the women underwent a urodynamic study to determine the type of incontinence. The urodynamic test included uroflowmetry, filling cystometry, Valsalva leak point pressure, the maximum urethral closure pressure, and a pressure flow study, in accordance with the good urodynamic practice guideline of the ICS.¹¹ Urethral hypermobility was also evaluated with ultrasound.

All patients included in the study were contacted postoperatively for a prospective follow-up assessment to complete data col-

lection. Following our hospital’s standard protocol, each patient underwent a physical examination with a stress test and uroflowmetry and completed validated subjective questionnaires. At follow-up, a micturition diary was collected, through which the number of pads used by the patient was retrieved. Additionally, POP was graded using the BW scale.

All patients completed the Patient Global Impression of Improvement (PGI-I), a 7-point scale with a range of responses from 1 “very much improved” to 7 “very much worse”,¹² a patient-satisfaction scale, a Likert-type scale of 0-10 that grades the patient’s satisfaction regarding continence (0 indicates “not satisfied” and 10 indicates “fully satisfied”), and Incontinence-Quality of Life (I-QoL) questionnaire.

The objective cure was determined using the stress test, and a successful procedure was defined as a negative stress test with a bladder volume of at least 250 mL (confirmed by flowmetry). Given the challenges in performing a standardized stress test with a bladder volume of at least 250 mL, if the bladder was not filled to 250 mL but the stress test was negative, the procedure was considered an objective success only if the self-reported number of pads used was zero. A positive stress test was always considered a failure. Subjective outcomes were assessed using the PGI-I questionnaire, with a score of ≤ 2 indicating success, and the satisfaction scale, with a score ≥ 8 indicating success.

Statistical analysis

Patients included in this study were divided into two groups according to the length of the follow-up. Descriptive statistics were applied to continuous variables. Inferential statistics was applied to assess statistically significant differences between groups for the baseline patient characteristics. Specifically, the Chi-square test was used for categorical variables and the Mann-Whitney U test for continuous variables, since none followed a Gaussian distribution (Kolmogorov-Smirnov test, $p < 0.05$). A p -value < 0.05 was considered statistically significant for all tests. Statistical analysis was performed using the Statistical Toolbox of MATLAB[®] release 2023b (The MathWorks Inc., Natick, MA, USA).

Table 1. Baseline characteristics of patients included in the study.

Characteristics	Group 1 (<5 years follow-up)	Group 2 (≥ 5 years follow-up)	p
Age at surgery, years, median (range)	57 (37-77)	57 (46-75)	0.93
BMI, kg/m ² , mean \pm standard deviation	25.37 \pm 3.94	27.11 \pm 3.52	0.12
Parity, median (range)	2 (0-5)	2 (0-7)	0.81
Fetal macrosomia, n (%)	4 (16.7)	5 (26.3)	0.44
Smoke, n (%)	6 (25)	6 (31.6)	0.63
Previous gynecological surgery, n (%)	3 (12.5)	5 (26.3)	0.25
Anterior prolapse, grade Baden-Walker 1, n (%)	8 (33.3)	9 (47.4)	0.35
MPCU, mean \pm standard deviation	56.58 \pm 20.36	60.89 \pm 23.71	0.52
Detrusor overactivity, n (%)	3 (12.5)	2 (10.5)	0.84
Normal compliance, n (%)	24 (100)	19 (100)	/
Type of incontinence:			
SUI, n (%)	19 (79.2)	15 (20.8)	0.99
MUI, n (%)	4 (1-5)	11 (7-13)	
Follow-up, years, median (range)	4 (1-5)	11 (7-13)	/

BMI, body mass index; MPCU, maximum urethral closure pressure; SUI, stress urinary incontinence; MUI, mixed urinary incontinence.

Results

A total of 43 patients who underwent TOT surgery between 2011 and 2023 met the inclusion criteria for this study and were available for follow-up. Their baseline characteristics are presented in Table 1. Inferential statistical analysis shows that the baseline characteristics of the two groups are comparable. Group 1, comprising patients with a follow-up period of 5 years or less, includes 24 patients, while group 2, consisting of patients with a follow-up period greater than 5 years, includes 19 patients.

The objective cure rates were 62.5% (15 out of 24) in group 1 and 63.2% (12 out of 19) in group 2, while the subjective cure rates were 83.3% (20 out of 24) in group 1 and 73.7% (14 out of 19) in group 2.

Considering the patients who were objectively cured and patients who have had, nevertheless, a reduction in the number of pads used after surgery, the overall success rates were 79.2% (19 out of 24) in group 1 and 84.2% (16 out of 19) in group 2 as reported in Table 2.

Immediate postoperative complications were observed in 2 patients. One patient experienced significant postoperative urine retention, necessitating catheter repositioning and a 6-day hospital stay. The other patient exhibited a vagal reaction, presenting symptoms of nausea, vomiting, and sweating. The observed long-term postoperative complications are reported in Table 3. A total of 2 cases of mesh erosion were observed; they were asymptomatic and treated with local estrogens. No patients required tape release or resection. Overall, 3 patients complained of groin pain. Based on uroflowmetry and personal history, voiding dysfunction (VD)

appeared *de novo* in 3 cases: 2 patients (8.3%) in group 1 and 1 patient (5.3%) in group 2. Among VD observed, one patient reported intermittent micturition and repeated urinary tract infections; another one complained of a weak micturition with a post-micturition residue of 100 mL, and the last one had intermittent micturition without urinary retention. No case required any medical intervention. Dyspareunia significantly increased in group 2. We observed *de novo* urgency and UUI in 10.5% and 15.8%, respectively, of patients with pure SUI in group 1 (n=19), and 13.3% and 27% of patients in group 2 (n=15) as described in Table 4.

I-QOL was required to evaluate the quality of life of the patients after the TOT surgery; median I-QOL score was 90.5 (range 74.7-97.7) and 92.03 (range 84.9-95.5) in groups 1 and 2, respectively (p=0.31).

Discussion

The goal of the SUI surgical intervention is to provide the right urethral support to avoid urine leakage under stress. MUS operations are a well-known, minimally invasive, and effective surgical treatment for SUI and, in the last decades, have become the most frequently used surgical option. Particularly, the trans-obturator way is preferred to the retropubic way due to the lower incidence of complications, shorter operation time, and hospital stay.^{13,14} Two approaches in TOT procedure exist, from the groin to the vagina (out-in), introduced by Delorme,⁸ subsequently modified by De Leval in in-out procedure.¹⁵

Regarding the success rate between TVT and TOT, contrasting

Table 2. Cure rates of patients included in the study.

Cure rate	Group 1 (<5 years follow-up), n (%)	Group 2 (≥5 years follow-up), n (%)	p
Objective cure rate	15 (62.5)	12 (63.2)	0.96
Subjective cure rate	20 (83.4)	14 (73.7)	0.44
Patient improved	4	4	-
Total: objective cure + patient improved	19 (79.2)	16 (84.2)	0.67

Table 3. Post-operative complications.

Post-operative complication	Group 1 (<5 years follow-up), n (%)	Group 2 (≥5 years follow-up), n (%)	p
Mesh erosion	1 (4.2)	1 (5.3)	0.86
Groin pain	2 (8.3)	1 (5.3)	0.69
Dyspareunia	0	3 (15.8)	0.04
Voiding dysfunction	2 (8.3)	1 (5.3)	0.69

Table 4. *De novo* urgency and urgency urinary incontinence onset in patients with pure stress urinary incontinence in group 1 (n=19) and in group 2 (n=15).

	Group 1 (<5 years follow-up), n (%)	Group 2 (≥5 years follow-up), n (%)	p
<i>De novo</i> urgency	2 (10.5)	2 (13.3)	0.68
<i>De novo</i> urgency urinary incontinence	3 (15.8)	4 (26.7)	0.68

data exist. Some studies report no different outcome between the two groups regardless of the years from intervention, while other authors show no significant difference between the groups at short-term follow-up but a significant continuing decline in efficacy for the TOT group at medium and long follow-up.¹⁶⁻¹⁸

A recent analysis of a prospective multicenter French register focused on MUS surgery showed that TOT has a lower risk of serious complications but a higher risk of surgical reoperation for recurrence than TVT.¹⁹

A recent prospective study, for the first time in the available literature, assessed the efficacy of TOT in-out implantation at the 17-year follow-up and it do not reveal any significant variation in the surgical outcomes over the follow-up period.²⁰

No significant difference was observed between out-in and in-out approaches in terms of objective and subjective cure rates, as reported in the 2017 Cochrane review,¹⁴ but there is moderate-quality evidence that VD is more frequent with the in-out procedure, appearing also to be more painful.⁸

The present work aims to investigate the possible variations in the efficacy and safety of the TOT out-in procedure over time, comparing the results in a short and a longer timeframe.

In the present study, the objective cure rate was 62.5% for patients within 5 years from the intervention (group 1) and 63.2% for patients with a longer follow-up (group 2). No significant difference in success rate in the two cohorts of patients was observed, indicating that the efficacy of the TOT procedure does not decrease over time, regardless of patients' aging, the mean age at follow-up being 60.9 years old for group 1 and 69.3 years old for group 2.

These results are in line with the literature. In a systematic review with meta-analysis, exclusively regarding long-term (>5 years) outcomes of TOT procedures (both out-in and in-out), objective and subjective cure rates were 64.4% and 81.3%, respectively.²¹ With regard specifically to the out-in procedure, a few studies have been published with a long-term follow-up that reported objective outcomes. Natale *et al.* published the only prospective study with a long follow-up (more than 120 months) and had an objective cure rate of 78.9%,²² while Verneker *et al.* reported an objective cure rate of 93.3%.²³ In this second study, the cure rate is markedly higher than those observed in the literature and our study, but it is a small retrospective study, and the status of "objective cured" was defined by a negative stress test alone, irrespective of bladder filling.

The present work's results are the consequence of a very strict definition of "cured patient": in our protocol, even the use of one pad a day was reported as a failure, regardless of the result of the cough test. This was performed without an upper limit of bladder filling; 10 patients had a volume greater than 300 mL before testing, and 2 patients even had 700 mL of bladder filling.

Considering the general improvement (objective cure plus reduction in pad use), the success rate rose to 79.2% and 84.2% for groups 1 and 2, respectively.

Considering the subjective success rate alone, it was 83.3% for group 1 and 73.7% for group 2, based on both a PGI-I score ≤ 2 and a patient satisfaction score ≥ 8 as used by other authors.^{24,25} These findings are consistent with the literature data. The 2017 Cochrane review and another meta-analysis found subjective cure rates of 43-92% and 81.3% for TOT, respectively.^{14,21}

Natale *et al.* found a 10-year subjective success rate of 62.6%. Verneker *et al.* had an even lower satisfaction rate at the 5-year follow-up, with only 46.7% of patients being completely satisfied; that can be due to the higher rate of postoperative lower urinary tract complications (such as urinary retention, increased frequency,

de novo urgency, and repeated urinary tract infections). The more frequent they are, the higher the objective cure rates.

VD is a known side effect of MUS procedures, probably caused by urethral obstruction or irritation due to the mesh, with a mean incidence of 5.5%, but that can affect up to 26% of patients in some studies.¹⁴ In a recent work published in *Lancet*, the incidence of MUS removal or section after 7 years from implantation, due to urinary retention, MUS erosion, and infection, is 3.59%.²⁶

In our study, VD had a low incidence. VD appeared *de novo* in 3 cases: 2 patients in group 1 (8.3%) complained of intermittent micturition, repeated urinary tract infections, and weak micturition; 1 patient (5.3%) in group 2 had intermittent micturition without urinary retention. All symptoms were reported of mild intensity and no medical intervention was required.

Regarding *de novo* overactive bladder (OAB), Serati *et al.* reported an incidence of 14% at 10 years,²⁷ while the Cochrane meta-analysis found an incidence of OAB, UUI, and urgency around 8% at short- and middle-term follow-up without a difference between TVT and TOT.¹⁴

In 2013, Lee *et al.* questioned the risk factors for developing urgency and incontinence after sling intervention, as they described *de novo* urgency onset after MUS intervention in 27.7% of patients with previous pure SUI at 50 months follow-up.²⁸

In our population, *de novo* urgency and UUI were described in 10.5% and 15.8% of patients in group 1, and 13.3% and 26.7% of patients in group 2, respectively. The differences are not statistically significant, with a slight increase in this percentage among patients in group 2. Verneker *et al.* reported OAB symptoms in 20% of patients. Natale *et al.* had *de novo* urgency in 7.3% of cases, with *de novo* UUI in 4.1%. Dyspareunia was significantly greater among patients in group 2, while no one in group 1 complained of dyspareunia as a post-operative complication (0 vs. 15.8% in groups 1 and 2 respectively, $p=0.04$). Given this data, dyspareunia seems more likely related to patient ageing and menopausal status, and not a specific complication of TOT surgery.

The long-term follow-up may also be a confounding factor in explaining the onset of urgency/UUI and dyspareunia. In fact, during such a long period, *de novo* onset of these symptoms could be influenced by several confounding variables, such as menopause, general comorbidities (*i.e.*, obesity), and cognitive deterioration, irrespective of MUS intervention. Regarding other complications, we observed no differences between the two study groups, consistent with literature data. Particularly in the case of mesh erosion, this finding is reassuring, showing that the incidence of this complication does not worsen over time. We had 2 cases of mesh erosion (one for each group), none of them requiring mesh removal or revision. Mild groin pain appeared in 3 cases, 8.3% in group 1 and 4.2% in group 2. These findings are slightly higher than the general literature data, as the Cochrane review found a rate of groin pain for TVT of 1.3%, and for TOT of 6.4%, always of short duration and with spontaneous resolution. Other meta-analyses confirm the higher incidence of groin pain in patients treated with TOT vs. TVT.^{29,30} Last, I-QoL, although lacking a pre-operative assessment to compare, demonstrated high scoring and a good perception of personal well-being without differences between the two groups.

Among the strengths of this study is the fact that the study groups were treated by the same surgical team over time, with the same technique and the same devices, making the two study groups effectively comparable from a surgical point of view, despite the long follow-up of some patients. Among the weaknesses is the low sample size, which does not allow the incidence of the rarest complications to be accurately assessed.

Conclusions

In conclusion, TOT out-in surgery performed for SUI appears to be a well-tolerated intervention with high success rates and low complication rates. This study shows, albeit on a limited sample, that these benefits are not limited in time but persist for many years after the intervention, both in terms of objective improvement of symptoms and in terms of satisfaction rate perceived by patients.

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Received: 4 February 2026; Accepted: 21 April 2026.

Contributions: Prisca Sozzani: project development, data collection, manuscript writing and editing. Francesca Longo: data analysis. Carola Minella: manuscript writing. Pier Luigi Montironi, Andrea Scoletta: supervision. All authors have read and agreed to the published version of the manuscript.

Conflict of interest: the authors declare that they have no competing interests, and all authors confirm accuracy.

Ethics approval and consent to participate: study approval was granted by the Ethics Committee of S. Croce Hospital (N. 8280 del 19/05/2023) and is subject the ethical standards of the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent: informed consent was obtained from all subjects involved in the study. Clinical data, once acquired, are stored in anonymized datasets and made available to the clinicians and researchers for scientific purposes.

Patient consent for publication: written informed consent was obtained from all participants for the publication of anonymized clinical data and images. No information enabling patient identification has been included in this manuscript.

Availability of data and materials: the datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Funding: no personal funds, grants, or other support were received during the preparation of this manuscript. The authors thank DIPROMED (Dipro Medical Devices S.R.L.) for providing funding to cover the open access APC. The authors confirm that the company had no involvement in the study design, execution, or interpretation of results.

Declaration of generative artificial intelligence and artificial intelligence-assisted technologies in the writing process: the authors declares that no generative AI or AI-assisted technologies were used in the writing, editing, or preparation of this manuscript.

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