

# Sub-Urethral Tape Treatment of Female Urinary Incontinence—Morbidity Assessment of the Trans-Obturator Route and a New Tape (I-STOP<sup>®</sup>): A Multi-Centre Experiment Involving 604 Cases

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## Abstract

**Purpose:** To make an assessment of the morbidity related to using the trans-obturator route (TOT); findings after one year for the 140 first cases and preliminary results of short term morbidity after 604 implants.

**Patients and Method:** This retrospective, multi-centre study involves the 604 first procedures with a 1–3 month follow-up. The mean patient age was 57 years. 92% of the patients underwent an isolated urinary incontinence cure and 8% had associated surgery. 47.3% of the cases had pure stress urinary incontinence and 52.7% had mixed incontinence. A 12-month minimum follow-up period was applied to the first 140 cases operated between September 2002 and January 2003. Patient assessment was made by a clinical examination in the first three months and their satisfaction rate expressed after 1 year.

**Results:** Operative complications were very few: 0.5% vesical perforations, 0.3% vaginal perforations, no urethral wounds, 0.8% 200–300 ml haemorrhages, two perineal haematomas (0.33%). The post-operative period was marked by: 1.5% transient retentions, 2.3% transient pain, 2.5% urinary infections, 1.3% transient dysuria.

The 1–3 month follow-up of 572 patients shows a 5.2% rate of de novo symptoms. Patient assessment of 131 subjects after one year revealed an encouraging satisfaction rate of 85.5% with a 1.5% rate of de novo dysuria and urgency. To date there have been no serious or specific complications attributable to the surgical route adopted. The morbidity is not affected by associated surgery.

**Conclusion:** The trans-obturator route combines low morbidity with a low rate of de novo symptoms on a large series. These results will have to be corroborated by further studies.

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**Keywords:** Trans-obturator route; Sub-urethral tape; Stress urinary incontinence; Morbidity

## 1. Introduction

Stress urinary incontinence surgery has been revolutionised by the arrival of the tension free vaginal tape technique (TVT) first described in 1995 by Ulmsten

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[1]. Follow-up assessments of over 5 years currently make it the “gold standard” technique [2,3].

Delorme’s preliminary work on the use of the trans-obturator route for sub-urethral tape implantation (the TOT technique) [4] has opened up an interesting perspective simplifying the surgical procedure and making it more innocuous. The TOT technique appealed to us from the outset and we decided to put it to the test of a multi-centre series trial. For the purpose we chose a new implant, whose characteristics match the ideal specification currently required for prosthetic sling materials [5,6] perfectly.

## 2. Equipment and method

Six centres and seven surgeons including four gynaecologists and three urologists took part in this multi-centre experiment. The first 140 patients underwent surgery between 1 September 2002 and 15 January 2003. They were then studied retrospectively to assess the morbidity of the technique and the implant. The encouraging results made us enlarge our series. We report the data concerning the 604 first and consecutive procedures performed to date. The aim of this retrospective study is to assess the surgical morbidity of the trans obturator route in the first 3 months following surgery.

### 2.1. Surgical technique

It is based on Delorme’s descriptions [4,7] and primarily differs in the device used. The prosthetic implant is placed under the mid-urethra and passes through the obturator foramen. Surgery commences with an anterior, vertical 15 mm vaginal incision at a point 10 mm below the urethral meatus. Dissection of the para-urethral spaces is then made laterally, with scissors, towards the ischiopubic ramus on either side. The resulting detachment leaves enough room for the index finger to pass. The external needle entry point is made in the genito-femoral fold by a short cutaneous incision made slightly above a horizontal line passing through the clitoral hood. The needle of the device is introduced through this orifice, initially in a direction perpendicular to the cutaneous plane. Once the obturator membrane has been crossed, it is orientated downwards and inwards in an oblique direction to reach the finger inserted in the para-urethral detachment space. It is then wound round the ischiopubic ramus, while the protecting finger remains in contact with the needle until it is exteriorised by the sub-urethral incision. The tape is then “clipped” to the needle tip and exteriorised via the genito-femoral fold after withdrawing the needle. The same procedure is carried out on the opposite side, and then tension-free adjustment is made to the tape under the mid-urethra. Vaginal closure is made with interrupted sutures using slow absorption thread to avoid premature wound dehiscence. Cutaneous closure is made with fast absorption thread. Cystoscopy is hardly ever performed. We feel it is essential to check the vaginal fornices for transfixion during surgery. During the course of our experiment the incision entry point was modified. At the beginning of the experiment the genito-femoral fold incision was made at the level of a horizontal line running over the urethral meatus. Gradually this point was raised above a horizontal line going through the clitoral hood. This modification became obvious to each surgeon, independently, without any consultation. Its effect is to increase the tape angulation to obtain an angle of 45° to the horizontal.

### 2.2. Prosthetic implant

The I-STOP<sup>®</sup> device we are using has been developed in collaboration with a company (CL Médical) based near Lyon (France). In terms of its structure and current composition, the tape matches the ideal specification currently required [5,6]. It presents the following characteristics:

- Exclusively mono filament polypropylene mesh: Ulmsten [6] has demonstrated it and the use of TVT<sup>®</sup> has confirmed it. Its material and manufacturing technique provide the highest tolerance to date.
- Aerated structure: macro pores of over 75 microns.
- No rope effect: the tape maintains its integrity right across its width despite sustained traction.
- It is supple and has no shape memory: easy to manipulate, so that it can be adapted in harmony with the patients’ anatomy.
- Non-aggressive edges: the tape sticks to the tissues without presenting any irritation.
- No particle release: through a specific cutting-out process. Systemic particle migration has been described only during periurethral injections of various materials [8–11]. It has not been possible to link any specific complication to the migration of a polypropylene particle to date. However we consider it important to include this parameter in the specification, to curb a potential risk, as the anatomical area and type of material used are similar in our procedure.
- Low weight per area: specific knit weave, fine thread and little material used.

### 2.3. Method

All the surgeons had TVT and vaginal surgery experience. In the series, the surgical indications comprised both pure stress urinary incontinence (when stress urinary incontinence is the only one symptom) and mixed or complicated urinary incontinence defined as a combination of incontinence symptoms (when another urinary symptom is associated to stress urinary incontinence). Pre-operative urodynamics was not systematically required by the surgeons when faced with typical pure stress urinary incontinence. However it was always performed in cases of mixed or complicated urinary incontinence. The length of hospitalisation, urinary catheterisation and the type of anaesthesia varied according to the individual centre and surgeon. The patients were assessed on the basis of a clinical examination and questioning before their hospital discharge and during the first 3 months following surgery. Patient assessment after 1 year of the 140 first cases was made subjectively by asking them to establish their satisfaction level and describe any persistent or de novo (new) urinary symptoms. Patient satisfaction expresses how well the functional result achieved matched their expectations of the surgical procedure.

### 2.4. Patients

The total population figure studied for the 1–3 month follow-up is 604. 140 patients had one-year follow-up. The mean patient age was 57 years. 556 patients (92%) had isolated TOT urinary incontinence treatment and 48 (8%) underwent associated surgery (prolapse surgery or hysterectomy) and were studied separately.

Stress urinary incontinence was pure in 47.3% of cases (34.5% of degree 2 and 11% of degree 3) while 52.7% suffered from mixed incontinence (33% of degree 2 and 17.7% of degree 3).

### 3. Results

#### 3.1. Peri-operative period (Table 1)

Surgery was possible in all cases. The results of the peri-operative period are listed in Table 1.

#### 3.2. Complications

Surgical complications of 604 procedures were very few (about 2%) as shown in Table 2. Our results on surgical morbidity do not reveal any digestive, vascular or urethral wounds. One of the three cases of bladder perforation occurred during a hysterectomy. The haemorrhages were classically treated simply by tamponage, but in one case of an isolated TOT procedure (0.16%) the tape had to be cut during surgery to control perineal venous bleeding. One perineal haematoma (0.16%) in a patient who underwent associated prolapse surgery required immediate revision surgery. We observed no serious or specific complications attributable to the surgical route adopted.

Post-operative complications were also moderate (7.5%) (Table 3). Transient pains disappeared after a few days' treatment with anti-inflammatory drugs and minor analgesics, except in one case (0.16%) with persistent pain 2 months after surgery (isolated TOT). One case (0.16%) of transient dysuria needed revision surgery on Day 1 to lower the tape and one

**Table 4**

Short term results: 1–3 months follow-up of 572 patients

	Isolated TOT	Associated surgery	Total
Patients: <i>N</i>	524	48	572
No improvement	18	–	18 (3.1%)
De novo symptoms (appeared after surgery)	28	2	30 (5.2%)

case (0.16%) of retention required section of the tape on Day 3. No patient had to practice self-catheterisation after hospital discharge. Two cicatrization faults occurred including one premature wound dehiscence and one secondary exposure of the tape after 2 months. They were simply covered over surgically without complication.

572 patients were assessed by clinical examination and questioning in the 3 months following surgery, the immediate failure rate and the urinary symptoms induced (de novo symptoms) are detailed in Tables 4 and 5.

Of the 140 first cases, nine patients (6.4%) were lost to follow-up after 1 year. The assessment was thus made on 131 patients and presented a satisfaction rate of 85.5% (Table 6). Four of the non satisfied patients required repeat surgery and 1.5%, complained of de novo symptoms (urgency and dysuria). No problems of infection on the tape have been noted.

**Table 1**

Peri-operative period

Anaesthesia		Length of operation		Hospitalisation		Urinary catheterisation		
General	Loco-regional	<15 min	<30 min	<24 h	<48 h	None	<12 h	<24 h
432 (71.5%)	172 (28.5%)	452 (75%)	545 (90%)	407 (67.4%)	558 (92.4%)	183 (30.3%)	287 (47.5%)	391 (64.7%)

**Table 2**

Surgical complications

	<i>N</i>	Bladder perforation	Vaginal perforation	Haemorrhage	Haematoma	Immediate section of tape	Other
Isolated TOT	556	2	2	4	1	1	–
Associated surgery	48	1	–	1	1	–	–
Total	604	3 (0.5%)	2 (0.33%)	5 (0.83%)	2 (0.33%)	1 (0.16%)	–

**Table 3**

Post-operative complications

	<i>N</i>	Transient retention	Transient perineal pain	Transient dysuria	Urinary infection	Cicatrization faults	Other
Isolated TOT	556	8	14	8	10	2	–
Associated surgery	48	1	–	–	5	–	–
Total	604	9 (1.5%)	14 (2.3%)	8 (1.3%)	15 (2.5%)	2 (0.3%)	–

**Table 5**

Details of de novo symptoms after 1–3 months

	Isolated TOT	Associated surgery	Total
Dysuria and urinary urgency	2	–	2 (0.35%)
Dysuria	15	1	16 (2.8%)
Urinary urgency	9	–	9 (1.6%)
Dyspareunia	1	1	2 (0.3%)
Perineal pain	1	–	1 (0.2%)

**Table 6**

Assessment after one year

Follow-up	1 year
Patients	131
Satisfied	85.5%
Not satisfied	14.5%
De novo dysuria and urinary urgency	2 (1.5%)
Re-operated patients	4 (3%)

#### 4. Discussion

With the benefit of scientific literature and several years' experience of practising TVT we recorded certain points that could lead improving this technique [3,12–17]. This extends to: post-operative dysuria and retention rates, the risk of visceral wounds, de novo symptoms rates and the tape-dependent “rope” effect.

The trans-obturator route technique was put forward by Delorme as a useful alternative to the retropubic route. It retains the urethral support principle whose role in stress urinary incontinence treatment is clearly explained by de Lancey's theory [18]. Moreover it enables the pre-vesical space to be preserved as it avoids intra-pelvic and retropubic passage, and consequently seems to limit the risks of not only visceral and vesical wounds, but more importantly digestive and vascular wounds. Anatomic studies rule out the risk of lesion to the obturator pedicle in theory [4]. We were able to observe low surgical morbidity on our first 140 cases. No visceral wounds or serious complications or haemorrhages occurred. This observation enabled us, like others [19], to continue our series in total safety without practising per-operative cystoscopy as a matter of course. The results after 604 procedures confirm the low morbidity. We recall that vesical perforation rate has been assessed at 0–7% as against the French national ANAES report [3] on TVT, which can rise to as much as 21% according to some exhaustive TVT reviews [13,14]. We report two cases of bladder perforation during an isolated TOT procedure. They both occurred in cases of associated major cystocele and were immediately noticed by the surgeon. The first tape was removed and a second tape was

placed without any consequences. A cystoscopy was performed at the end of both procedures.

There were also very few post-operative complications in comparison with the literature on TVT. The immediate retention rate, between 2.3 and 27% in scientific literature [13,14] was 1.5% in our series and required section of the tape in one case (0.16%). The cases of immediate post-operative dysuria improved rapidly and no patient needed to practice self-catheterisation after being discharged. The 2.3% of transient perineal pains rapidly receded except in one case in which pain was still present but improving after 2 months. They do not amount to obturator nerve trauma. The cicatrization fault rate of 0.3% falls within the mean of the publications studied, which give a range of 0.8–2% [3]. In our series premature separation of the cicatrix and secondary exposure occurred. In both cases, the incision was simply closed up and the tape covered. These two cases further bolstered our choice of tape which did not present any infectious development. Probably the most interesting result is the rate of de novo symptoms (urgency and dysuria), which is only 4.7% for the 572 patients assessed after 3 months and 1.5% for the 131 patients assessed after one year. We recall that the literature on TVT records 5–38% of de novo dysuria cases and 1–36% of de novo instability cases [13,14]. Another point is that morbidity does not seem to be affected by associated surgery (prolapse treatment, hysterectomy).

Our results obtained after one year, demonstrate an encouraging satisfaction rate of 85.5%. We chose to assess the patients subjectively by asking them to express their satisfaction level and any urinary symptoms. Our series has not been objectively assessed as the pre-operative and post-operative urodynamics were not systematic and the quality of life was not taken into account.

Our results must be interpreted in the light of the fact that 52.7% of the patients operated presented mixed urinary incontinence sometimes combined with sphincter insufficiency. These operative indications are the same as those retained by surgeons practising TVT, which now extend beyond the treatment of pure stress urinary incontinence.

Our group is quite heterogeneous, firstly in terms of the specialities (urologists and gynaecologists) and the sector of activity (public and private health). The series includes each surgeon's learning curve. These observations enhance the good feasibility and safety results of the trans-obturator technique even more. However the way each centre is run and the practices of each individual surgeon give rise to differences in the type of anaesthetic, the length of the hospitalisation and indwelling catheterisation.

These results are really encouraging in confirming the usefulness of the trans-obturator technique and the quality of the tape used. This study is currently being pursued prospectively, as it is vital that these first results are substantiated on a greater number of cases over a longer post-operative period.

## 5. Conclusion

Our approach is part and parcel of our determination to improve a technique and product that have already been

giving very good results. Stress urinary incontinence surgery must meet the demands of functional surgery with low operative risk and low de novo morbidity. The trans-obturator route appears to achieve gains in terms of morbidity and safety combined with a low rate of de novo symptoms. In our view this result is due to combining a pertinent surgical technique with an implant that matches the specific constraints of this surgery. Corroboration on the basis of a larger series is required. This calls for further studies to make an objective and prospective assessment of patients and a comparison with the “gold standard” technique (TVT).

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## Editorial Comment

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The authors described the morbidity after three months follow-up in a large series of 604 patients with stress urinary incontinence who have been operated by a sub-urethral tape using the trans-obturator route. Hopefully the 48 patients who had associated procedures have been separated from those with isolated procedures. This data confirms that trans-obturator

route avoids digestive or iliac vessels lesions and dramatically limits bladder perforation. But trans-obturator route also considerably limits de novo symptoms including acute retention, chronic retention, dysuria or urgency. Why is it so? One explanation is the following. Both procedures are tension-free ones. But experience has proven that some TVT could be placed anyway with too much tension and needed to be secondarily released. In trans-obturator route, as the tape is placed horizontally between the two ischiopubic ramus the urethra is sustained and no more tension is

possible. It is not the case with TVT. The tape could be placed just at the level of the mid urethra but more tension is always available (by retraction of the tape or technical fault for example). Concerning the angle of the tape under the urethra I don't agree with the authors. The angle is given by three points. The mid urethra and the two points under the ischiopubic ramus. Maybe when you enter the skin at the level of a line crossing the clitoris hood it is more easy to reach these points in a proper manner so that the angle is around 45° but it could also be possible to reach these points by

entering the skin in a lower level. So the skin entering point is not as important as the position under the ischiopubic ramus.

So trans-obturator route is now enthousiasming surgeons by its low morbidity rate. But one must be cautious because what has made the success of TVT is also the results concerning continence with time. Sub-urethral tape by trans-obturator route has to prove the same efficacy and the same functional results. We are waiting for such large series with functional results nicely documented.