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ORIGINAL ARTICLE

Transobturator adjustable tape (TOA) permits to correct postoperatively the tension applied in stress incontinence surgery

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Abstract
Introduction and hypothesis The adjustable transvaginal tape (TVA) has shown to allow adjustment of tension thus permitting correction of postoperative incontinence or obstruction. An adjustable transobturator mesh has been checked.
Methods Seventy-seven incontinent women received transobturator adjustable tape (TOA). Patients were monitored 1, 6, and 12 months post-surgery and annually thereafter by medical history, cough stress test, flowmetry, post-void residual (PVR), and incontinence quality of life, international consultation on incontinence-short form, and patient global impressions of improvement (PGI-I) questionnaires.
Results After adjustment, all patients rendered continent; none had PVR. On no occasion was vesical catheterization necessary. Mean follow-up was 24.7±10.3 months. Objective cure rate was 90% with 6.5% having greatly improved. The PGI-I questionnaire showed 90.7% of patients to be better or very much better than before. Q_{max} was 21.3± 7.2 ml/s. No infection was identified. Vaginal extrusion occurred in one patient.
Conclusions Our data demonstrate that the TOA allows postoperative adjustment of tension thus permitting correction of postoperative incontinence or obstruction.

Keywords Adjustable vaginal tape · Female stress urinary incontinence · Prosthesis and implants · Questionnaires · Results · TOA

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Introduction

The transobturator vaginal tape (TOT) technique was introduced with the aim of avoiding visceral and vascular injuries and to eliminate the obstructive component of tension free vaginal tape (TVT). TOT procedure has shown to be in several randomized comparative studies [1, 2] as safe and effective in the surgical treatment of stress urinary incontinence as TVT technique.

Unfortunately, although insertion through the obturator muscles reproduces the natural suspension fascia thus theoretically reducing the risk of obstruction, voiding dysfunctions has occurred after TOT procedure. Some studies suggest that there are less voiding dysfunctions after TOT than after TVT [3]; others do not find any significant difference [1, 2].

It seems that, as it happens in TVT procedure, there is a delicate balance after TOT implant between incontinence, continence, and obstruction, and it is difficult to calculate the correct degree of tension to be applied during surgery. When the tape is too loose, incontinence persists. On the

Table 1 Clinical characteristics of the patients

Characteristics	Values
Age[a]	58.8 (10.4)
Body mass index[b]	28.2 (20.2–47.8)
Years of incontinence[a]	6.5 (5.3)
Previous surgery[c]	
Previous hysterectomy	20 (26%)
Previous incontinence surgery	7 (9.1%)
Grade of incontinence[c]	
Severe	34 (44.2%)
Moderate	37 (48.1%)
Mild	6 (7.8%)
Grade of pelvic organ prolapse[c]	
Uterine prolapse≥grade II	4 (5.3%)
Vault prolapsed≥grade II	7 (9%)
Cystocele≥grade II	14 (18.2%)
Rectocele≥grade II	5 (6.5%)
Urgency[c]	60 (77.9%)
Urgency incontinence[c]	54 (70.1%)
Pads (*n*)/day[b]	3 (1–8)
Urodynamic study	
Maximum cystometric capacity (ml)[a]	415 (109)
Q_{max} (ml/s)[b]	25 (6–53)
Post-void residual[c]	2 (2.6%)
VLPP (cm H_2O)[b]	45 (30–90)
P*det* Q_{max} (cm H_2O)[b]	25 (2–59)
Detrusor overactivity[c]	20 (25.9%)

VLPP Valsalva leak point pressure, P*det* Q_{max} detrusor pressure at maximum flow

[a] Mean (standard deviation)

[b] Median (range)

[c] *N*(%)

other hand, when the tape is too tight, urinary obstruction is produced.

The adjustable transvaginal tape (TVA) has shown to allow adjustment of tension for a number of days after surgical intervention thus permitting correction of post-operative incontinence or obstruction [4].

An adjustable transobturator mesh has been recently developed. Our aim is to check if this approach permits postoperative correction of tension. In this paper, we present our first results.

Materials and methods

Since January 2005, 77 patients coming to our department with stress or mixed urinary incontinence agreed to be enrolled in the trial and receive adjustable transobturator mesh implant (transobturator adjustable tape (TOA); Agency for Medical Innovations, Im Letten 1, 6800 Feldkirch, Austria). Patients younger than 18 years of age, those with any neurological disease, have had radiotherapy, or had more than two anti-incontinence procedures, were excluded. The local ethics committee approved the study, and all women gave their written consent.

Preoperative evaluation included medical history, physical examination with full bladder (250 ml of saline solution), flowmetry, post-void residual (PVR) urine measurement, complete multichannel urodynamic study, and incontinence quality of life (I-QOL) and international consultation on incontinence-short form (ICIQ-SF) questionnaires, both of which have been validated in Spanish.

Urinary incontinence was classified as recommended by the international continence society and graded according to the Ingelman-Sundberg classification. Pelvic organ prolapse was classified according to the halfway system. Table 1 shows the preoperative characteristics of the patients.

Surgical technique

TOA is a macroporous polypropylene monofilament non-elastic tape. Like TVA tape, it contains two groups of polypropylene strings, the first group consisting of two strings on either side situated 1.5 cm from the midline of the tape which will be externalized via the anterior vaginal wall (Figs. 1 and 2) and serve, when pulled down, to reduce tension. The second group is formed of three strings in each branch of the tape situated at different distances from the midline. These are externalized via the same orifice through which the mesh is and serve, when pulled up, to increase the tension (Fig. 3). The only difference with TVA tape is

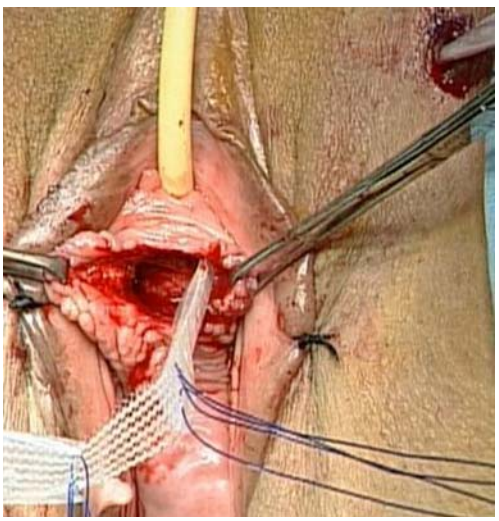

Fig. 1 The left TOA arm has been passed. The inferior threads are clearly shown

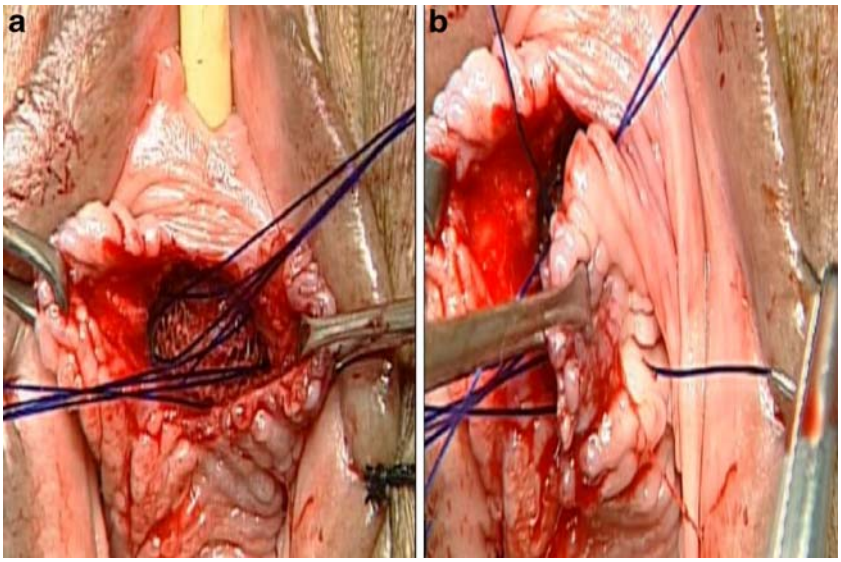

Fig. 2 The inferior threads must be crossed in order to move the tape in the right direction in case it is necessary to release the tension (**a**), and then the strings are externalized via the anterior vaginal wall (**b**)

the distance between the inferior and the superior threads which is shorter in TOA.

The insertion technique is similar to that of the TOT procedure. The TOA tape is situated below the proximal urethra via a small incision in the anterior vaginal wall. The tension is adjusted with minimal tension by placing the scissors between the tape and the urethra. A curve tunneller is used to pull the tape. Its configuration equally permits the in-out and the out-in procedures. The in-out procedure was performed on seven patients and the out-in on the rest.

The plastic envelope is removed, and the redundant portion of the mesh is cut (Fig. 3a). Depending on the distance from the urethra to the skin, one, two, or none of the lateral superior strings are also cut. It is useful to separate and fix with forceps the inferior threads during surgery in order to avoid tangling. In all cases, a Foley catheter was inserted for bladder drainage. Intravenous antibacterial prophylaxis was administered to all the patients.

In 60 patients (78%), only the TOA was implanted. In 17 patients (22%), another procedure was carried out simultaneously: three hysterectomies, nine anterior mesh implants, three anterior plasties, four posterior plasties, five Richter, two Prolifts, and three open sacrocolpopexies. Interventions were performed using intradural or general anesthesia. When a graft was implanted, it was done through a different vaginal incision than TOA tape, and the tension adjusted on the graft was inferior to the TOA tape tension.

Immediate postsurgical evaluation

On the day following surgery or later depending on the patient's condition (the latest adjustment was made on day

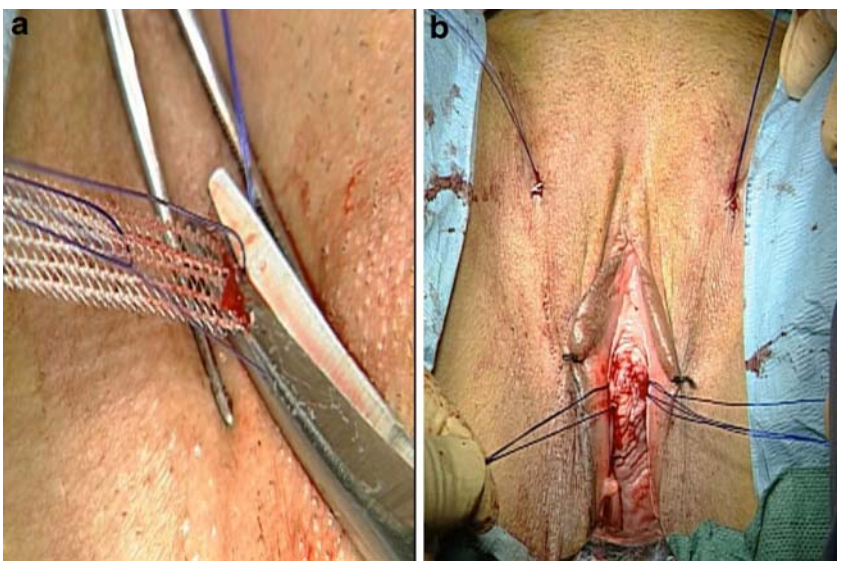

Fig. 3 The right redundant mesh with two superior threads is being removed and one thread will be left in place (**a**). The procedure has been ended. All threads, superior and inferior, have been externalized (**b**)

5 in one case of simultaneous sacrocolpopexy surgery), micturition is evaluated:

1. Filling the bladder with 250 ml of saline solution.
2. Asking the patient to cough in supine and standing positions.

If there is leakage, the inguinal strings on one side are pulled up approximately 0.5 cm, and step 2 is repeated. The cycle is repeated until continence is achieved before continuing with the evaluation:

3. Measurement of uroflowmetry and PVR urine volume.

If the maximum flow rate is less than 10 ml/s and/or there is more than 50 ml of urinary residual, then, tension is released from the mesh by pulling down on one side only of the vaginal strings, approximately 0.5 cm. Continence is tested, and then step 3 is repeated.

When the patient is continent, maximum flow rate is equal to or greater than 10 ml/s, and when there is no urinary residual, the strings are cut and extracted, and the patient is discharged.

Follow-up evaluation of results

In the first year, all patients were monitored 1, 6, and 12 months post-surgery and annually thereafter by a medical history, cough test with full bladder (250 ml of saline solution), flowmetry, and PVR urine measurement. All of the patients were given the validated in Spanish I-QOL, ICIQ-SF, and PGI-I questionnaires in all revisions of the follow-up period. Objective cure for stress incontinence was defined as no leakage on cough provocation test. Subjective cure was defined as answering "never" to the ICIQ question: How often do you leak urine? It has also been analyzed whether subjective failure was due to stress, urge, or mixed incontinence (item 6, ICIQ-SF).

Statistical analysis

Frequency tables are presented for categorical variables and mean (±SD) and median (inter-quartile range) for continuous variables. Comparison of normally-distributed variables was carried out using Student's *t* test and non-continuous parameters with the chi-square test. Statistical significance was set at $P<0.05$.

Statistical significance was determined with Kruskal–Wallis test (categorical variables) and Spearman's rho (continuous variables). A linear model of regression with robust estimation of the standard error was calculated, including variables with *P* value lower than 0.10. Analysis was carried out using SPSS 10.

Results

Immediate postoperative evaluation

Fifty-one patients (66%) were found to be objectively continent in the immediate postsurgical evaluation. Twenty-six patients (34%) showed a greater or lesser grade of incontinence. Eight of the 51 continent patients (10% of all patients) had a maximum flow rate inferior to 10 ml/s and/or urinary residual superior to 50 ml.

The tension was adjusted in 34 (44%) patients; in 26 (34%), the tension was increased, and in 8 (10%), the tension was decreased. After adjustment, all patients were continent, and none had PVR urine. The mean Q_{max} in patients not requiring adjustment was 18.0 (SD 5.2, range 10–33) and 15.1 (SD 6.0, range 8–33) in those who did need adjustment ($P=0.027$). Five patients were discharged with a Q_{max} inferior to 10 ml/s. On no occasion was vesical catheterization necessary.

After decreasing the tension of the mesh, the patients whose postsurgical Q_{max} values were inferior to 10 ml/s increased from 6.7 ml/s (SD 2.2, range 5–10) to 12.7 ml/s (SD 4.8, range 8–24; $P=0.001$).

A significant relationship was found between TOA implant alone, TOA plus concomitant prolapse surgery, and the need for adjustment ($P=0.03$). Forty percent versus 70% had to be adjusted.

The mean hospitalization was 1.9 days (SD 0.7) in cases of TVA implant alone and 4 days (SD 1.5) when another procedure was performed simultaneously. There were no cases of bladder, bowel, nerve, or major vessel injury.

Follow-up evaluation

The mean follow-up period was 24.7 months (SD 10.3, range 12–52). In the last revision, 69 patients (90%) were objectively stress continent, 5 (6.5%) had considerable improvement, and in three patients (3.5%), the treatment failed. Additional pelvic floor surgery did not have any significant influence ($P=0.519$), neither had the need for adjustment ($P=0.323$).

The subjective evaluation of pre- and postoperative incontinence and the type of incontinence according to the ICIQ-SF questionnaire items 2, 3, and 6 are shown in Table 2. Concomitant pelvic floor prolapse surgery did not affect the subjective results ($P=0.689$), neither had the need for adjustment ($P=0.425$).

Seventy patients stopped using pads, and seven used a mean number of 1.44 (SD 0.5, range 1–2) per day. Vaginal erosions occurred in one patient at 3 months after surgery. Partial excision and vaginal wall reclosure was sufficient to be cured. One patient had the left edge of the mesh

Table 2 Results of the quality of life and symptoms questionnaires

Questionnaire	Item	Preoperative (n=69)	Postoperative
ICIQ-SF	3. Frequency[a]		
	Never	0	43 (55.8%)
	≤1/week	1 (1.4%)	15 (19.5%)
	2–3/weeks	3 (4.3%)	4 (5.2%)
	About once a day	6 (8.7%)	9 (11.7%)
	Several times a day	38 (55.1%)	5 (6.5%)
	All the time	21 (30.4%)	1 (1.3%)
	4. Quantity[a]		
	None	0	45 (58.4%)
	A small amount	10 (14.5%)	24 (31.2%)
	A moderate amount	26 (37.7%)	5 (6.5%)
	A large amount	33 (47.8%)	3 (3.9%)
	5. Impact[b]		
	Global index	8 (3–10)	0 (0–10)
	(3+4 +5)	16 (9–20)	2 (2–20)
	6. Type of incontinence[a]		
	Continent	0	43 (55.8%)
	Urge incontinence	0	25 (32.5%)
	Stress incontinence	11 (15.9%)	5 (6.5%)
	Mixed incontinence	58 (84.1%)	4 (5.2%)
I-QOL[b]	22 items	27.2 (0–80.6)	93.1 (5.6–100)
PGI-I[a]	Very much better		56 (72.7%)
	Much better		14 (18.2%)
	A little better		6 (7.8%)
	No change		1 (1.3%)
	A little worse		0
	Much worse		0
	Very much worse		0

ICIQ-SF global index: 2=no bother, 20=a lot of bother; I-QOL: 22=worst quality of life, 100=good quality of life

[a] N(%)

[b] Median (range)

removed because of a foreign body granuloma and intractable pain, resulting in complete recovery.

The Q_{max} value on final examination was 21.3 ml/s (SD 7.2, range 8–38), significantly greater (P=0.001) than that corresponding to when the patients were discharged (16.7, SD 5.7, range 8–33). The need for adjustment significantly (P=0.004) influenced Q_{max} values (18.8±6.7 versus 23.5± 7.1 ml/s). It was also influenced (P=0.013) by concomitant prolapse surgery (17.5±5.4 versus 22.5±7.4 ml/s).

Urinary urgency, evaluated by clinical history, disappeared in 27 cases (45%) and was ameliorated in 29 (49%). In two patients (8%), there was de novo development and was worse in another two cases (6%) where it existed previously.

Table 2 shows, together with the subjective results, the pre- and postoperative results of question number 5 of the ICQS-SF (analog scale of 0 to 10 relating to effects on lifestyle), the global evaluation of this questionnaire, the I-QOL questionnaire, and the results of the PGI-I questionnaire.

Univariate analysis (Table 3) shows the variables associated with a reduced quality of life in our patients. Multivariate analysis indicates that postsurgical urge incontinence and mixed urinary incontinence (ICIQ-SF) affects quality of life, decreasing QOL points by 14.6 and 29.9, respectively.

Discussion

The two most frequent problems after stress incontinence surgery are persistence of incontinence and voiding dysfunction, both of them related to how loose or how tight the tape is implanted.

TOT procedure cure rate varying from 51% to 95%, depending on the definition used for success, the outcomes instruments, and discrepancies in studied population [5, 6]. Complete urinary retention has occurred from 0% to 13.3% [2, 7] after TOT procedure [2, 7], and tape sectioning or tape adjustment were necessary in up to 5% of the cases [5]. Porena et al. found de novo voiding symptoms after TOT implant in 6.7% of their cases, and in 7%, the preoperative voiding symptoms worsened [1].

Table 3 Relationship of variables with I-QOL questionnaires

Variables	Values
Categorical variables: univariant analysis	
Previous urgency[d]	0.782
Previous urge incontinence[d]	0.558
Grade of incontinence[e]	0.714
Associated prolapsed surgery[d]	0.931
Needing adjustment[d]	0.128
Subjective continence on clinical history[f]	0.079
Post-sling urgency[d]	<0.001
Post-sling urge incontinence[d]	<0.001
Post-sling use pads[d]	0.295
Continence on physical examination[d]	0.009
Post-sling diagnostic according to ICIQ item 3[g]	0.001
Continous variables: univariant analysis	
Final revision Q_{max}	0.467
Discharged Q_{max}	0.409
Years of incontinence	0.666
BMI	0.671
Age at surgical intervention	0.764
Linear regression with robust estimation of standard error (dep: quality of life)	
Post-sling urgency	0.000
Post-sling diagnostic according to ICIQ-SF item 3	
SUI	0.052
MUI	0.030
UUI	0.278

BMI Body mass index

[a] Median (inter-quartile range)

[b] Non-parametric Kruskal–Wallis test

[c] Non-parametric Spearman's rho correlation

[d] 0=No, 1=yes

[e] 0=Mild, 1=moderate, 2=severe

[f] 0=Dry, 1=drops, 2=stream

[g] 0=Continent, 1=SUI, 2=MUI, 3=UUI

After suburethral tape implant, there are also a number of cases with obstructive voiding dysfunction but clinically silent. Salin found that 70% of patients with TVT procedure and Q_{max} inferior to 15 ml/s were strictly asymptomatic [8]. The concern here is that it remains unknown if long-term obstructive voiding dysfunction in women has consequences on bladder or the upper urinary tract [9].

Our sample includes patients with pure and mixed incontinence, and so, it is not a homogeneous one. However, we report separately each of the selected variables, those influenced only by stress incontinence (cough test–objective cure) and those either by stress or urge incontinence (complete dry rate–subjective cure), analyzing then whether subjective failure was due to stress, urge, or mixed incontinence (Table 2). This analysis allows a more accurate outcome to be conveyed and corrects the non-homogeneity of the sample. Finally, pre- and post-surgery quality of life and voiding function have been studied, together with the previous variables, in order to analyze more accurately the success or failure of the procedure.

We placed the TOA tape, as in the TVA procedure, in the proximal urethra rather than the midurethra. Kaum and Wolf [10], using mesh labelled with radio-opaque strings in the TVT procedure, reported the same results for midurethral and proximal positioning of the mesh. Their results and our TVA and TOA results suggest that the tension applied to the mesh is a more important factor than its mid or proximal positioning in the urethra with respect to success rate and complications [4].

Previous to adjustment of the mesh, complete objective continence (checked with full bladder with 250 cc saline solution) in the immediate postoperative period was 66% (50 pt). However, eight out of these 50 postoperative continent patients, despite the minimal tension applied, leaving the tape very loose, required loosening of the mesh due to obstruction.

Tightening of the mesh corrected leakage in every case. On occasions, after tightening, loosening of the mesh was necessary to reverse obstruction and vice versa. These cases further demonstrate the delicate balance between incontinence and obstruction and the difficulty in calculating the correct degree of free tension to be applied during surgery.

The Q_{max} cutoff of 10 ml/s in the immediate postoperative period was chosen arbitrarily. We questioned whether a superior flow might have lead in the long term to a higher rate of incontinence. Furthermore, there is no reference in the literature for Q_{max} values in the immediate postoperative period. Obstruction here has been related to PVR measurement, usually arbitrarily over 100 cc. We were more strict than that and chose over 50 cc PVR measure-

ment as significant, as 98% of our healthy patients have less than that.

Loosening of the mesh, without affecting continence, resulted in a significant increase in flow and elimination of urinary residual, thus adding to the evidence to suggest that the tension applied to the mesh is, as happened in TVT procedure, occasionally superior to that necessary to achieve continence and may cause obstruction [4], often with minimal or no symptoms [8].

In five cases, it was not possible to obtain a maximum flow rate superior or equal to 10 ml/s; a minimal reduction of tension produced incontinence while a minimal increase resulted in significant urinary residual. Four of these patients had preoperative Q_{max} equal or inferior to 15 ml/s. Bumsik et al. and Salin et al. found reduced preoperative maximum flow to be predictive of urinary retention post-TVT [8, 11]. Wheeler [12] et al. found that 77.3% of their patients with Q_{max} less than 15 cc per second failed to pass a voiding trial. This may translate a certain vesical hypoactivity, and it is difficult in these cases to find the correct balance to allow emptying and cure incontinence. Our five patients mentioned above are continent and have not required self-catheterization.

The need for the mesh adjustment was significantly greater when TOA implant was associated with concomitant prolapse surgery. The exact influence of associated pelvic surgery on the outcome of anti-incontinence surgery is unknown. Schrafford Koops et al. found in a multicentric study that concomitant prolapse surgery did not affect the TVT results, the majority of their cases being cystoceles [13]. Costantini et al. found the frequency of postoperative incontinence to be significantly greater in patients who had undergone Burch procedure and colpopexy versus colpopexy alone [14]. Brubaker et al. reported opposite results [15].

It might be that different procedures and differences in their performance can have different influences and lead to different results. One possible explanation is the excessive horizontalization of the bladder urethral angle due to overcorrection of anterior vaginal wall produced by excessive traction or by the direction of traction. In our cases, eight patients out of 17 would have continued to be incontinent without the possibility of adjustment, and three would have been obstructed.

All of the patients were objectively continent and without urinary residual when discharged. In no case was vesical catheterization necessary. This is in contrast to the previously published occurrence of voiding dysfunction in the early postoperative period [3, 7].

In general, adjustment of the mesh produced minor discomfort, although in some patients, it was necessary to infiltrate the trajectory of the mesh with local anesthetic. It is easier to tighten the mesh than to loosen. Tightening of the mesh may be done easily either in supine or with the patient standing, while loosening of the mesh was much easier with the patient in gynecological position. This, together with our concern about subclinical obstruction, made that it was always attempted to place the mesh with minimal tension.

A 1.9 day hospital stay is long. However, this stay reflects the dynamics of our hospital and is the same duration as the stay we had previously with the TVT technique. The adjustment can be carried out on the same day of surgery when the patient has fully recovered from anesthesia. It is also possible to discharge the patient without withdrawing the adjustment threads and to adjust them 3 or 4 days later as an outpatient.

The objective success rate of treatment of stress incontinence lowered slightly over time, from 100% to 90% completely continent and 6.5% greatly improved, something that has also been reported by other authors [16]. Our only failures were produced in the early postoperative period. A possible cause for this could be the sliding of the implanted mesh.

Success rates after TOT procedures vary widely, depending on the definition used for success and the characteristics of the studied population [1, 2, 5, 6]. Our high objective success rate with quite strict criteria in a non-homogeneous sample is probably explained by the ability to adjust the tension applied during surgery in the postoperative period.

The subjective evaluation of continence reveals a result far lower than that obtained via objective evaluation; only 56% of our patients never leak urine. Subjective cure for us is equivalent to complete dryness collected by questionnaire and results depend on the existence of urgency incontinence. Thirty-three percent of our patients indicate urgency as the cause of their subjective failure, 5% mixed incontinence, and only 6% pure stress incontinence (Table 2). According to these figures, our subjective cure rate for stress incontinence would be 88%. Munir et al. and Ward and Hilton using the TVT procedure reported that only 20% and 36%, respectively, of their patients are completely dry [17, 18]. Kobashi and Govier using SPARK procedure report that 36.6% of patients never leak urine [19]. The difference between these and our figures can be equated to the number of patients in which it was necessary to increase tension of the mesh due to persisting incontinence in the immediate postoperative period. However, it is impossible to make any comparison between centers if all preoperative and postoperative variables are not reported.

There were no major complications, and no urethral erosion or infection was identified. Vaginal erosion occurred in one patient, and it was located in the lateral fornix. After local excision, it healed without further consequences. The percutaneous strings seem not to increase the risk of tape infection.

The maximum flow during the follow-up period was significantly higher than in the immediate postoperative period. It is not known whether this is due to resolved postoperative oedema or even to postoperative discomfort. It is also possible that there was slight sliding of the implanted mesh.

Urinary urgency, evaluated by clinical history, disappeared or was ameliorated in 94% of cases and was worse in two cases (6%) where it existed previously. It appeared de novo in two of the 24 cases, where it did not previously exist (8%). The mean maximum flow in these last four patients was not significantly different to those without urgency. This, along with the absence of urinary residual and voiding symptoms, makes a diagnosis of obstruction improbable. So far, it has not been necessary to perform urethrolysis in any of our patients.

The quality of life questionnaires demonstrate the highly significant improvement of quality of life after implant of the TOA mesh. The PGI-I confirms this with 91% of our patients being much better or very much better than before. There is a good correlation between objective cure and level of satisfaction. However, the correlation was poor between subjective cure and level of satisfaction. The high level of satisfaction may be justified by the important reduction in the quantity of urine leaked after surgery and the disappearance or amelioration of urgency. The patients' perception of "cure" may not necessarily imply complete cure of incontinence and may rather reflect the degree of impact the change of symptoms has on the individual's lifestyle [19].

Postoperative urgency incontinence, as reported elsewhere [4, 20], was the only analyzed factor affecting quality of life in the multivariate study.

In conclusion, our results show that persistence of stress incontinence and the development of obstruction after surgery depend largely on the tension applied to the mesh, looser or tighter, during the procedure. They also demonstrate that the transobturator approach (TOA), like the transvaginal procedure (TVA), allows postoperative adjustment of tension thus permitting correction of postoperative incontinence or obstruction. This does not increase surgical complications.

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Conflicts of interest Prof. J. Romero Maroto has a patent pending. International application no. PCT/ES03/00128.

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