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ORIGINAL ARTICLE

Transvaginal adjustable tape: an adjustable mesh for surgical treatment of female stress urinary incontinence

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Abstract After transvaginal adjustable tape, approximately 15% of patients still suffer incontinence, and voiding dysfunction is present in a relatively important number of patients. Transvaginal adjustable tape (TVA) permits postoperative readjustment of tension, suggesting that better results could be obtained. Sixty-four incontinent women received TVA. Patients were monitored 1, 6, and 12 months post-surgery and annually thereafter by medical history, cough stress test, flowmetry and post-void residual test (PVR), incontinence quality of life, International Consultation on Incontinence Questionnaire-Short Form, and Patient Global Impressions of Improvement (PGI-I) questionnaires. After adjustment, all patients rendered continent, and none had PVR. On no occasion was vesical catheterization or uretholysis necessary. Mean follow-up was 40±12.9 months. Objective and subjective cure rate were 94% and 56%, respectively. Q_{max} was 22.3±9.9 ml/s. The PGI-I questionnaire showed 94% of patients to be better or very much better than before. Our data suggest that with TVA tape, better results can be obtained, furthermore, without increasing surgical complications.

Keywords Adjustable vaginal tape · Prosthesis and implants · TVA · Urinary incontinence · Stress

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Introduction

The transvaginal adjustable tape (TVT) procedure cures urinary stress incontinence in a high percentage of cases [1–3]. However, approximately 15% of patients still suffer a certain level of incontinence, and the procedure also leads to postoperative voiding dysfunction in a relatively important number of patients [4–6].

The trans-obturator tape technique, other than avoiding visceral and vascular injuries, aims to eliminate the obstructive component of TVT, although preliminary results do not wholly confirm its success [7, 8].

There is a delicate balance, after tension-free tape implant, among incontinence, continence, and obstruction, as it is difficult to calculate the correct degree of tension to be applied during surgery. When the tape is too tight, urinary obstruction is produced. On the other hand, when the tape is too loose, incontinence persists.

Our aim was to present the results of a suburethral tape that allows adjustment of tension for a number of days after surgical intervention, thus permitting correction of postoperative incontinence or obstruction.

Materials and methods

Since May 2002, 76 incontinent patients have received adjustable TVA mesh implant (Agency for Medical Innovations, Im Letten 1, 6800 Feldkirch, Austria) in our Department. Six patients were lost for follow-up, and six had a follow-up period of less than 12 months. The remaining 64 patients fulfilled the criteria for the setting of this prospective study. 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 urine measurement, and complete multi-channel urodynamic study [9]. The last 20 patients in the study completed the quality of life (QoL) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaires [10, 11], both of which have been validated in Spanish [12].

Urinary incontinence was classified as recommended by the ICS and graded according to the Ingelman Sunderberg classification. Pelvic organ prolapse was classified according to the half-way system.

Table 1 shows the preoperative characteristics of the patients.

Surgical technique

TVA (transvaginal adjustable tape) and TOA (transobturator adjustable tape) are macroporous polypropylene monofilament non-elastic tapes (Fig. 1). They contain two groups of polypropylene strings (Fig. 2): 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 (Fig. 3) 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. 4). The only difference between TVA and TOA tapes is the distance between the inferior and the superior threads which is shorter in TOA.

Table 1 Clinical characteristics of the patients

Characteristics	Values
Age[a]	58 (10)
Body mass index[b]	28.5 (21.2–39.6)
Years of incontinence[a]	6.37 (5.8)
Previous surgery[c]	
Previous hysterectomy	14 (22%)
Previous incontinence surgery	4 (6.8%)
Grade of incontinence[c]	
Severe	40 (63%)
Moderate	11 (16%)
Mild	13 (21%)
Grade of pelvic organ prolapse (30 patients)[c]	
Uterine prolapse ≥ grade II	7 (10%)
Vault prolapsed ≥ grade II	5 (7%)
Cystocele ≥ Grade II	18 (28%)
Urgency[c]	37 (58%)
Urge incontinence[c]	30 (47%)
Pads (*n*)/day[b]	3 (1–16)
Urodynamic study	
Maximum cystometric capacity (ml)[b]	256.5 (162–500)
Q_{max} (ml/s)[b]	23.5 (4–77)
Post-void residue[c]	6 (9.3%)
VLPP (cm H_2O)[b]	35 (30–90)
Pdet Q_{max} (cm H_2O)[b]	25 (10–75)
Detrusor overactivity[c]	17 (26.5%)

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

[a] Mean (standard deviation)

[b] Median (range)

[c] *N*(%)

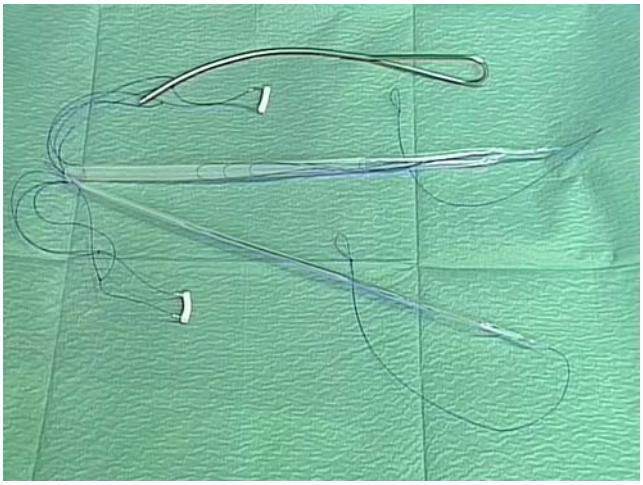

Fig. 1 TVA tape set. The strings will permit postoperative adjustment of the tension of the mesh

The TVA tape is situated below the proximal urethra via a small incision in the anterior vaginal wall, and minimal tension is applied. The mesh was passed from the suprapubic area to vagina in 14 patients and from the vagina to the suprapubic surface in 50 patients.

The insertion technique is similar to that of the TVT and suprapubic arc sling (SPARC) procedures. A tunneller, the curvature of which can be increased or decreased depending on the surgeon's preference, is used to pull the tape

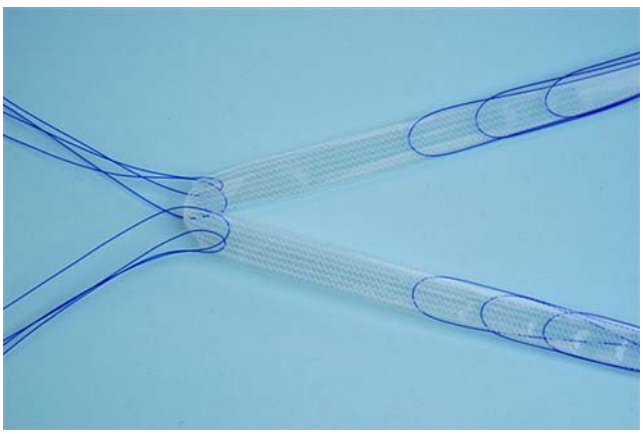

Fig. 2 TVA tape contains two groups of polypropylene strings on each branch: the inferior to reduce tension, the superior to increase tension

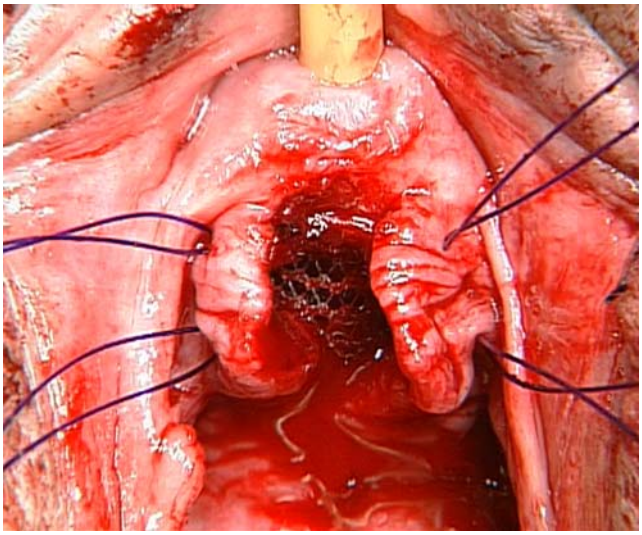

Fig. 3 The inferior strings are externalized via the anterior vaginal wall. Minimal tension is applied to the tape

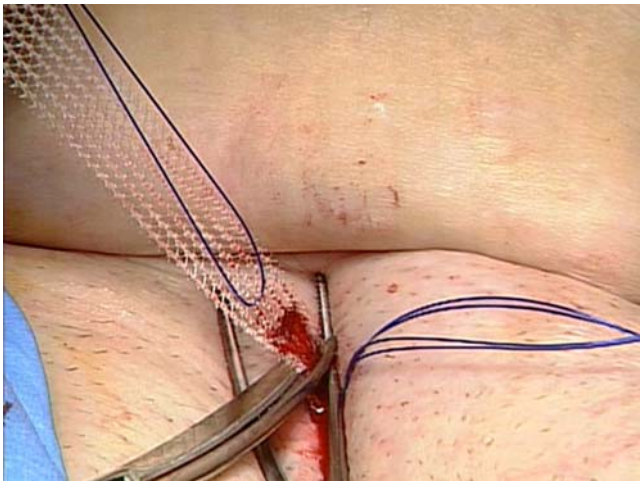

Fig. 5 The redundant portion of mesh is cut in hypogastrium and, depending on the distance from the urethra to the skin, one, two, or none of the lateral superior strings are also cut

from the vagina to the suprapubic area or alternatively from the suprapubic surface to the vagina. The plastic envelope is removed, and the redundant portion of mesh is cut. Depending on the distance from the urethra to the skin, one, two, or none of the lateral superior strings are also cut (Fig. 5). It is useful to separate and fix with forceps the threads during surgery to avoid them tangling. In all cases, a Foley catheter was inserted for bladder drainage.

In 34 patients (53%), only the TVA was implanted. In 30 patients (47%), another procedure was carried out simultaneously: seven hysterectomies, 15 anterior mesh implants, seven anterior plasties, four posterior plasties, and five sacrocolpopexies. Interventions were performed using intradural anesthesia.

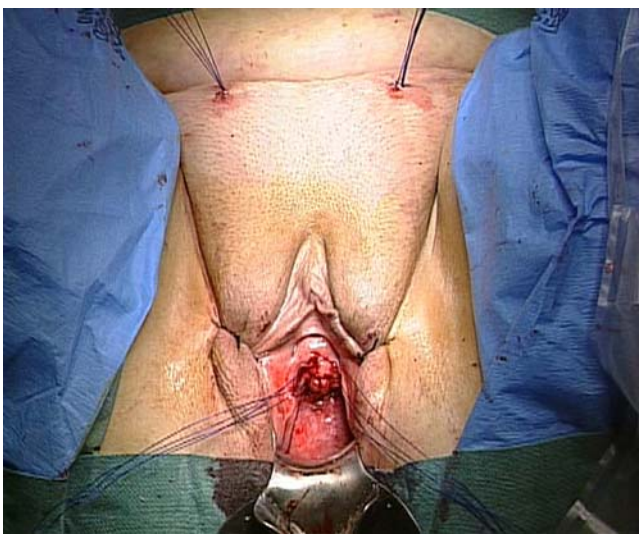

Fig. 4 Final result. The strings have been externalized

Immediate post-surgical evaluation

On the day after surgery or later, depending on the patient's condition (the latest adjustment was made on day 5 in one case of simultaneous sacro-colpopexy 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 suprapubic 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. Uroflowmetry and post-void residual urine measurement.

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 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 post-void residual urine measurement. All of the patients were given the validated QoL, ICIQ-SF, and Patient Global Impressions of Improvement (PGI-I) [13] questionnaires at least at the last revision

but, in most cases, throughout 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), 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 a p value lower than 0.10. Analysis was carried out using SPSS 14 and STATA 8.

Results

Immediate postoperative evaluation

Forty-eight patients (75%) were found to be objectively continent in the immediate post-surgical evaluation. Sixteen patients (25%) showed a greater or lesser grade of incontinence. Ten of the 48 continent patients (15.6% 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 26 (40.6%) patients; in 16 (25%), the tension was increased, and in ten (15.6%), the tension was decreased. After adjustment, all patients were continent, and none had post-void residual urine. The mean Q_{max} in patients not requiring adjustment was 15.7 (SD 4.9, range 10–32) and 13.8 (SD 3.9, range 8–22) in those who did need adjustment ($p=0.080$). Four 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 post-surgical Q_{max} values were inferior to 10 ml/s increased from 7 ml/s (SD 1.9, range 3–9) to 11.1 ml/s (SD 2.3, range 8–15; $p=0.001$).

No relationship was found between TVA implant alone and that associated with prolapse surgery and the need for adjustment ($p=0.35$).

The mean hospitalization was 2 days (2.2±0.3) in cases of TVA implant alone and 5 days (5.1±1.6) when another procedure was performed simultaneously. There were no cases of bowel, nerve, or major vessel injury.

Follow-up evaluation

The mean follow-up period was 40 months (SD 12.9, range 12–60). In the last revision, 60 patients (94%) were objectively stress continent, two (3%) had considerable improvement, and in two patients (3%), the treatment failed. Additional pelvic floor surgery did not have any significant influence ($p=0.365$)

The subjective evaluation of pre- and postoperative incontinence and the type of incontinence according to the ICIQ-SF questionnaire questions 2, 3, and 6 are shown in Table 2. Concomitant pelvic floor prolapse surgery did not affect the subjective results ($p=0.681$).

Table 2 Results of the quality of life questionnaires

Questionnaire	Item	Preoperative	Postoperative
ICIQ-SF	3. Frequency[a]		
	Never	0	36 (56.3%)
	≤1/week	0	9 (14%)
	≤2–3/week	0	9 (14%)
	About once a day	0	3 (4.7%)
	Several times a day	14 (70%)	6 (9.3%)
	All the time	6 (30%)	1 (1.6%)
	4. Quantity[a]		
	None	0	35 (54.6%)
	A small amount	0	26 (40.7%)
	A moderate amount	14 (70%)	3 (4.7%)
	A large amount	6 (30%)	0
	5. Impact[b]		
	Global Index	8.5 (4–10)	0 (0–8)
	(3 + 4 + 5)[b]	17 (12–20)	2 (2–16)
	6. Type of incontinence[a]		
	Continent		34 (54%)
	Urge incontinence		18 (27%)
	Stress incontinence	34 (53%)	8 (12.7%)
	Mixed incontinence	30 (47%)	4 (6.3%)
I-QOL[b]	22 items	25 (0–70)	95.5 (26–100)
PGI-I[a]	Very much better		42 (65.6%)
	Much better		18 (28.1%)
	A little better		1 (1.6%)
	No change		2 (3.1%)
	A little worse		1 (1.6%)
	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)

Fifty-five patients stopped using pads, and nine used a mean number of 1.44 (SD 0.5, range 1–2). No infection, vaginal, or urethral erosions were identified.

The Q_{max} value on final examination was 22.3 ml/s (SD 9.9, range 9–50), significantly greater (p=0.001) than that corresponding to when the patients were discharged (14.89, SD 4.67, range 8–32). Neither the prolapse surgery (p=0.236) nor the need for adjustment (p=0.133) significantly influenced Q_{max} values.

Urinary urgency, evaluated by clinical history, disappeared in 12 cases (32%) and was ameliorated in 17 (45%). In four patients (15%), there was de novo development and was worse in four cases (11%) 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 (analogue scale of 0 to 10 relating to effects on lifestyle), the global evaluation of this questionnaire, the Incontinence Quality of Life (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 (Table 3) indicates that only post-surgical urge incontinence affects quality of life, decreasing QoL points by 14.13.

Discussion

The TVT procedure cures stress incontinence in a variable percentage of cases, between 67% and 95% [1–3]. However, adverse effects include voiding dysfunction in up to 60% of patients [5], tape release being performed in up to 8% of the cases (2). As far as we know, this is the first time that an adjustable regular mesh has been described that allows postoperative adjustment of the tension applied during surgery, enabling us to correct any persisting stress incontinence and to avoid obstruction [14].

We placed the TVA tape in the proximal urethra rather than the midurethra. Kaum and Woolf [15], using mesh labeled with radio-opaque strings, reported the same results for midurethral and proximal positioning of the mesh. Their results and ours 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.

The sample includes patients with pure and mixed incontinence. However, the variables influenced by stress incontinence (cough test—objective cure) and by urge incontinence (complete dry rate—subjective cure) have been

Table 3 Relationship of variables with I-QoL questionnaire

Variables	Values				
Categorical variables: univariant analysis	0[a]	1[a]	2[a]	3[a]	p[b]
Previous mictional urgency[d]	96.59 (14)	89.77 (20)	–	–	0.017
Previous urge incontinence[d]	95.45 (15)	89.77 (18)	–	–	0.134
Grade of incontinence[e]	88.07 (17)	86.36 (28)	95.45 (13)	–	0.202
Associated prolapse surgery[d]	95.45 (15)	92.61 (18)	–	–	0.648
Needing adjustment[d]	92.61 (14)	95.45 (19)	–	–	0.949
Post-sling mictional urgency[d]	97.73 (9)	85.23 (33)	–	–	<0.001
Post-sling urge incontinence[d]	96.59 (10)	77.27 (47)	–	–	<0.001
Continence on physical examination[d]	75.00 (45)	95.45 (14)	–	–	0.068
Post-sling diagnostic according to ICIQ-SF item 6[f]	97.73 (5)	86.93 (45)	75.00 (51)	80.68 (18)	<0.001
Continuous variables. Univariant analysis	Correlation coefficient[c]			p	
Final revision Q_{max}	0.217			0.105	
Previous Q max.	0.221			0.093	
Years of incontinence	−0.056			0.666	
BMI	−0.126			0.352	
Age at surgical intervention	−0.246			0.065	
Linear regression with robust estimation of the standard error					
Dep: quality of life	Coefficient	Robust SE	t	$P>\|t\|$	95% CI
Urge incontinence post-sling	−14.13497	4.174360	−3.39	0.001	−22.48493, −5.78501
_constant	94.00811	1.990868	47.22	0.000	90.02578, 97.99044
R^2=0.5209					

[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—Continent, 1—Stress incontinence, 2—Mixed incontinence, 3—Urge incontinence

analyzed separately. It has also been analyzed 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 for the non-homogeneity of the sample.

Previous to adjustment of the mesh, objective continence in the immediate postoperative period was 75%. Despite the minimal tension applied, leaving the tape very loose, ten of the postoperative continent patients required loosening of the mesh due to obstruction.

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 post-void residual measurement.

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 occasionally superior to that necessary to achieve continence and may cause obstruction, often with minimal or no symptoms [16], the long-term consequences of which are unknown [17]. Voiding dysfunction has been reported 3 years after surgery [18], and Leng et al. [19] have described a relationship between the time until urethrolysis and persistence of symptoms after the same.

On occasions, after tightening of the mesh to correct leakage, 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.

In four 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 residue. Three of these patients had preoperative Q_{max} values of 7, 8, and 15 ml/s. Bumsik et al. [20] and Salin et al. [16] found reduced preoperative maximum flow to be predictive of urinary retention post-TVT. 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 four patients mentioned above are continent and have not required self-catheterization.

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 it, and for this reason, it was always attempted to place the mesh with minimal tension. Loosening of the mesh was much easier with the patient in gynecological position, while tightening of the mesh may be done with the patient standing.

All of the patients were objectively continent when discharged and without urinary residual. In no case was vesical catheterization necessary. This is in contrast with the previously published high occurrence of voiding dysfunction in the early postoperative period [5].

A 2-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 the 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 94%, something that has also been reported by other authors [2]. Concomitant prolapse surgery did not affect the results, as reported elsewhere [21] Success rates after TVT or SPARC procedures range from 67% to 95% [1–3]. Our high objective success rate 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. Munir et al. [22] report that only 20% of their patients are completely dry, Ward and Hilton [3] report a figure of 36%, and Kobashi and Govier [23] using the SPARC procedure report that 36.6% of patients never leak urine. 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. The subjective results, however, depend on the existence of urgency incontinence, and it is impossible to make any comparison between centers if all variables are not reported.

Twenty-seven percent of our patients indicate urgency as the cause of their subjective failure, 4% mixed incontinence, and only 6% pure stress incontinence (Table 2). According to these figures, our subjective cure rate for stress incontinence would be 83%.

There were no major complications, and no vaginal erosion, urethral erosion, or infection were identified. The percutaneous strings seems 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 edema or even to postoperative discomfort. It is also possible that there was slight sliding of the implanted mesh.

Urinary urgency disappeared or was ameliorated in 77% of cases where it previously existed, appeared de novo in 4

of the 27 cases were it did not previously exist (15%), and was worse in four cases (11%) where it existed previously. The mean maximum flow in these last eight 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. There must therefore be causes other than obstruction, possibly nerve lesion or inflammatory reactions to the mesh, that contribute in some cases to the development of mictional urgency. So far, it has not been necessary to perform urethrolysis in any of our patients.

The QoL questionnaires demonstrate the highly significant improvement of quality of life after implant of the TVA mesh. The PGI-I confirms this, with 94% of our patients much better or very much better than previously. 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 [22].

Postoperative urgency incontinence, as reported elsewhere [24, 25], was the only analyzed factor affecting quality of life in the multivariate study.

Two techniques for postoperative tension adjustment have been published previously. REMEX is a more complex technique. Good results have been reported in 95% of cases [26]. The SAFYRE technique requires adjustments under local or regional anesthesia and an incision of the skin to locate the columns of polymer. It also necessitates surgical incision of the anterior vaginal wall if control of the appropriate tension is desired. The authors report a 92% success rate with this procedure [27].

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 TVA mesh procedure permits postoperative adjustment of tension. These data suggest that better objective and subjective results than those achieved with the traditional non-adjustable mesh can be obtained, furthermore without increasing surgical complications.

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

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