



# Adjustable transobturator sling for the treatment of primary stress urinary incontinence

Dmitry Shkarupa<sup>1,2</sup> · Nikita Kubin<sup>2</sup> · Olga Staroseltseva<sup>2</sup> · Ekaterina Shapovalova<sup>3</sup>

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## Abstract

**Introduction and hypothesis** The purpose of the study was to evaluate the rate of postoperative voiding dysfunction after the insertion of an adjustable transobturator sling for the treatment of primary stress urinary incontinence (SUI). The secondary aim was to assess the objective and subjective cure rates and the impact of the surgery on quality of life.

**Methods** This prospective study included 171 patients with primary SUI who underwent insertion of an adjustable transobturator tape. A postoperative tension adjustment algorithm that included a cough stress test (CST), uroflowmetry and postvoid residual volume (PVR) measurement was applied in all patients the day after surgery. The baseline and control postoperative evaluations included vaginal examination, CST, Q-tip test, uroflowmetry and PVR measurement, 1-h pad test and administration questionnaires (UDI-6, IIQ-7, PISQ-12, ICIQ-SF).

**Results** The day after surgery 65 patients (38.0%) required tape tension adjustment: an increase in tension in 53 patients (31.0%) and a decrease in 12 (7.0%). Continence was achieved in all patients. No patients showed voiding dysfunction after adjustment. Follow-up data for 12 months were available in 157 patients (91.8%). The objective and subjective cure rates were 96.2% and 97.5%, respectively. There was no statistically significant decrease in  $Q_{max}$  ( $p = 0.899$ ) or increase in PVR ( $p = 0.187$ ). According to the questionnaires scores, quality of life was improved in all patients.

**Conclusion** The adjustable transobturator sling minimizes the risk of postoperative voiding dysfunction and allows high objective and subjective cure rates to be achieved in patients with primary SUI. The technique also improves the patient's quality of life.

**Keywords** Adjustable device · Adjustable sling · Midurethral sling · Stress urinary incontinence · Transobturator tape · Voiding dysfunction

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✉ Ekaterina Shapovalova  
katerina\_andmed@mail.ru

<sup>1</sup> Department of Urology, North-Western Medical University n.a. I.I. Mechnikov, 41, Kirochnaya Street, Saint-Petersburg 191015, Russia

<sup>2</sup> Department of Urology, University Clinic, Saint-Petersburg State University, 154, Fontanka Embankment, Saint-Petersburg 190103, Russia

<sup>3</sup> Gynecology Department, University Clinic, Saint-Petersburg State University, 154, Fontanka Embankment, Saint-Petersburg 190103, Russia

## Introduction

Stress urinary incontinence (SUI) is defined as the presence of a complaint of involuntary leakage on effort or exertion, or on sneezing or coughing, according to the standardized terminology of the International Continence Society [1]. This is a widespread pathology: according to numerous studies, every second woman who complains of involuntary leakage suffers from this type of incontinence. SUI occurs in 4% of women aged 20–24 years and the frequency increases up to 12–35% in patients older than 40 years [2–4].

Implantation of a synthetic midurethral sling (MUS) is considered the “gold standard” for the treatment of SUI. As first described in 1995 by Ulmsten and Petros, MUS was implanted via the retropubic route [5]. Later, in 2001 implantation via the transobturator route was described by Delorme as

an alternative route for suburethral sling implantation that minimizes intraoperative complications [6, 7]. Based on the Integral theory, this synthetic tape implanted in the “tension-free” manner aimed to reinforce the pubourethral ligament, resulting in continence [8]. However, the average frequency of voiding dysfunction after transobturator tape (TOT) implantation is 5.9% (0–33.9%), so this complication ranks third after de novo urgency and pelvic pain [9]. Moreover, up to 21.3% of women who undergo TOT implantation for the treatment of SUI need a reoperation for urinary retention or voiding dysfunction [9]. Insufficient tension of the MUS is usually evident in the early postoperative period, and this is considered “failure of the surgery” [10].

The discussion above indicates the imperfection of the tension-free technique for MUS implantation that led to the development of adjustable synthetic slings. This type of sling gives the surgeon the opportunity to adjust the tension of the tape both during the operation and in the early postoperative period. Such systems as Remeex (Neomedic International), Safyre (Promedon), and TOA and TVA (A.M.I.) were developed to solve this problem. There are few data in the literature on the use of these devices. However, in published studies, the authors mentioned the need for tension adjustment in 27.3–46.8% of women [11–13]. This points to the existence of the problem of inadequate tension during surgery.

The primary aim of this study was to evaluate the rate of postoperative voiding dysfunction after insertion of an adjustable transobturator sling for the treatment of primary SUI. The secondary aims were to assess the objective and subjective cure rates and the impact of the surgery on quality of life.

## Materials and methods

This prospective single-arm study was started in January 2015 and was closed in June 2016. It was registered and approved by the ethics committee of the University Clinic of Saint-Petersburg State University. Women complaining of involuntary urine leakage with SUI confirmed by a cough stress test (CST) performed in the lithotomy and standing positions, 1-h pad weight test (>2 g/h) and urodynamics were enrolled. Conservative therapy (behavior modification, pelvic floor muscle training) as primary treatment had been ineffective in all patients selected. Exclusion criteria included urethral hypomobility (Q-tip <30°), intrinsic sphincter deficiency (diagnosed before hospital admission with a urodynamic study), pelvic organ prolapse stage 2 or more according to the Pelvic Organ Prolapse Quantification (POP-Q) system, previous surgical treatment for SUI or pelvic organ prolapse, and urinary tract infection. Patients with detrusor hyperactivity were also excluded. Participants received thorough information and provided signed consent.

Preoperative assessment included detailed urogynecological history, physical and pelvic examination, CST and Q-tip test, uroflowmetry and ultrasound measurement of postvoid residual volume (PVR), and a 1-h pad test. CST was performed in both the lithotomy and standing positions with the bladder self-filled to 300–400 ml as confirmed by ultrasound. Patients completed questionnaires translated and validated in Russian: the Urinary Distress Inventory-6 (UDI-6), the Incontinence Impact Questionnaire-7 (IIQ-7), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), and the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) [14].

## Surgical technique

All surgical procedures were performed under general (intravenous) anesthesia by two experienced urogynecologists. Patients received antibiotics intravenously (amoxicillin clavulanate according to their weight) during the hour before the operation and orally for two postoperative days. After hydrodissection (10 cm<sup>3</sup> of sterile saline) of the anterior vaginal wall in the midurethral area, a 1.5-cm incision was made. The paraurethral tissues were dissected bilaterally in a direction about 90° to the inferior ramus of the pubic bone and the perineal membrane was perforated with Metzenbaum scissors. The tape was then placed in the channel using the introducer and passed through the obturator membrane and thigh tissues 1.0 cm below the musculus adductor longus tendon in the inside-out manner. A monofilament polypropylene sling with atraumatic edges was used as supplied with two adjustment polypropylene monofilament threads in the central part of the tape (UroSling; Lintex, St. Petersburg, Russia). The selected tape has a stable and unstretchable structure. Therefore during first 2 days after the operation it is possible to decrease tape tension by gently pulling the adjustment threads caudally under local anesthesia, and conversely to increase tape tension by pulling the distal edges of the UroSling (that are left uncut during the procedure). The distal end of the tape and the adjustment thread of the same side are marked using the same color (white or blue) to determine the direction of traction (Fig. 1).

The sling was implanted in the tension-free manner. Metzenbaum scissors were used as a spacer in the presence of an 18–20 Fr urethral catheter. An absorbable running suture was then placed on the anterior vaginal wall incision such that the adjustable threads passed out of the incision between the stitches. Additionally, a single suture was placed on the edges of the vaginal wall incision between the adjustment threads for better tissue approximation. The distal ends of the sling were left uncut under a sterile drape. The adjustment threads were put into the vagina, and vaginal packing was placed and removed with the urethral catheter within 6–8 h.

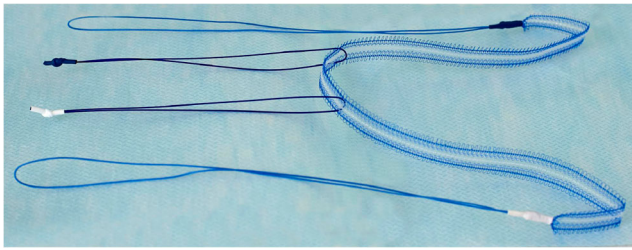


Fig. 1 The UroSling tape with adjustment threads in the central part

## Sling adjustment

On the day after surgery, all patients underwent urogynecological examination that consisted of a CST in both the lithotomy and the standing positions with the bladder filled to 300–400 ml, uroflowmetry and ultrasound measurement of PVR. The algorithm for sling adjustment is shown in Fig. 2.

If the CST was positive, the sling was tightened by pulling the distal ends until leakage during the CST stopped. If voiding dysfunction was present (obstructed flow on uroflowmetry, i.e.  $Q_{max} < 12$  ml/s, and/or PVR  $> 100$  ml) the sling tension was decreased by pulling the adjustable threads in the caudal direction (Fig. 3). Pain was controlled during this procedure by administration of a nonsteroidal antiinflammatory drug (ketoprofen) and by local anesthesia with infiltration of a small amount of 1% lidocaine paravaginally and subcutaneously. The result of the adjustment was considered positive if the CST was negative with absence of voiding dysfunction. On the first day after surgery a CST, uroflowmetry and PVR measurement were performed at least twice to confirm that the optimal tape position had been achieved. On the second day after surgery continence status was evaluated again. If the CST was negative and there

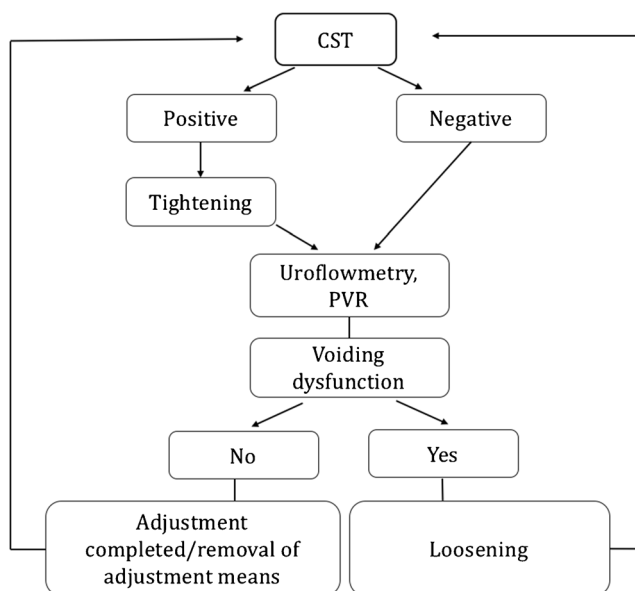


Fig. 2 Sling adjustment algorithm

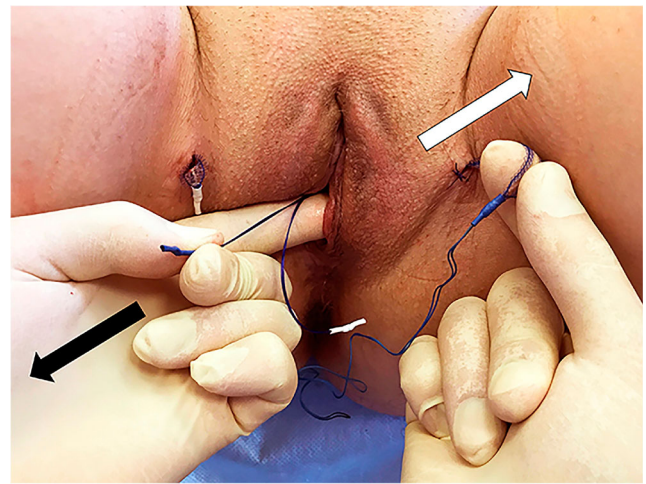


Fig. 3 Mechanism of sling tension adjustment: the white arrow shows the direction of traction to increase the tension; the black arrow shows the direction of traction to decrease the tension. The tape is displaced strictly in the direction of the sling placement axis

was no voiding dysfunction, the distal ends of the sling and adjustable threads were cut. If the tests were positive, the adjustment was repeated.

## Outcome measures

Patients were evaluated postoperatively by physicians of the Department of Urology at 1, 6 and 12 months, and then annually. The postoperative evaluation was similar to the preoperative evaluation. The primary efficacy endpoint was the absence of postoperative voiding dysfunction:  $Q_{max} > 12$  ml/s and PVR  $< 100$  ml. Secondary outcomes included objective and subjective cure rates and patient satisfaction. The definition of objective cure was a negative CST and a negative 1-h pad weight test ( $< 2$  g/h). Subjective effectiveness was defined as answering “never” to the first ICIQ-SF question “How often do you leak urine?”. Patient satisfaction was assessed using the questionnaire item in which the patient could answer “no”, “almost satisfied” or “satisfied” to the question “Are you satisfied with the results of the surgery?”. Quality of life was assessed by comparing preoperative and postoperative questionnaire results (UDI-6, IIQ-7, PISQ-12, ICIQ-SF).

## Statistical methods

The clinical results were analyzed using STATISTICA for Windows software (version 10; StatSoft, Tulsa, OK). A set of descriptive statistics was used for the quantitative parameters: mean values, standard deviations, and minimum and maximum values. The parameters studied were processed by comparing the initial data with the values obtained during the observation period. Data were compared using the sign test and the Wilcoxon signed ranks test. The frequency characteristics of the qualitative parameters were analyzed using the

nonparametric chi-squared test and Fisher's test. A *p* value of <0.05 was considered the criterion indicating statistical reliability of the conclusions, as is conventional in the medical sciences.

## Results

The study group consisted of 171 patients (selected according to the inclusion criteria from among the patients consecutively admitted to our center for surgical treatment during the period from January 2016 to June 2016) with a mean age of  $54.6 \pm 10.6$  years. The patient demographics are shown in Table 1, and patient responses to the UDI-6 and IIQ-7 questionnaires are presented in detail in Table 2.

The UroSling adjustable transobturator sling was successfully implanted in all patients. The mean surgery time was  $13.9 \pm 6.5$  min (range 8–25 min), and the mean intraoperative blood loss volume was  $57.3 \pm 16.7$  ml (range 10–250 ml). The average hospital stay was  $2.2 \pm 0.6$  days (maximum 4 days). No intraoperative damage to the urethra or bladder occurred in any patient, nor any clinically significant bleeding.

On the first day after surgery, 65 patients (38.0%) needed adjustment of the sling tension. Tension was increased in 53 patients (31.0%) due to a positive CST. In 7 patients (4.1%), CST was positive only in the standing position). Tension was decreased in 12 patients (7.0%) due to the uroflowmetry curve indicating obstruction ( $Q_{\max} < 12$  ml/s) and PVR >100 ml. No patient showed bladder outlet obstruction (BOO) after

sling tension had been decreased. On the second day after surgery, tension was readjusted in 8 patients (4.7%) with an increase in 7 (4.1%) and a decrease in 1 (0.6%; Table 3).

Follow-up data for 12 months were available in 157 patients (91.8%). Six patients declined the invitation to attend for examination at 1 month because they lived at some distance from the clinic and reported no leakage or complaints, and eight patients (all of whom showed cure at 6 months) failed to attend at 1 year. The objective cure rate following surgery was 96.2%. Preoperative uroflowmetry values and PVR were not significantly different from those at 12 month. No patient showed mesh extrusion, wound infection (despite sling tensioning under office conditions) or chronic groin pain. De novo urgency (grade II complication, Clavien-Dindo classification) developed in the postoperative period in 8 patients (5.1%). The subjective cure rate was 97.5%. The questionnaire results indicated statistically significant improvement in quality of life, continence and sexual life (Tables 1 and 2). Concerning patient satisfaction with the results of surgery, 94.9% of patients (149 of 157) were satisfied and 2.5% (4 of 157) were almost satisfied.

## Discussion

MUS is the most studied type of mesh among all synthetic implants used for reconstructive pelvic surgery. According to published data, the effectiveness of TOT procedure is up to 94.6% [15]. The reverse side of the coin of achieving continence is the risk of postoperative development of BOO as a result of excessive tension. The average frequency of this complication after TOT is 4.0% (0–26.0%) according to a Cochrane systematic review [7]. Blaivas et al. [9], in a review of 8,287 patients who had undergone TOT insertion, found an average rate of BOO of 5.9% (0–33.9%) and an average rate of surgical treatment for postoperative BOO of 2.3% (0–21.3%) [9]. If the tape tension is insufficient the incontinence may persist. According to interview results, more than 80% of surgeons considered that sling tension plays an important or very important role in the procedure [16]. To identify the optimal tension, 30% of surgeons relied on the preoperative Valsalva leak point pressure results, more than 15% performed an intraoperative CST, and others used the Q-tip test or intraoperative cystoscopy [16]. Unfortunately, there is no clear guidance on how to achieve the appropriate tape tension as none of the methods mentioned above provides reliable results.

The relevance of the sling tension problem is confirmed by the fact that the first adjustable sling was produced within 3 years of publication of the first articles devoted to SUI treatment with MUS. In 1999 an adjustable system (Remeex) was developed. The evolution of adjustable slings followed the path of construction simplification, creating a less “invasive”

**Table 1** Characteristics of the patients at baseline and of the remaining patients at 12 months

Characteristic	Baseline ( <i>n</i> = 171)	12 months ( <i>n</i> = 157)
Age (years)	54.6 ± 10.6	55.1 ± 9.8
Disease duration (years)	7.1 ± 5.3	7.5 ± 4.7
Parity	1.8 ± 0.7	1.8 ± 0.9
Menopause	100 (58.5)	93 (59.2)
Body mass index (kg/m <sup>2</sup> )	27.9 ± 3.7	26.4 ± 4.1
Previous hysterectomy	14 (8.1)	14 (8.5)
Positive CST	171 (100)	6 (3.8)
1-h pad weight >2 g/h	171 (100)	10 (6.4)
$Q_{\max}$ (ml/cm)	28.9 ± 9.2	28.1 ± 7.6
PVR (ml)	23.5 ± 19.7	24.6 ± 15.9
Questionnaire scores		
PISQ-12	20.4 ± 7.7	22.3 ± 5.3**
ICIQ-SF	14.0 ± 4.1	0.7 ± 2.1***
UDI-6	48.1 ± 17.2	3.9 ± 9.2***
UIQ-7	45.4 ± 21.0	3.8 ± 9.3***

The data are presented as means ± standard deviation or number (%) of patients

\**p* < 0.05, \*\**p* < 0.01, \*\*\**p* < 0.001 (statistically significant differences)

**Table 2** Patient responses to the UDI-6 and IIQ-7 questionnaires

Questionnaire	Question	Response	Baseline ( <i>n</i> = 171)	12 months ( <i>n</i> = 157)			
UDI-6	Do you experience, and if so, how much are you bothered by:	Urine leakage related to coughing, sneezing, or laughing?	Not at all	0 (0)	157 (100)		
			Somewhat	32 (18.7)	0 (0)		
			Moderately	69 (40.3)	0 (0)		
			Quite a bit	48 (28.1)	0 (0)		
			Total	22 (12.9)	0 (0)		
			Small amounts of urine leakage (that is, drops)?	Not at all	151 (88.3)	153 (97.4)	
				Somewhat	2 (1.2)	2 (1.3)	
				Moderately	10 (5.8)	2 (1.3)	
				Quite a bit	8 (4.7)	0 (0)	
				Total	0 (0)	0 (0)	
				Urine leakage associated with a feeling of urgency; that is, a strong sensation of needing to go to the bathroom?	Not at all	171 (100)	153 (97.5)
					Somewhat	0 (0)	1 (0.6)
			Moderately	0 (0)	2 (1.3)		
			Quite a bit	0 (0)	1 (0.6)		
			Total	0 (0)	0 (0)		
IIQ-7	How do symptoms or conditions in the following usually affect your:	Ability to do physical activities such as walking, swimming, or other exercise?	Not at all	91 (53.2)	154 (98.1)		
			Somewhat	38 (22.2)	3 (1.9)		
			Moderately	25 (14.6)	0 (0)		
			Quite a bit	17 (9.9)	0 (0)		
			Total	0 (0)	0 (0)		
			Emotional health (nervousness, depression, etc)?	Not at all	29 (17.0)	151 (96.1)	
				Somewhat	76 (44.4)	5 (3.2)	
				Moderately	54 (31.6)	1 (0.6)	
			Quite a bit	12 (7.0)	0 (0)		

The data are presented as number (%) of patients

adjustment mechanism and decreasing the use of synthetic materials. Other adjustable retropubic sling systems have been developed for TOT insertion including TVA, Safyre and TOA. The latest reported short-term objective effectiveness of adjustable slings is 84.4–93.7% [12, 17, 18]. It should be mentioned that there are two single-incision slings (SIS) available on the market: the adjustable Ajust™ and Altis™ [19, 20]. These systems solve the problem of intraoperative tape tension adjustment, that is impossible with the traditional SIS procedure. However, the problem of determining the appropriate tape tension intraoperatively remains as relevant for these slings as for other MUS. So in our article, we call

“adjustable” only those kits that allow the sling tension to be changed during the postoperative period.

In previous studies, the rates of postoperative tape tension adjustment have been in the range 27.3–46.8% [11–13, 17, 18, 21]. The fact that tightening was required more frequently than loosening in most of the studies indicates that the initial tension is frequently insufficient. This would lead to failure of the surgery if there were no adjustment mechanism. In the latest Cochrane meta-analysis including 39 randomized controlled trials with a total of 3,028 patients, the average short-term ( $\leq 1$  year) efficacy of TOT was found to be 85.8% (50.0–94.6%) [7]. These data show that, although in most studies the cure rate following MUS was high, in some studies this technique was found to be effective only in every second case. Apart from the patient’s risk factors, the experience of the surgeon affects the effectiveness and complications of the surgery [22]. The opportunity to adjust the tape tension the day after surgery allows high procedure efficiencies to be achieved even by surgeons with moderate experience.

Although the adjustable sling was developed almost in parallel with MUS, we found only 23 publications in the PubMed database using the keywords “adjustable” and “urinary incontinence”. This small number can be explained by the

**Table 3** Adjustment of the implanted slings

Type of adjustment	Postoperative day	
	First	Second
Tension increase, <i>n</i> (%)	53 (31.0)	7 (4.1)
Tension decrease, <i>n</i> (%)	12 (7.0)	1 (0.5)
All adjustments, <i>n</i> (%)	65 (38.0)	8 (4.6)

“outlaw” status of these techniques. The adjustable sling appears in the latest guidelines but its use is recommended as part of a structured research program [23]. Until now adjustable systems have been considered only as an alternative to MUS in patients with complicated SUI: with urethral hypomobility, intrinsic sphincter deficiency, previous SUI surgery, preoperative urinary obstructive symptoms. The crucial difference between our study and the others is that we used the adjustable sling in patients with primary SUI without such complications. Of 171 patients, 65 (38.0%) needed adjustment of the tape tension. Interestingly, this rate is comparable to those reported in patients with procedural complications in the studies discussed above. Moreover, the greater frequency of tightening than of loosening was confirmed in our study in which tension was increased in 31.0% and decreased in 7.0% of patients.

Using the adjustable sling together with an algorithm for achievement of optimal tape tension that included CST (lithotomy and standing), uroflowmetry and PVR, we achieved absence of voiding dysfunction in the early postoperative period and during the first 12 months and the short-term objective cure rate was very high (96.2%). It should be noted that published statistics of average rates of postoperative BOO often reflect the number of patients with significant PVR. Meanwhile, according to the latest studies, so-called “latent” obstruction characterized by the presence of voiding dysfunction symptoms without PVR can occur. Obstructive symptoms including straining, position-dependent micturition, slow stream and hesitancy have been reported to occur in 11.0–18.0% of patients following TOT insertion [24]. The adjustable transobturator sling provides optimal quality of voiding based not only on objective measures but also on patient complaints. The latter indicate high subjective cure rates and patient satisfaction that in our study were 97.5% and 97.4%, respectively.

Implantation of an adjustable sling may lead to more patient interventions than traditional MUS insertion, but this is the price of high short-term effectiveness and the absence of any kind of voiding dysfunction. The use of an adjustable transobturator sling and an algorithm for optimal tape tension led to continence in both the standing and lithotomy positions. Patnam et al. found that in up to 15% of patients CST may be positive in the standing position but negative in the lithotomy position [25]. In our study seven patients (4.1%) needed an increase in sling tension in the postoperative period due to a positive standing CST.

The adjustable transobturator sling used in our study has a simple construction that does not require additional incisions or tricky adjustment. The use of the adjustable tape did not lead to an increase in the duration of surgery or hospital stay in comparison with regular MUS procedures. Patients could easily have been discharged on the day of surgery, but due to some specific organizational reasons of the healthcare system

most remained in hospital (minimum hospital stay in our clinic is 2 days). This is why our average hospital stay was relatively high at  $2.2 \pm 0.6$  days. There were no significant intraoperative or postoperative complications. In conclusion, the adjustable sling minimizes the risk of postoperative voiding dysfunction and provides high short-term objective and subjective cure rates.

There were some limitations in this study. First, the short follow-up period (12 months). Second, the study was not randomized. Also, the study did not include patients with predictive factors for failure. The strengths of the study include a prospective design, a homogeneous cohort and the use of validated questionnaires for measurement of subjective outcomes. Long-term studies and evaluating the effectiveness of the UroSling adjustable sling in patients with procedural complications are planned.

## Conclusion

The use of the adjustable transobturator sling in combination with an algorithm for the achievement of optimal tape tension that included CST (lithotomy and standing positions), uroflowmetry and PVR allowed the risk of postoperative voiding dysfunction to be minimized and high objective and subjective cure rates to be achieved in patients with previously untreated SUI, and also led to improvements in patient quality of life.

## Compliance with ethical standards

**Conflicts of interest** None.

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