



The Evaluation of the Effect of Suburethral Transobturator Sling on the Urethra Using Ultrasound Examination

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Abstract

Background: *Despite the use of suburethral tapes for many years, the mechanism of their action and the reasons for their failures have not been thoroughly understood.*

Objectives: *The aim of this study was to analyze the impact of the TOT tape on changes in urethral mobility depending on its location. Additionally, the urethral funneling was evaluated.*

Material and methods: *57 patients with SUI symptoms had TOT implanted. Ultrasound examinations were performed before and 3–6 months after surgery, among others, urethral length, suburethral tape location, bladder neck mobility, and urethral funneling were evaluated.*

Results: *77.2% of patients were cured, while 22.8% were not cured. After tape insertion, a reduction in bladder neck mobility parameters was observed in the group of patients with preoperative hypermobile urethras, regardless of the therapeutic outcome. The average distance of the tape from the hypoechoic area of the urethra was smaller in cured patients, while the relative tape position did not differ significantly between cured and not cured women. Before surgery, all patients had a long urethral funneling. Postoperatively, all non-cured patients had a long funneling, while in cured patients, no long urethral funneling was observed.*

Conclusions: *The TOT suburethral tape reduced urethral mobility to a similar extent in cured and not cured women. The effect on UM was noticeable in patients with preoperative hypermobile urethrae. The obtained TOT tape locations did not affect the degree of UM reduction. Patients in whom the TOT tape was located closer to the hypoechoic zone of the urethra had a greater chance of effective elimination of SUI symptoms. It was confirmed that the assessment of the urethral funneling during PFS-TV may be useful for confirming SUI and for assessing the effects of SUI treatment after suburethral tape implantation.*

Key words: *TOT, urethral mobility, PFS-TV, SUI, urethral funneling*

Introduction

Urinary incontinence (UI) in women, along with the increasing phenomenon of aging society, is an increasingly serious health and social problem. In the group of women with UI, the largest percentage, amounting to about 50–60%, is stress urinary incontinence (SUI) [1].

Many urogynecologists believe that the assessment of urethral mobility (UM) is important during preoperative diagnosis of SUI [2, 3, 4]. Currently, ultrasound is increasingly used in urogynecology for complex evaluation in studies and everyday practice, among others, for visualization and measurement of UM and the location of the suburethral tape [5].

In modern urogynecology, various ultrasound methods are used: 2D, 3D, and 4D, performed with a transabdominal, transvaginal or transrectal probe. There are more and more studies devoted to pelvic floor sonography performed with a transvaginal probe (PFS-TV) [2, 3]. Pelvic floor sonography performed with a transvaginal probe (PFS-TV) is now used in the studies more often, but still the number is not high [2, 3].

Currently, due to the method of implantation, we distinguish three types of tapes: retropubic tapes (RT), trans-obturator tapes (TOT), and „mini-slings” [6]. Despite many years of their use, the mechanism of action of these procedures and the causes of their failures are not fully understood.

The results of UM changes after RT implantation are ambiguous [7, 8]. Very little is known about the effect of TOT implantation on UM, which is often used in Poland.

There is no consensus on the place of SUI diagnostic methods used nowadays in contemporary urogynecology [2, 9–11]. Individual studies indicate the potential usefulness of urethral funneling assessment during PFS-TV to confirm SUI, but there is too little data on this subject [12, 13].

The aim of the study was to analyze the effect of the TOT on UM depending on tape location and the obtained therapeutic effect. An additional aim was to analyze the occurrence of urethral funneling in patients with SUI symptoms and cured after TOT implantation.

Material and methods

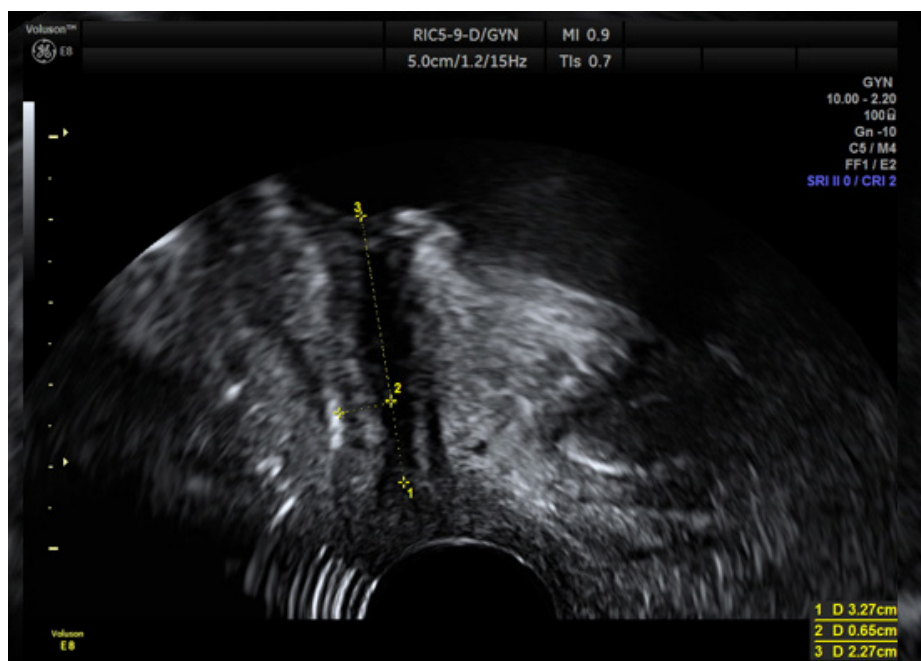
A retrospective study included 57 patients after implantation of the TOT (Ethicon) between January 2005 and December 2005 due to SUI, who reported for a check-up within 3–6 months after the surgery.

The study included patients who had not previously undergone surgery due to SUI and who had not been found to have significant pelvic organs prolapse – on the POP-Q scale, the reductions were 0 or 1 in all three compartments [14]. SUI from the standardized interview was confirmed during a cough test performed in a standing position with a urinary bladder filled up to 200–300 ml and during a urodynamic study (UD) performed according to the criteria of the International Continence Society (ICS) [15].

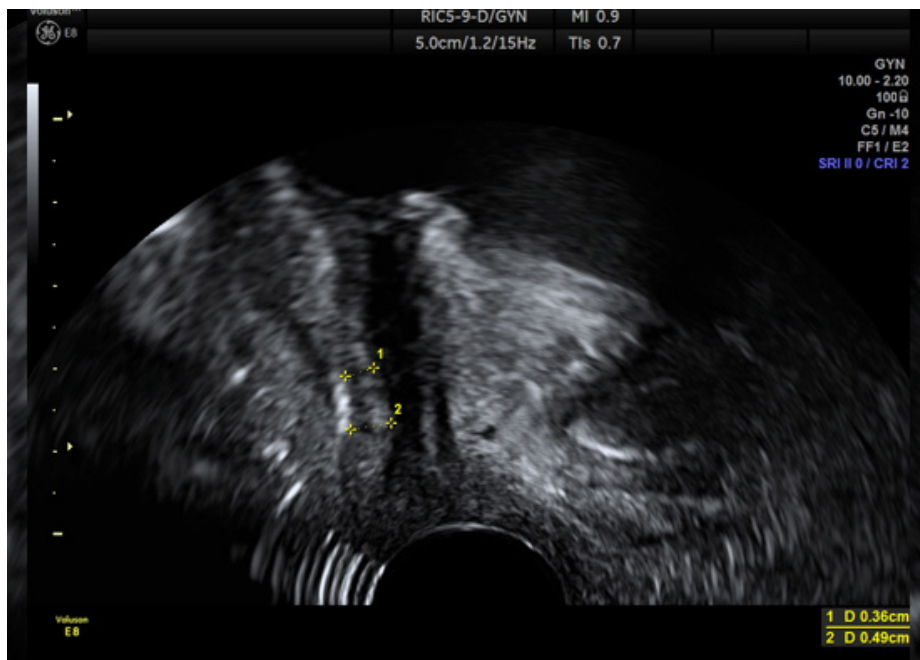
During preoperative and postoperative visits, GE devices were used for ultrasound examinations: Voluson 730 GE PRO and Expert, with a GE RIC5-9E 5-9 MHz transvaginal probe with a 6.5 MHz ultrasound beam setting and an angle of 160°, in a semi-sitting position on a gynecological chair. The ultrasound examination was performed with the bladder filled to 200–300 ml transvestibularly with a transvaginal probe according to the technique developed by Kociszewski (PFS-TV) [16, 17]. After placing the probe in the long axis of the patient at rest, the ultrasound length of the urethra and the location of the TOT were measured. To determine the location of the tape, the RTP parameter (relative tape position, the percentage ratio of the distance between the center of the tape and the internal urethral opening (TP-AC parameter) and the ultrasound length of the urethra (UL) (AB) were used (Figure 1), as well as the TUD parameter (tape-urethra distance, the distance of the tape from the hypoechoic zone of the urethra (Figure 2) [18, 19]. To measure the UM at rest and during maximum straining, the location of the internal urethral opening in relation to the pubic symphysis was measured (Figure 3a & 3b). Based on the obtained UM values, the BND parameter (vertical mobility in the X axis) and the vector parameter were calculated in accordance with the previously described methodology [16, 20]. Depending on the preoperative values of the vector parameter, for some analyses, the patients were divided into three

groups: with hypomobile (vector parameter ≤ 5 mm), normomobile (vector parameter between >5 and 15 mm), and hypermobile (vector parameter >15 mm) urethrae [3, 10].

Figure 1. Tape-urethra distance

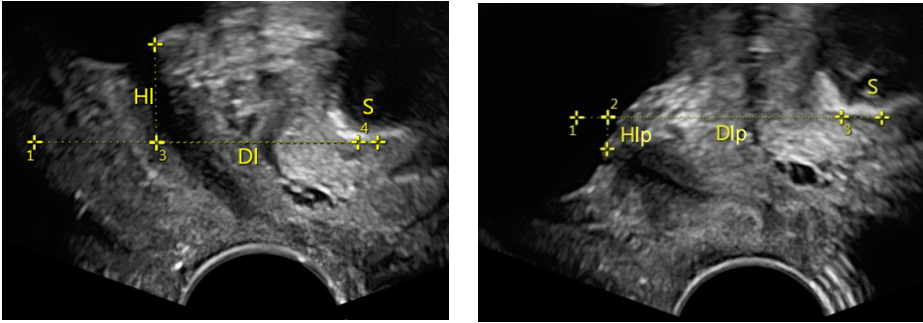


Relative tape position was calculated as the percentage ratio of the distance from the center of the tape to the internal urethral opening to the ultrasound length of the urethra. 1 — urethral length, 2 — reflects the position of middle part of the tape on the axis of the urethra, 3 — distance of the middle part of the tape from the bladder neck
Source: own elaboration.

Figure 2. Tape-urethra distance (TUD)

Distance between tape and hypoechoic zone of urethra 1–2 the tape – urethra distance (TUD), the shortest value was chosen for the evaluation in the study.

Source: own elaboration.

Figure 3a, 3b. PFS-TV images of urethra mobility

3a = at rest and 3b = at maximal Valsalva maneuver S — pubic symphysis; DI – distance between pubic symphysis and line perpendicular to bladder neck at rest; Dlp – distance between pubic symphysis and line perpendicular to bladder neck at maximal Valsalva maneuver; HI – distance between internal urethral orifice and line perpendicular to pubic symphysis at rest; Hlp – distance between internal urethral orifice and line perpendicular to pubic symphysis at maximal Valsalva maneuver

Source: own elaboration.

After rotating the transvaginal probe dorsally, in order to obtain an angle of incidence of the ultrasound beam of at least 60 degrees relative to the patient's long axis during straining, the presence and length of the urethral funneling were assessed. The purpose of rotating the transducer was to improve the visualization of the bladder neck area [12]. In accordance with previous studies, a long funneling (above 50% of the UL with visible urine flow on ultrasound) and a short funneling (below 50% of the UL without visible urine flow) were distinguished. Situations when the funneling was not visible were defined as: no funneling [12, 13].

The TOT tape implantation was performed according to the ½ rule developed by Kociszewski et al. by experienced operators. According to this rule, the vaginal mucosa incision was started under the urethra at a distance of ½ of the ultrasound UL [17].

After the surgery, patients who did not have clinical symptoms of SUI and the cough test was negative were classified into the cured group. Patients with

clinical symptoms of SUI, confirmed during the cough test, were classified into the non-cured group. There was no plan to create a group for patients whose condition improved.

The statistical analysis of the obtained research results was conducted using the Statistica software, version 13.3 (licensed to UMED), and the statistical functions of Excel from the MS Office suite. After testing the normality of the obtained research results, a Student's t-test was used to compare the differences between the mean values of two different groups. For comparing treatment results, a Paired t-Test was applied. To compare the significance of the distribution fractions between the two studied groups, a chi-square test (either multinomial or 2x2 table) was used. To compare two series of measurements obtained by different methods, after testing the normality of the distributions, a linear correlation analysis was conducted, the regression equation was determined, and Pearson's linear correlation coefficient was calculated. The significance of the correlation was tested using the Student's t-test, p-values <0.05 were considered statistically significant, while values above were considered statistically insignificant. For the comparison of two research methods, Bland-Altman analysis was applied.

The study received approval from the Ethics Committee at the Medical University of Łódź.

Results

The average age was 61 years (42–80), with an average BMI of 27 kg/m² (20–37). The patients had an average of two childbirths (0–5), 7% were nulliparous, 25% primiparous, and 68% multiparous. 74% delivered vaginally, 8% reported instrumental delivery using forceps or vacuum, and 18% underwent cesarean section. 17 patients (29.8%) had a history of vaginal hysterectomy, while 12 (21%) had abdominal hysterectomy. There was no case of previous operation in anterior and central compartment, 5 (8.8%) patients had posterior repair in the past.

In addition to symptoms of SUI, 22 patients (38.6%) presented with mild symptoms of OAB before surgery. No significant micturition disorders were noted in any of the patients.

No significant complications were observed during the perioperative and postoperative periods. In three patients, there was increased bleeding during tape implantation, requiring compression for a few minutes. In one case, a small hematoma was visualized by ultrasound next to the urethra after surgery, which did not affect micturition and resolved spontaneously within 4 weeks. No significant post-void residual urine was found in any patient. 8.8% of patients continued to report symptoms of dry OAB. None of the patients experienced de novo urgency after surgery.

In the study group of 57 patients, postoperative cure of SUI was observed in 44 patients (77.2%), while 13 patients (22.8%) were classified as not cured.

The average urethral length (UL) before surgery was 31.8 mm, with the longest urethra measuring 40 mm and the shortest 25 mm. In 31 cases, the vaginal mucosa incision before TOT implantation was initiated 10 mm from the external urethral meatus, in 10–12 mm, in 5–8 mm, in 3–11 mm, in 3–13 mm, in 3–14 mm, in 1–15 mm, and in 1 case 16 mm. A very strong correlation was found between urethral length and the site of vaginal mucosa incision ($r = 0.806$), with statistically significant results ($p < 0.001$).

Before surgery, no cases of urethral hypomobility were found among the analyzed patients. Urethral normomobility was observed in 21 patients (36.8%), and urethral hypermobility in 36 patients (63.2%).

The values of the parameters defining UM, BND, and vector decreased significantly ($p < 0.001$) 3–6 months after TOT insertion. The ΔD parameter decreased, but the difference was not statistically significant (Tab. 1).

Comparison of patients with preoperatively identified normomobile and hypermobile urethras showed that the reduction was related to patients with hypermobile urethras (Tab. 2). However, no differences in the changes of these parameter values were found between cured and non-cured patients (Tab. 3). Pearson correlation analysis between the percent tape position index (RTP) and the distance from the tape to the hypoechoic area of the urethra (TUD) versus the difference in UM before and after surgery (BND parameter and vector) showed no correlation between the variables (correlation range $r = -0.0125$ to 0.04089), and all results were not statistically significant (Tab. 4).

During the analysis of TOT localization, it was found that the TUD distance ranged from 2 mm to 9.4 mm (average 4.5 ± 1.7), while the RTP range was 51.7%–82.9% (average 66.6 ± 7.4). A statistically significant difference was found between the group of cured and non-cured patients in terms of average TUD (3.8 mm vs. 6.7 mm; $p < 0.001$). In non-cured patients, the TOT tape was located more distally, but the average RTP values did not differ significantly between the two groups (65.9% vs. 68.9%) (Tab. 3).

The result indicates a reduction in urethral mobility along the vertical axis following the implantation of the suburethral tape, but we found statistically significant differences only in women with hypermobile urethra. It is possible that after the procedure, the internal urethral meatus moves closer to the pubic symphysis during straining, but no statistically significant differences were obtained compared to the preoperative assessment. This issue requires further investigation in a larger group of patients.

Before surgery, all patients were found to have a long urethral funneling with urine leakage visible during PFS-TV: the shortest funneling was 50%, the longest 100% (average 57%). At the follow-up visit during PFS-TV, all non-cured patients were found to have a long urethral funneling: the shortest funneling was 51%, the longest 98% (average 64%). In cured patients, no cases of a long urethral funneling were found; in 20.5% of cured patients, a short funneling was found ($n = 9$, average 26%), and in 70.5% ($n = 35$) no urethral funneling was found. Evaluation of patients in whom funneling was found after TOT implantation, preoperatively, the funneling was narrower in the cured group compared to the non-cured group (4.24 vs. 5.28 mm). Postoperatively, the funneling width increased in the cured group (5.18 ± 2.96 mm) and decreased in the non-cured group (5.07 ± 2.42 mm). None of the results were statistically significant. A statistically significant difference was found in the length of the funneling after surgery between the groups of cured and non-cured patients ($p < 0.001$). In the cured patients with persistent funneling, there was a statistically significant shortening of the funneling after surgery ($p < 0.001$) (Tab. 3).

Table 1. Comparison of urethral mobility changes in patients before and after TOT implantation

Table 1	Mean \pm SD	Min	Max	Median	Paired t-test
preoperatively BND (mm)	17.90 \pm 8.35	3.4	36.0	18.4	<0.001
postoperatively BND (mm)	13.19 \pm 7.63	1.1	42.0	11.2	
preoperatively vector (mm)	18.66 \pm 8.14	6.0	36.3	19.1	<0.001
postoperatively vector (mm)	13.90 \pm 7.49	1.1	42.4	12.4	
preoperatively Δ D (mm)	-0.07 \pm 4.96	-9.9	11.2	-1.4	NS
postoperatively Δ D (mm)	-0.72 \pm 4.07	-10.0	12.9	-0.6	

NS-statistically insignificant result

Source: own elaboration.

Table 2. Comparison of urethral mobility changes caused by TOT implantation in patients with normomobile and hipermobile urethras

Table 2	Mean \pm SD	Min	Max	Median	t-Student test
preoperatively vector – postoperatively vector hipermobile urethra (mm):	-9.37 \pm 8.46	-25.5	14.0	-8.9	<0.001
preoperatively vector – postoperatively vector normobile urethra (mm)	3.14 \pm 5.82	-7.5	16.6	1.9	
preoperatively BND – postoperatively BND hipermobile urethra (mm)	-9.46 \pm 8.89	-27.1	14.0	-9.8	<0.001
preoperatively BND – postoperatively BND normobile urethra (mm)	3.42 \pm 5.37	-4.4	16.3	2.2	
preoperatively Δ D – postoperatively Δ D hipermobile urethra (mm)	-1.45 \pm 6.43	-15.9	12.4	-0.3	NS
preoperatively Δ D – postoperatively Δ D normobile urethra (mm)	0.72 \pm 4.72	-7.7	10.2	1.4	

NS-statistically insignificant result

Source elaboration.

Table 3. Comparison of the studied variables between the group of cured and non-cured patients

Table 3	Mean ±SD	Min	Max	Median	t-Student test
preoperatively funneling length in cured patients (mm)	19.03±3.08	15.0	25.0	18.1	NS
preoperatively funneling length in non-cured patients (mm)	22.27±7.89	14.7	39.5	17.5	
postoperatively funneling length in cured patients (mm)	9.58±4.05	4.7	17.0	7.5	<0.001
postoperatively funneling length in non-cured patients (mm)	20.68±6.53	13.7	35.1	17.9	
preoperatively funneling width in cured patients (mm)	4.24±2.20	1.5	7.7	4.0	NS
preoperatively funneling width in non-cured patients (mm)	5.28±2.51	1.2	11.0	5.1	
postoperatively funneling width in cured patients (mm)	5.18±2.96	2.5	12.3	5.6	NS
postoperatively funneling width in non-cured patients (mm)	5.07±2.42	1.3	9.8	4.9	
preoperatively BND in cured patients (mm)	17.64±8.32	5.3	36.0	18.4	NS
preoperatively BND in non-cured patients (mm)	18.77±8.39	3.4	32.0	18.8	
postoperatively BND in cured patients (mm)	13.92±7.79	2.6	42.0	11.6	NS
postoperatively BND in non-cured patients (mm)	10.71±6.48	1.1	28.0	10.2	
preoperatively vector in cured patients (mm)	18.37±8.19	6.0	36.3	18.8	NS
preoperatively vector in non-cured patients (mm)	19.67±7.92	6.0	32.7	20.2	
postoperatively vector in cured patients (mm)	14.61±7.66	2.6	42.4	13.1	NS
postoperatively vector in non-cured patients (mm)	11.50±6.33	1.1	28.1	11.1	
preoperatively ΔD in cured patients (mm)	-0.22±4.88	-8.6	11.2	-1.4	NS
preoperatively ΔD in non-cured patients (mm)	0.41±5.18	-9.9	9.0	-1.4	
postoperatively ΔD in cured patients (mm)	-0.85±4.10	-10.0	12.9	-0.7	NS
postoperatively ΔD in non-cured patients (mm)	-0.29±3.96	-9.2	6.8	-0.2	

Table 3	Mean \pm SD	Min	Max	Median	t-Student test
postoperatively TUD in cured patients (mm)	3.80 \pm 1.04	2.0	6.8	3.7	<0.001
postoperatively TUD in non-cured patients (mm)	6.66 \pm 1.55	3.8	9.4	6.5	
postoperatively RTP in cured patients (mm)	65.91 \pm 6.88	51.7	81.9	65.6	NS
postoperatively RTP in non-cured patients (mm)	68.93 \pm 8.27	57.1	82.9	69.2	

The results of urethral funneling pertain to patients with a persistent funneling post-surgery, with 9 patients in the cured group and 13 in the non-cured group. NS-statistically insignificant result
Source: own elaboration.

Table 4. Pearson's linear correlation coefficient between TUD/RTP and the change in urethral mobility

Table 4	RTP	TUD
Δ vec	r=-0.0123 NS	r=0.03931 NS
Δ BND	r=-0.0125 NS	r=0.04089 NS
Δ D preoperatively – Δ D postoperatively	r=-0.0327 NS	r=-0.0189 NS

NS-statistically insignificant result

Source: own elaboration.

Discussion

New generations of suburethral slings have been used for over 20 years. However, the mechanism of their action and the causes of failures have not been fully understood to this day. One of the important factors influencing the effectiveness of suburethral slings is the preoperative urethral mobility (UM) [3]. The impact of sling implantation on UM and its clinical significance has not been clearly defined.

UM after RT implantation was evaluated using the Q-tip test and ultrasound (PFS-TV and PFS-TA) [21]. The Q-tip test showed that after surgery, UM decreased in patients with a hypermobile urethra, unlike hypomobile

urethras [22, 23]. The Q-tip test has several drawbacks, including the lack of standardization [22]. The results of studies using ultrasound are inconsistent. In PFS-TV, Lo did not observe any changes in bladder neck mobility [24], while Masata observed a decrease in UM along the entire length of the urethra [25]. In PFU-TA, Masata [8] and Huang [26] found a decrease in the mobility of the entire urethra and bladder neck, while Wen showed a decrease in UM only in the middle part [7].

The TOT sling is often used as an alternative to RT. Studies using PFS-TV suggest different biomechanical properties of slings inserted retropubically and through obturator foramen [17, 27]. It has been shown that to optimize TOT outcomes, it should be implanted at the mid-urethra [17, 28, 29], while RT should be implanted more distally [27]. Therefore, the results concerning RT cannot be automatically transferred to TOT.

The results of studies using PFU-TA concerning changes in bladder neck and urethral mobility after TOT implantation are inconclusive, showing a decrease in UM in the proximal and middle parts without any changes in the distal part and around the bladder neck [21] or a decrease in bladder neck mobility [28, 30]. To the authors' knowledge, there are no studies on changes in UM after TOT implantation using PFS-TV. Additionally, it has not been analyzed whether the changes in mobility are related to preoperative mobility and the location of the sling implantation. Our study suggest that TOT may have different influence on post-operative UM.

An optimal diagnosis of different types of urinary incontinence (UI), including SUI, remains a source of controversy. Differential diagnosis primarily involves medical history, voiding diary, cough test, pad test, urodynamic studies, PFU-TA, and PFS-TV [12, 13].

In our studies, a statistically significant reduction in bladder neck mobility and the VECTOR parameter was observed in both cured and not cured patient groups. Additionally, the location of the sling in the transverse axis of the urethra (TUD parameter) had an effect – in cured patients, the sling was placed closer to the urethra than in not cured patients. This is consistent with reports by Wen and Wlazlak, indicating that the tighter the sling is placed, the lower the risk of urinary incontinence [3, 7]. No statistically significant differences

were confirmed in RTP parameter values between cured and not cured patients. The individualized planning of the suburethral sling implantation site was the reason for the small variation in the obtained TOT implantation sites along the long axis, and the number of study groups was not large.

The reduction in UM was observed in both cured and not cured patients. This parameter seems to be unhelpful in assessing the correct positioning of the sling. Our study results suggest that the impact of the TOT sling on UM may differ in patients with very good and good mobility.

The clinical role of urethral funneling was evaluated in a few studies, showing that it was observed during ultrasound evaluation in 18.6% to 100% of cases [12]. The diversity is probably due to significant differences in ultrasound technique and patient conditions. In the previous two studies, examinations performed with the same technique using PFS-TV in women with full bladders yielded results consistent with our study [12, 13]. Long urethral funneling was observed preoperatively in all patients, while postoperatively, it was observed only in non-cured patients. TOT implantation led to the elimination of urethral funneling in 79.5% of cases, while in 20.5%, short urethral funneling was observed. In cured women with persisted funneling, the length was lower, while width did not differ comparing to preoperative measurements. This raises a question about possible differences in pathophysiology of urethral funneling depending, for example, on urethral intrinsic sphincter efficiency.

Our study has its limitations. The group of women analyzed was relatively small, the observation period was short, and the study was retrospective. The small number of patients had unsatisfactory outcomes in eliminating SUI symptoms compared to surgeries using RT, which led the centers participating in the study to discontinue TOT surgeries in favor of RT implantation. However, surgeries using TOT are still frequently performed in Poland, so expanding knowledge about the mechanisms of sling action is necessary. The limited number of publications using PFU-TA and the lack of analyses using PFS-TV, in our opinion, add value to the study. The surgeries were performed by experienced operators, with individually planned procedures based on the ultrasound-determined urethral length, in patients without previous urogynecological surgeries, and with normomobile and hypermobile urethras. Very clear cure criteria

were applied, without including a group of patients with partial improvement. The comprehensive pre- and postoperative analysis included, among other things, the use of PFS-TV and the assessment of the urethral funneling.

Conclusions

The TOT suburethral tape reduced urethral mobility to a similar extent in cured and not cured women. The effect on UM was noticeable in patients with preoperative hypermobile urethrae. The obtained TOT tape locations did not affect the degree of UM reduction.

Patients in whom the TOT tape was located closer to the hypoechoic zone of the urethra had a greater chance of effective elimination of SUI symptoms.

It was confirmed that the assessment of the urethral funneling during PFS-TV may be useful for confirming SUI and for assessing the effects of SUI treatment after suburethral tape implantation.

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