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CLINICAL ARTICLE

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Tunable tension tape versus transobturator tape in treatment of stress urinary incontinence in women: Randomized controlled trial

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Abstract

Introduction: The synthetic mid-urethral slings are currently considered to be the most widely used technique for the surgical treatment of stress urinary incontinence (SUI). The most challenging aspect of the existing approaches is to achieve the optimal tension of the sling which treatment results are directly dependent on. To solve this problem, sling systems enabling an adjustment of the tension in the early postoperative period were created. A comparative study of the effectiveness and safety of such a system and a nonadjustable sling seems to be a relevant task.

Materials and Methods: A double-blind, randomized, multicenter trial enrolled 320 patients with a mean age of 55.2 ± 11.2 years and confirmed SUI. Patients were randomized into two groups: the first group underwent a standard synthetic suburethral sling (transobturator tape [TOT]) procedure and the second group underwent a tunable tension tape sling (TTT) procedure. All patients underwent stress test, uroflowmetry and ultrasound scan to determine the postvoid residual volume. Urinary Distress Inventory Short Form 6, International Consultation on Incontinence Questionnaire—Short Form, Pelvic Organ Prolapse Incontinence Sexual Questionnaire 12 questionnaires were used to assess subjective efficacy.

Results: Enhancement of prosthesis tension in the second group was required in 44 (28%) patients. Due to the possibility of tightening of the sling in the early postoperative period, the operation was effective in 143 (89%) patients in the adjustable sling group and in 109 (68%) patients in Group 1, $p < 0.001$. Loosening of the sling tension was performed in 25 (16%) patients in Group 2. The signs of obstructive voiding symptoms at the follow-up time of 36 months remained in Group 1 in 13 (8%) patients. Subjective satisfaction with treatment on the PGI-I scale was higher in Group 2: 100 (62%) versus 132 (82%), $p < 0.001$.

CLINICAL TRIAL REGISTRATION: The study was registered at clinicaltrials.gov prior to patients enrollment and given the identifier NCT03958695.

Conclusion: A synthetic mid-urethral TTT is superior to a standard nonadjustable sling in long-term effectiveness and safety.

KEYWORDS
adjustable sling, stress urinary incontinence, suburethral sling, urogynecology

1 | INTRODUCTION

Stress urinary incontinence (SUI) is the most common type of urinary incontinence in women at any age with its prevalence ranging from 4% (20–24 years old) to 12%–35% (over 40 years old).[1]

The synthetic midurethral sling, introduced nearly 30 years ago, is the most widely used technique for surgical treatment of SUI which has rightly become the gold standard. This approach is considered to be an effective treatment in more than 90% of cases. Unfortunately, it is not all that simple. The largest meta-analysis, published in the Cochrane database and including data from 68 clinical trials, showed that short-term effectiveness of the synthetic suburethral sling ranged from 52% to 98%.[2] Another qualitative meta-analysis, which included data from 11 randomized trials and aimed to evaluate long-term effectiveness, showed only a 64% short-term effectiveness.[3] There is a wide range of effectiveness reported and it is not clear why this is.

There is an important aspect of SUI treatment, which both patients and doctors tend to neglect. Not only is it crucial to return to a woman the ability to control the bladder but also to maintain a normal urination. Bladder obstruction is one of the most common postoperative complications after the sling surgery, where the risk of its development is around 6% (2%–33.9%).[4] It is important to consider that some patients do not experience postvoid residual urine, and obstruction in this case is manifested in symptoms such as spraying, splitting, forced body position and straining.[5,6] All these symptoms significantly reduce quality of life and may even result in the inability to use public bathrooms.

The cornerstone of achieving effectiveness as well as reducing the risk of postvoid urine retention is adhering to the tension-free principle included by the founders of this method. The lack of a standardized approach to the implantation technique presents a challenge, and a tension-free result is achieved by leaving a gap between the loops and the urethra, however, the size of this gap is subjective and can vary depending on a surgeon.[7] As a solution to this problem, sling systems were developed enabling an adjustment of the tension in the early postoperative period.[8,9] This procedure demonstrated good results in the treatment of complicated forms of urinary incontinence. However, at present, there are no qualitative studies aimed at evaluating the effectiveness, safety, and feasibility of using adjustable suburethral slings. There is not an unequivocal position on this matter among the scientific community, which makes this study relevant.

Aim: The aim of this study was to test the hypothesis that a transobturator midurethral sling with the ability to adjust the tension in the early postoperative period is a safer and more effective method for correction of uncomplicated SUI in women compared to the loop placed in accordance with the standard transobturator technique.

2 | MATERIALS AND METHODS

2.1 | Endoprosthesis

In this research, the use of the endoprosthesis in the form of a ribbon (1.1 × 45 cm) made from monofilament polypropylene and polyvinylidene fluoride threads was observed (UroSling, Lintex). Tunable tension tape (TTT) technology was applied to the implant using two pairs of adjustment loops; traction over the external adjustment loops ensures an increase in the tension of the implant, while internal loops decrease the tension. The colored marks are designed to accurately identify correspondence of external and internal adjustment loops to the traction direction (Figure 1).

2.2 | Inclusion criteria and randomization

A double-blind, randomized, multicenter study includes women diagnosed with SUI. Inclusion criteria were a positive standardized stress test (ICS-UCST)[10] in two positions, unsuccessful conservative therapy in the previous 6 months and completed informed consent. Exclusion criteria were comprised of complaints on urinary urgency, prolapse stage II, and higher according to POP-Q classification, earlier SUI-related surgeries and obturator muscles pain during palpation performed in the gynecological chair (Figure 2). The rest of the patients were assigned into two groups using block randomization method with stratification: the first group

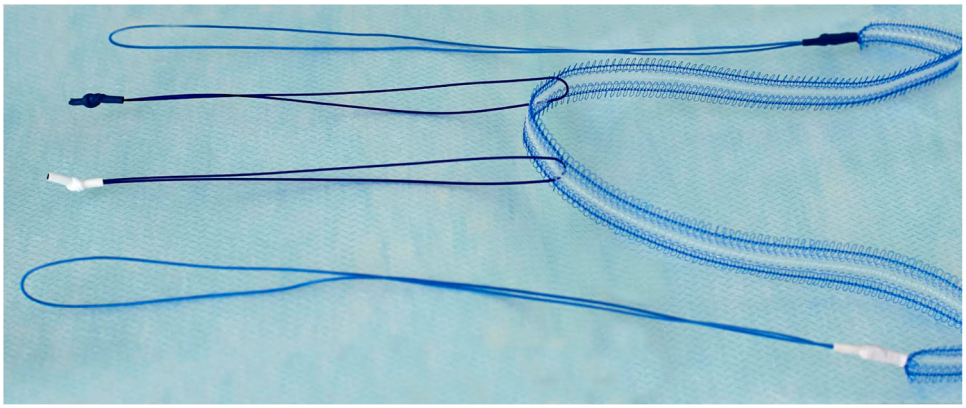

FIGURE 1 Appearance of the endoprosthesis. The colored marks on the adjustment loops correspond to the specific side of the traction.

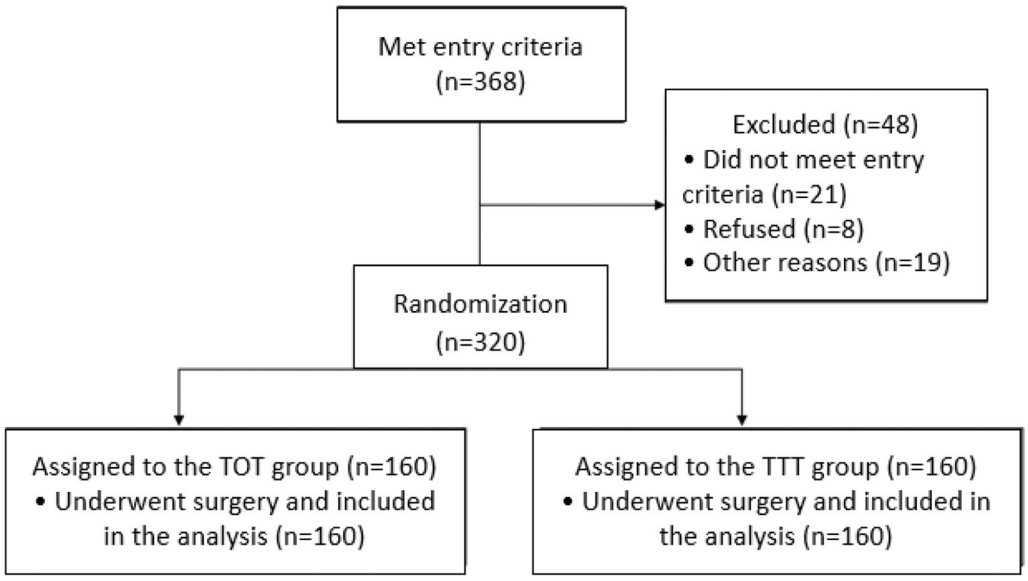

FIGURE 2 Patients disposition flow diagram.

of patients underwent a classic synthetic suburethral sling procedure using a standard inside-out transobturator tape (TOT) approach, whereas the second group—suburethral tuneable tension tape (TTT).

2.3 | Surgery procedure

All operations were performed by surgeons who perform at least 200 such operations per year in two clinical centers. The procedure included access to the middle-third urethra in the projection, dissection of the paravaginal tissues in the direction of the obturator foramen followed by the trocar insertion using the "inside-out" technique and positioning the tension-free sling.

The surgeon was not aware about the group, which the patient was assigned to, until the sling placement was performed and wound closure. The adjustable sling that is used in this study has two adjustable loops in the middle unlike a standard sling. Sling implantation method does not differ from the implantation of a standard sling except for the ends of the tape and adjustable loops are left or removed after surgery. In case of the TOT group, the surgeon cut the ends of the tape and adjustable loops excluding the possibility of adjustment in the postoperative period. In the TTT group, the ends of the tape were not cut but fixed under the sterile patch (Figure 3).

2.4 | Follow-up

The day following surgery as well as after every other follow-up examination, all women underwent uroflowmetry and ultrasonography to measure postvoid residual

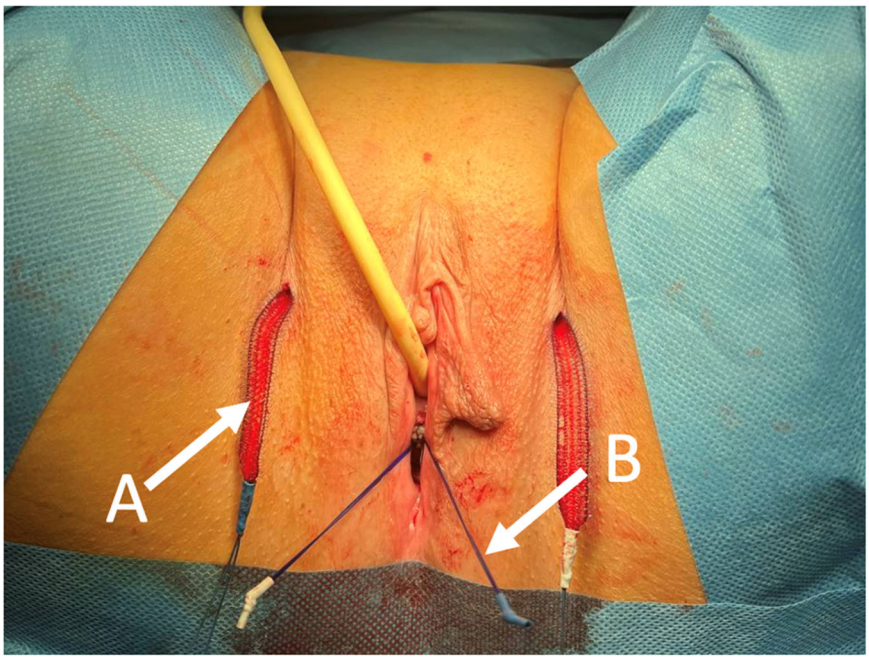

FIGURE 3 Positioning of the tunable tension tape after implantation: A—external adjustment loops; B—internal adjustment loops. The internal adjustment loops are immersed in the vagina, the outer loops are placed under the sterile patch.

urinary volume at least two times during first 2 days after surgery. In the early postoperative period, patients in the TOT group were offered to perform intermittent self-catheterization until obstruction resolved provided there were some obstruction symptoms (decrease in the peak flow >15 mL/s and/or postvoid residual was >50 mL, obstruction according to Liverpool and Siroky nomograms, position-dependent voiding and straining). In the TTT group, in case there were any obstruction symptoms patients underwent noninvasive loosening of the tape under local anesthesia. This sequence of procedures consisting of uroflowmetry, measurement of postvoid residual urine volume and adjustment was repeated until normal urination indicators were achieved.

The day following surgery as well as after every other follow-up examination women in both groups were assessed using an ICS-UCST test in two positions (standing and sitting in a gynecological chair). The results in the TOT group were only recorded while in the TTT group provided the cough stress test was positive women underwent noninvasive tightening of the tape under local anesthesia (Sol. Lidocaine 1%, infiltration anesthesia in the area of skin wounds) followed by another uroflowmetry and postvoid residual urinary volume measurement. The adjustment was performed until the best result was achieved by subjective (easy and normal urination) and objective evaluation methods (stress test, uroflowmetry, and ultrasonography). At least two more follow-up examinations were carried out once the results were satisfying. In case another adjustment was required at least two more follow-up examinations were performed until the desired result was achieved. On the day of patient's discharge (2nd day of the post-operative period), the adjustment loops and sling ends were removed. It is important to mention that a patient from the TTT group will be staying in the hospital until a required effect is achieved and adjustable ends are removed.

Follow-up examinations were performed at intervals 1, 12, 24, and 36 months after surgery. To assess subjective symptoms, patients filled out the following questionnaires UDI-6 (Urinary Distress Inventory Short Form 6), ICIQ-SF (International Consultation on Incontinence Questionnaire—Short Form), PISQ-12 (Pelvic Organ Prolapse Incontinence Sexual Questionnaire 12).

All patients were asked to use visual analogue scale (VAS) to rate pain three times: first day after surgery, immediately after implant adjustment (the group where it was applicable) and on the day of patient's discharge.

Patients completed the PGI-I scale after 36 months of being monitored. Response 1 and 2 was considered criteria for clinical subjective improvement.

2.5 | Sample size calculation

The hypothesis is that TTT is noninferior to TOT for SUI treatment. Sample size was calculated assuming TOT effectiveness rate of 85%, and 10% difference in effectiveness with 80% power was considered as clinically significant. Drop-out rate of 15% within 3 years was taken into consideration while planning this study. Thus, 320 women with SUI or urodynamic mixed urinary

incontinence with predominate SUI meeting inclusion and exclusion criteria are planned to be included in the study.

2.6 | Statistics

Categorical variables are expressed as absolute numbers and percentage. Quantitative variables are expressed as median and interquartile range. Pearson's chi-square Test or Fisher's exact test (in the event of deviation from the expected values) were used for comparison of these variables. Nonparametric unpaired Mann–Whitney rank test was used to analyze quantitative variables and paired Wilcoxon rank test was used to assess change dynamics in each group. A $p < 0.05$ was considered statistically significant. All calculations were performed using R 4.2.1 programming language software in the interactive RStudio environment. For block randomization "blockrand" package was used. Randomization was performed by a researcher, who was blinded about patients' data.

3 | RESULTS

A total of 320 participants with SUI were included in this study (Table 1). Patients in both groups were comparable in terms of baseline characteristics before treatment.

Intraoperative data such as surgery duration, blood loss, and number of intraoperative complications were compared in both groups (Table 2).

TABLE 1 Baseline demographic characteristics of patients.

Characteristic	TOT, $N = 160$	TTT, $N = 160$	p Value
Age	56 (46, 64)	56 (46, 62)	0.9
Pregnancies	4 (3, 5)	4 (2, 5)	0.5
Vaginal delivery	2 (1, 2)	2 (1, 2)	0.053
Abortion/miscarriage	2 (1, 3)	2 (1, 3)	0.3
Body mass index	28 (25, 31)	27 (24, 31)	0.3
UDI-6 points before surgery	42 (33, 62)	42 (30, 54)	0.3
PISQ-12 before surgery	23 (0, 33)	24 (0, 32)	0.6
ISIQ-SF before surgery	14 (10, 18)	13 (10, 16)	0.4
Peak flow, mL/s	37 (29, 46)	35 (28, 44)	0.4
Average flow, mL/s	20 (15, 26)	19 (14, 25)	0.6

Abbreviations: PISQ-12, Pelvic Organ Prolapse Incontinence Sexual Questionnaire 12; TOT, transobturator tape; TTT, tunable tension tape; UDI-6, Urinary Distress Inventory Short Form 6.

TABLE 2 Intraoperative and early postoperative data.

Characteristic	TOT, $N = 160$	TTT, $N = 160$	p Value
Surgery duration, minutes	15 (15, 20)	15 (15, 20)	>0.9
Blood loss, mL	15 (10, 20)	15 (10, 20)	>0.9
VAS points after surgery	3.00 (2.00, 3.00)	3.00 (2.00, 3.00)	0.8
Obstruction flow	29 (18%)	25 (16%)	0.6
Positive stress test, 1 day after surgery	42 (26%)	44 (28%)	0.8
Urinary tract infection	4 (2.5%)	6 (3.8%)	0.5
Vaginal wall, bladder injury	0	0	>0.9
Wound infection	0	0	>0.9

Abbreviations: TOT, transobturator tape; TTT, tunable tension tape; VAS, visual analogue scale.

Obstruction flow symptoms in the first 24-h after surgery and until tightening adjustment of the tape was observed in 29 (18%) participants in the TOT group and 25 (16%) participants in the TTT group ($p = 0.6$). It should be noted that nine patients in Group 1 performed self-catheterization due to a large postvoid residual volume (≥100 mL), the remaining 20 patients complained only about difficulties with urination. Women in the TTT group underwent the procedure of loosening of the tape using the above-described technique: postvoid residual volume of more than 100 mL was observed in four women and 21 women complained about urinary obstruction. Adjustment of tightening of the tape in the second group ensured satisfactory urodynamic characteristics, normalization of urination process and absence of postvoid residual urine in all patients who earlier had obstruction flow symptoms. Enhancement of the prosthesis tightening in the early postoperative period (first 24-h after surgery) was required in 44 (28%) patients in the TTT group where leakage of urine was observed. It is worthwhile mentioning that in 11 women leakage of urine was observed in the upright position. On the second day of the operation, seven (4%) patients in the TTT group underwent readjustment of tightening of the suburethral sling: enhancement of tightening in six (4%) cases and loosening in one (0.6%). VAS points in the first postoperative hours were 3 (2, 3) in the TOT group and 3 (2, 3) in the TTT group with $p = 0.8$. Pain syndrome was rated at 1 (1, 1) and 1 (0, 2) point in the TOT and TTT groups, respectively, ($p = 0.5$) on the day of patient's discharge. In the process of the implant adjustment, intensity of pain syndrome was rated at 3 (2, 4) points in the TTT group (Table 2).

One month after surgery, significant obstruction flow was present in four (2%) patients in the nonadjustable sling group and further sling dissection was required. Despite not having postvoid residual urine, 15 (9%) patients still experienced moderate obstruction flow symptoms (position-dependent voiding and straining), which had a negative impact on their quality of life. In the TTT group, three (2%) patients reported spraying.

Cough stress test was positive in 44 (28%) patients in the TOT group and nine (5.6%) patients in the TTT group. The difference was statistically significant—$p < 0.001$. After 12 months, these indicators were 49 (31%) and 13 (8.1%) respectively, ($p < 0.001$). A total of 13 (8%) patients in the TOT group continued to report feeling discomfort while voiding (position-dependent voiding, straining, and spraying). At a period of 36 months, surgery was objectively ineffective in 52 (32%) patients in the TOT group and 17 (11%) patients in the TTT group ($p < 0.001$). Obstruction flow symptoms remained in 13 (8%) patients in the TOT group. Dynamic of stress test changes from surgery to the primary endpoint (36 months) is demonstrated in Figure 4.

Results of the questionnaires aimed to evaluate subjective effectiveness 1 month after surgery were the following: UDI-6—13 (0, 21) points in the TOT group versus 13 (0, 21) points in the TTT group ($p = 0.4$), ICIQ-SF—(0 (0, 3) points in the TOT group versus 0 (0, 4) points in the TTT group ($p > 0.9$). These results showed a decrease in relation to the baseline indicators, however, no statistically significant differences between groups were found.

Urodynamic parameters such as volume voiding (350 [276, 474] vs. 345 [245, 484], $p = 0.4$), peak flow (33 [25, 41] vs. 31 [25, 39], $p = 0.4$) and postvoid residual volume (0 [0, 0] vs. 0 [0, 0], $p = 0.10$) in the TOT and TTT groups respectively did not show a statistically significant difference in the first month. Even though urinary obstruction was observed more often in the TOT group, robust statistics such as median and interquartile range, used for urodynamic parameters description, did not show any significant changes up until the follow-up examination of 36 months.

At the follow-up time of 36 months objective data was received from 138 (86%) patients in the TOT group and 132 (82.5%) patients in the TTT group. A total of 22 (14%)

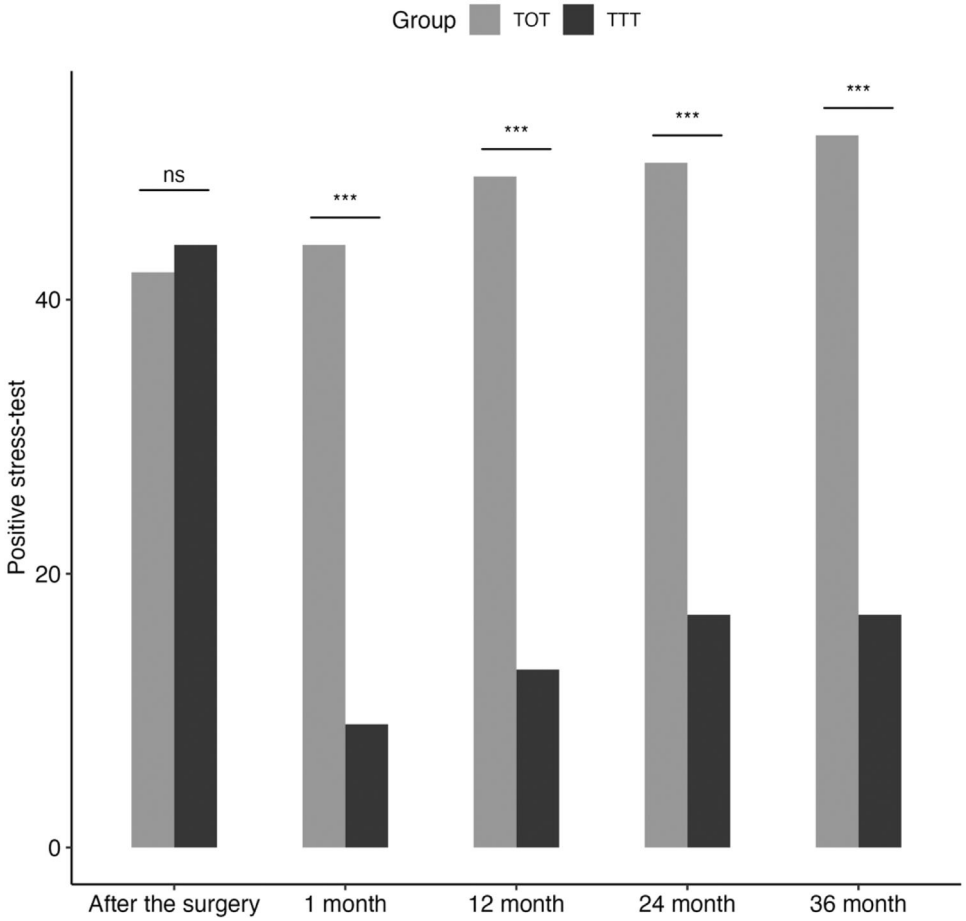

FIGURE 4 Stress-test changes. ns, nonsignificant. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

TABLE 3 Follow-up results.

Characteristic	TOT, $N = 160$	TTT, $N = 160$	p Value
Positive stress-test	52 (32%)	17 (11%)	**<0.001**
Obstructive voiding symptoms	13 (8%)	0	**<0.001**
UDI-6 points, 36 months	0 (0, 0)	0 (0, 0)	0.7
PISQ-12 points, 36 months	26 (14, 36)	30 (0, 36)	>0.9
ICIQ-SF points, 36 months	2 (0, 3)	1 (0, 3)	0.6
PGI-I points, 36 months			**0.003**
1	86 (54%)	114 (71%)	
2	14 (8.8%)	18 (11%)	
3	27 (17%)	14 (8.8%)	
4	25 (16%)	10 (6.2%)	
5	8 (5.0%)	4 (2.5%)	
Postvoiding residual, 36 month	0 (0, 0)	0 (0, 0)	0.4
Peak flow, 36 month	33 (26, 41)	31 (25, 39)	0.4
Average flow, 36 month	19 (14, 24)	18 (14, 24)	0.5

Note: Bold values indicate $p < 0.05$.

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire—Short Form; PISQ-12, Pelvic Organ Prolapse Incontinence Sexual Questionnaire 12; TOT, transobturator tape; TTT, tunable tension tape; UDI-6, Urinary Distress Inventory Short Form 6.

patients in the TOT group and 28 (17.5%) patients in the TTT group could not come in for the examination due to personal reasons. These patients provided information over the phone and by filling out questionnaires. Final examination results are presented in Table 3. Overall satisfaction with treatment according to the PGI-I scale was 100 (62%) in the TOT group and 132 (82%) in the TTT group, $p < 0.001$. Moreover, the median was 1 (1, 3) and 1 (1, 2) in the TOT and TTT groups, respectively, $p < 0.001$. There were no cases of implant erosion, chronic pelvic pain, nor wound infections during the follow-up period.

4 | DISCUSSION

The synthetic midurethral sling is a well-studied and effective treatment technique for SUI. According to the available studies, short-term effectiveness of this treatment method is observed in almost 98% of cases; however, minimum cure rates do not exceed 52%. On the other hand, the most common postoperative complication is urinary obstruction. Blaivas JG and co-authors found that out of 8287 cases of suburethral sling treatment urinary obstruction was developed in 5.9% (0%–33.9%) cases,[4] moreover, 2.3% (0%–21.3%) of those patients required surgical intervention. This data corresponds to our findings where the operation was initially effective only in 72%–74% of cases regardless of implantation method. At the same time, urinary obstruction after surgery was observed in every fifth case.

One of the most important factors in effectiveness of the suburethral sling is a degree of its tension. According to survey results, more than 80% of surgeons assume that sling tension plays a major role in the procedure.[11] Unfortunately, there are no clear guidelines how to achieve a required loop tension since none of the above-mentioned methods is reliable. It is worth to take into consideration that in addition to risk factors in patients, surgeon's experience has a direct impact on effectiveness and number of complications.[12] As a solution to the tension problem, suburethral slings enabling an adjustment of the tension in the postoperative period were suggested (REMEEX, TVA, TOA, SAFYRE, UroSling). According to the studies, adjustment frequency ranged between 27.3% and 46.8% and short-term effectiveness was 84.4%–93.7%.[9,13–16] It should be noted that the above-described systems were used mostly in patients with more complex SUI (hypomobile urethra, Intrinsic urethral sphincter deficiency, etc.). At the same time, patients with standard SUI underwent considerable amount of adjustments as well.[9] Within our study, 43.6% patients required tension adjustment.

The midurethral TTT in comparison with other methods is reported to be a more effective treatment for postoperative complications and reduces the risk of SUI recurrence.[17] Moreover, the studies showed that from 10% to 18% of patients experience «latent» obstruction after sling placement characterized by obstructive voiding symptoms excluding postvoid residual urination.[5,6,18] Using the midurethral TTT in the early postoperative period may reduce the risk of developing urinary obstruction, further interventions and also enhance effectiveness of surgical treatment of SUI. In our study, most of the women with voiding disfunction (12.8%) complained about obstructive voiding symptoms specifically. Unfortunately, most of them continued having the above-mentioned complaints even at a later point of observation. At the same time, tension adjustment allowed to resolve urinary obstruction symptoms beside no complications were observed.

Sling adjustment process may cause local discomfort. To prevent pain local anesthesia may be used, any allergies should be reviewed before. In the day of discharge from the hospital, patients in both groups

equally reported no postsurgery pain or discomfort. The same results were obtained in the case study by Palma and co-authors.[16]

It should be noted that the desired effect was achieved in all patients in the TTT group within 2 days of postoperative period. However, in case further adjustment is required, hospitalization would be extended. This could be a limiting factor for using TTT.

Once the adjustable sling is implanted using TTT technology its ends, passed out of the incision, are left uncut under a sterile patch until the day of discharge, which could increase the risk of developing wound infection. The slings used in our study are made of bionert materials wicking free. The use of adjustable loop does not seem to increase infection risk based on the findings of this study.

5 | STRENGTHS AND LIMITATIONS

This study that aims to assess effectiveness and safety of adjustable slings in comparison with standard nonadjustable slings is unique for its value to the scientific committee. Some important aspects of the study should be mentioned. First, all operations were performed by pelvic floor specialists/urologists in a medical reference center which provides services to a great number of patients with this kind of dysfunction, which may make it challenging to reproduce results obtained in other hospitals. In addition, only TOT was assessed while effectiveness of retropubic sling technique was not included in the study design.

6 | CONCLUSION

The synthetic midurethral TTT is superior to the standard nonadjustable synthetic suburethral sling in long-term effectiveness. Moreover, it reduces the risk of postoperative obstruction, which enhances treatment safety and results satisfaction among patients with SUI.

AUTHOR CONTRIBUTIONS

Nikita Kubin: Development of the research concept; review of publications on the topic of the article; collection of material; writing and editing of the text. **Rustam Shakhaliev**: Research concept development and design; review of publications on the topic of the article; text writing and editing. **Ivan Labetov**: Review of publications on the topic of the article; writing and editing the text; statistical analysis of the data and their interpretation. **Gleb Kovalev**: Review of publications on the topic of the article; text writing and editing. **Andrei Shulgin**: Research concept development and design; text editing; review of publications on the topic of the article. **Alexey Nuriev**: Material collection; review of publications on the topic of the article. **Dmitry Shkarupa**: Research concept development and design; text editing; final publication approval.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study was approved by the local independent ethics committee of the Saint-Petersburg State University Hospital n.a. N.I.Pirogov, no. 05/20 dated 05/21/2020. All materials used in this article are original and do not require any special permission. Written informed consent was obtained from the patients.

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