Does the suburethral sling change its location?

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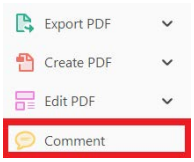

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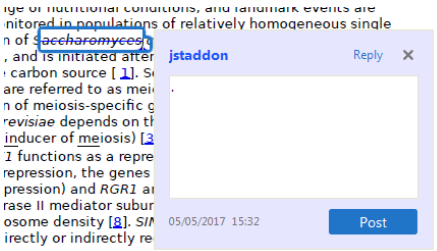

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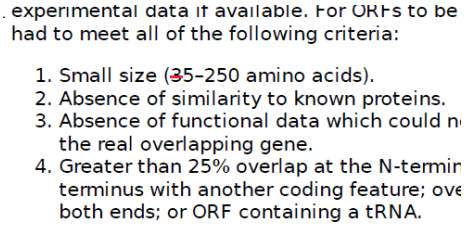

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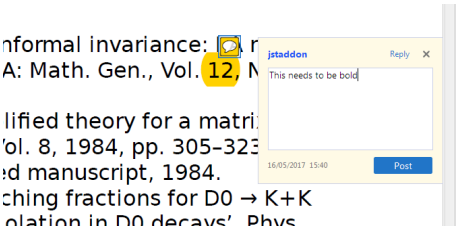

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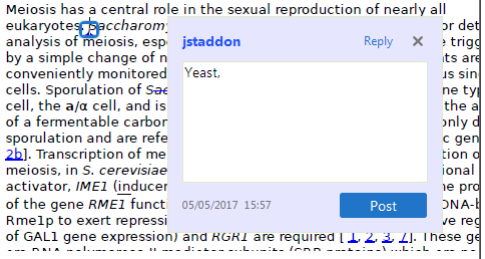

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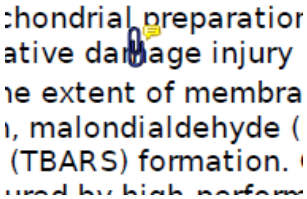

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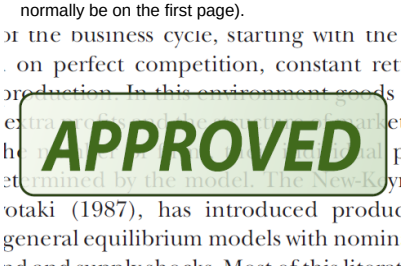

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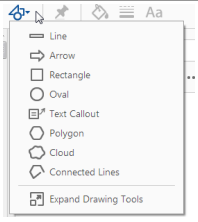

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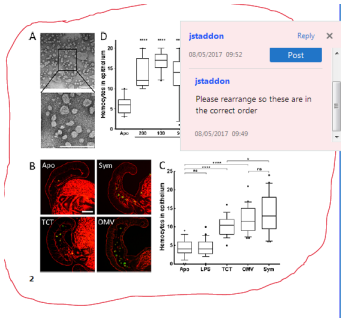

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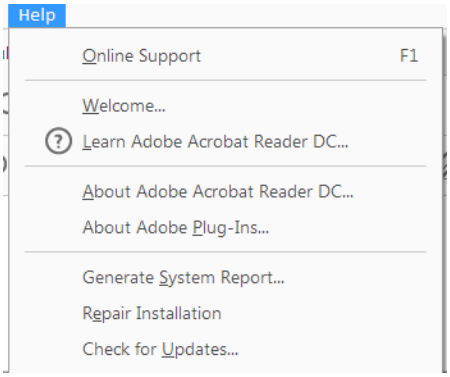

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Original Article

Does the suburethral sling change its location?

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Abbreviations & Acronyms
BMI = body mass index
SUI = stress urinary incontinence
TOT = ??????
TVT = ??????

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Objectives: To ascertain whether a phenomenon of sling migration exists after suburethral sling placement, whether this might be responsible for suboptimal sling location and persistent incontinence, and whether a link exists between sling dislocation or migration and risk factors, such as obesity or age.

Methods: The present prospective cohort study was carried out in a group of 244 patients who underwent retropubic sling implantation. Sling location was determined by means of pelvic floor ultrasound, and calculated relative to the individual patient's urethral length measured before the procedure. The sling location was visualized on 1 day, and 1 and 6 months post-surgery. Overweight/obese and elderly patients were analyzed separately to assess the possible influence of those factors on sling location.

Results: The mean urethral length in the studied cohort was 28.76 ± 3.67 mm. The mean tape position 1 day post-surgery was 66.18 ± 8.43% of the urethral length, and it did not change 1 and 6 months post-surgery in the whole group. Similar results were obtained in elderly and overweight/obese patients.

Conclusions: Suboptimal sling location appears to result from incorrect surgical technique, and should be diagnosed and treated early after the primary surgery. Sling location does not change after mid-term follow up.

Key words: complications, operative surgical procedures, stress urinary incontinence, suburethral slings, ultrasound.

Introduction

SUI is defined as loss of urine on effort or exertion.[1] SUI deteriorates the quality of life, as well as sexual and social functioning.[2]

Suburethral slings were first introduced by Petros and Ulmsten 30 years ago. The surgery was based on animal studies where a tape inserted beneath the midurethra created an artificial structure to reinforce the pubourethral ligament.[3] The principle of the technique was based on implantation of the sling in the area of the urethra's high-pressure zone, as the authors observed that such location provides the best treatment results. The high-pressure zone extends between the point of the maximum urethral closure pressure and the urethral knee. It was estimated that it is located in 50% and 75% of the urethral length. According to the Ulmsten and Petros technique that applies to all suburethral sling modalities, the vaginal incision should extend from 1 cm beneath the external orifice of the urethra to provide optimal sling location.[4]

It was shown that proximal (too close to the bladder neck) location of the sling is associated with persistent or recurrent SUI.[5,6] It is related to the lack of midurethral support on exertion. The length of the urethra described in anatomy textbooks is approximately 3–5 cm.[7]

Consequently, it was suggested that surgery modification based on the individual vaginal incision, dependent on the measurement of the urethral length to reassure the optimal sling location, provides better results as far as an objective cure rate is considered.[8,9]

There has been an ongoing discussion regarding the question whether suboptimal sling location is dependent on primary incorrect implantation or rather connected with translocation of the sling. Some authors suggest that shifts in the position of the sling relative to the bladder neck are caused by sling migration.[10]

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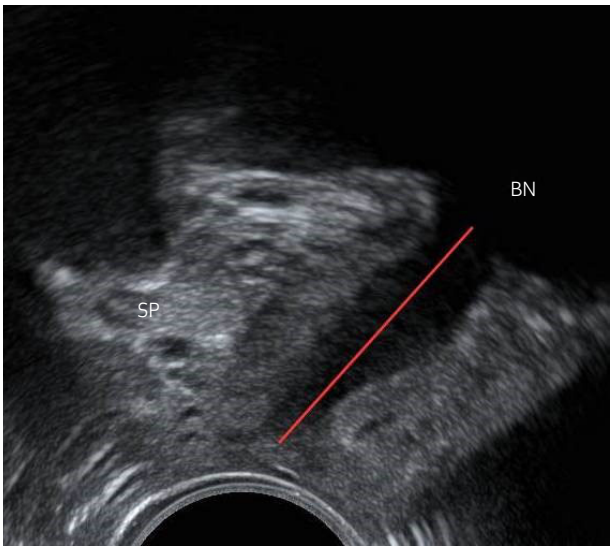

6 12 **Fig. 1** BN, bladder neck; SP, symphysis pubis.

The question of obesity and age as risk factors for recurrent or persistent SUI has also been widely discussed.[11–14] It is postulated that the lower efficacy of suburethral slings in overweight/obese patients might be connected with higher intra-abdominal pressure and poor pelvic floor function. Similar mechanisms are discussed in elderly patients who have worse connective tissue.

The aim of the study was to ascertain whether a phenomenon of sling migration exists after the surgery and might be responsible for suboptimal sling location, as well as whether there is a possible link between shifts in tape location or migration with obesity or age.

Methods

The present prospective cohort study was carried out between 2013 and 2016 in the 1st Department of Obstetrics and Gynecology of Medical University of Warsaw in Warsaw, Polan. All consecutive patients who underwent SUI surgery with retropubic sling (TVT Blue, Gynecare, •••, •••) were enrolled 5 in the study (n = 244). The inclusion criteria were SUI and consent for surgery. The procedure was carried out in a standard manner with minimal dissection as described by Ulmsten, by five surgeons under general anesthesia.[4] An intraoperative cough test was carried out in all cases.

Pelvic floor ultrasound was carried out in a standardized manner, with the patient in a semi-sitting position with the bladder filled to 300 mL. The probe (a 3.6- to 8.3-MHz vaginal transducer) was placed in the vaginal introitus at the level of the external urethral orifice. With the probe in this position, the bladder, urethra, suburethral vagina and pubic symphysis were visualized in the median sagittal plane, according to Interdisciplinary S2k Guideline: Sonography in Urogynecology.[15]

The following parameters were assessed:

1. Length of the hypoechogenic core of the urethra before the surgery (Fig. 1).

C - LOW RESOLUTION FIG

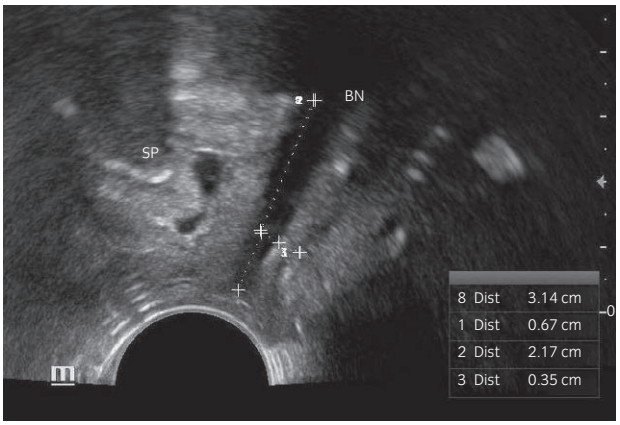

Fig. 2 Xxxxxxx. 13

2. Sling location in relation to the urethral length (%) measured as the distance from the bladder neck to the middle part of the sling (Fig. 2).

The ultrasound examination was carried out before the surgery (urethral length), 1 day after the surgery, and 1 and 6 months after the surgery (tape location). The place of the vaginal incision was adapted to the urethral length according to the one-third rule:[8] The sonographic length of the urethra 7 was measured, the result was divided by three and thus the exact site of vaginal incision was defined. The effectiveness of the procedure was checked 6 months post-surgery. Success was defined as a negative cough test and a negative 1-h pad test (≤2 g).

The protocol for the research project was approved by the ethics committee of Medical University of Warsaw and it conforms to the Declaration of Helsinki.

Descriptive statistical analysis expressing the quantitative variables, such as the mean (standard deviation), and categorical, such as percentages and frequencies, were carried out using Statistica version 12. The association between the 8 degree and type of non-adherence using the Student's t-test and variance analysis (ANOVA) with the quantitative variables were assessed. A value of $P \leq 0.01$ was considered statistically significant.

Results

A total of 244 patients were enrolled. Of these, 220 accomplished 6-month follow up. A total of 24 patients were lost to follow up (10%). The mean age of the women was 58.50 ± 10.65 years. The mean BMI was 27.35 ± 4.18. Among 244 patients, 174 were overweight or obese (as defined by the World Health Organization: overweight BMI >25, obese BMI >30) and 35 of them were aged >70 years (we established an age cut-off of 70 years, as those patients are usually considered by specialist boards as requiring geriatric care).

The mean BMI in overweight/obese patients was 29.21 ± 3.4. The mean age in the group of elderly patients was 75.34 ± 4.13 years. The urethral length distribution was normal: 28.76 ± 3.67 mm (minimum 19.50, maximum 39 mm; Fig. 3).

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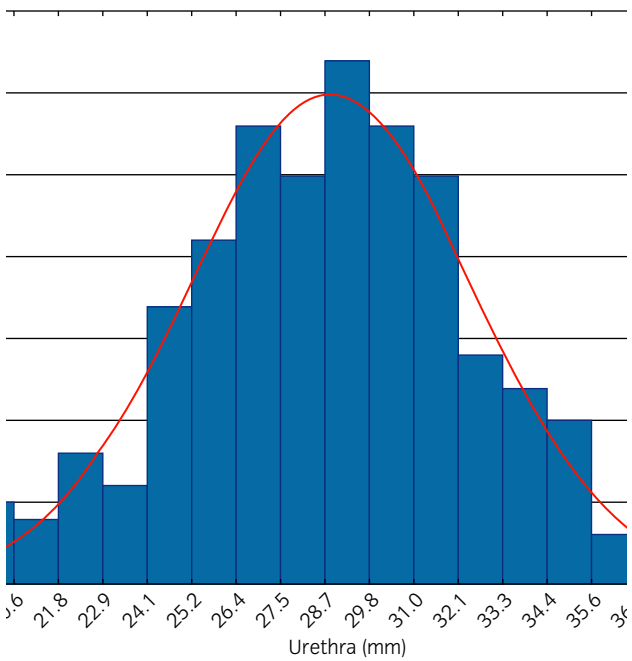


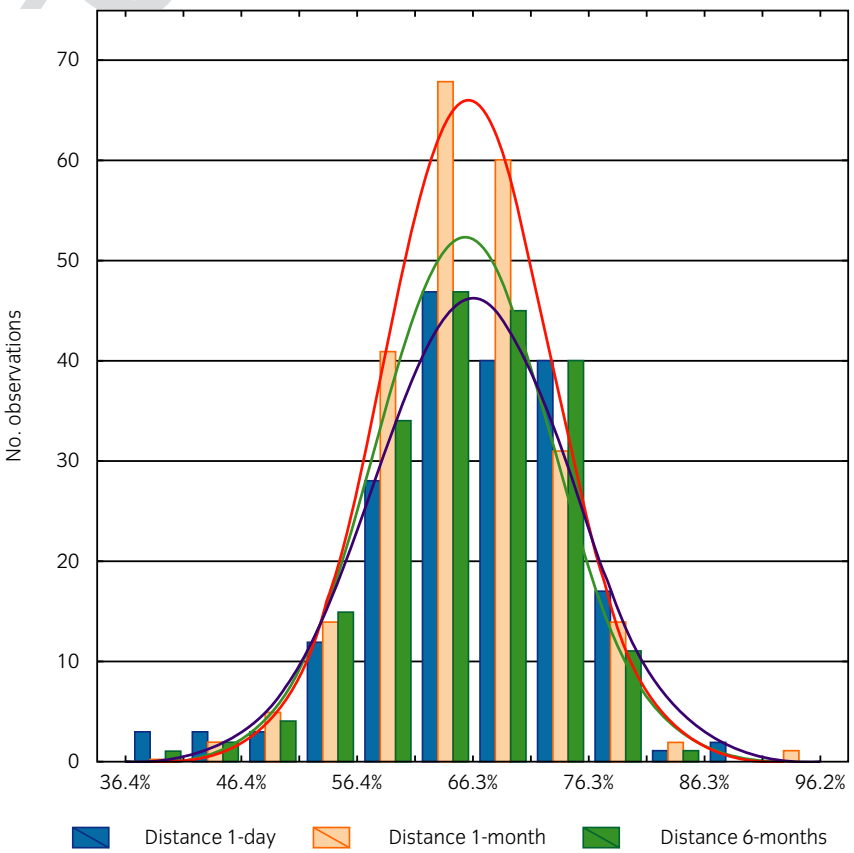
Fig. 3 Xxxxxxx.

The mean location of the sling in the cohort group was 66.18 ± 8.43% of the urethral length on the first day post-surgery. The sling location did not shift 1 and 6 months post-surgery (65.81 ± 7.23% and 65.50 ± 7.23%, respectively). The sling location distribution in relation to urethral length was normal the first day, as well as 1 and 6 months later (Fig. 4).

The distance from the bladder neck to the middle part of the sling also did not change as assessed in absolute numbers (shown in mm form the bladder neck; Figs 5,6,7).

In the group of obese patients, the mean sling location was 66.55 ± 7.53% of the urethral length 1 day after the procedure, and did not change after 1 and 6 months post-surgery (65.98 ± 6.71% and 65.87 ± 7.43% of urethral length, respectively). Similar results were obtained in the elderly patients (62.37 ± 9.97% 1 day after the surgery, 63.67 ± 6.83% 1 month and 62.85 ± 7.08% of urethral length 6 months after the procedure). We noticed subtle changes in the sling location within individual patients during the observation period. None of them were statistically significant. The changes were associated with ultrasound measurement method error. An error of 1–1.5 mm in sling position estimation is acceptable in the described method, as it does not influence the overall result.

The cure rates in the whole group as well as in the elderly and overweight/obese groups are summarized in Table 1. We did not obtain significant differences in cure rates between the examined patients. Patients with negative (≤2 g) 1-h pad test and cough test carried out 6 months after surgery were considered cured. All the patients noticed a cure or improvement of SUI symptoms. None of the patients had an ineffective sling.



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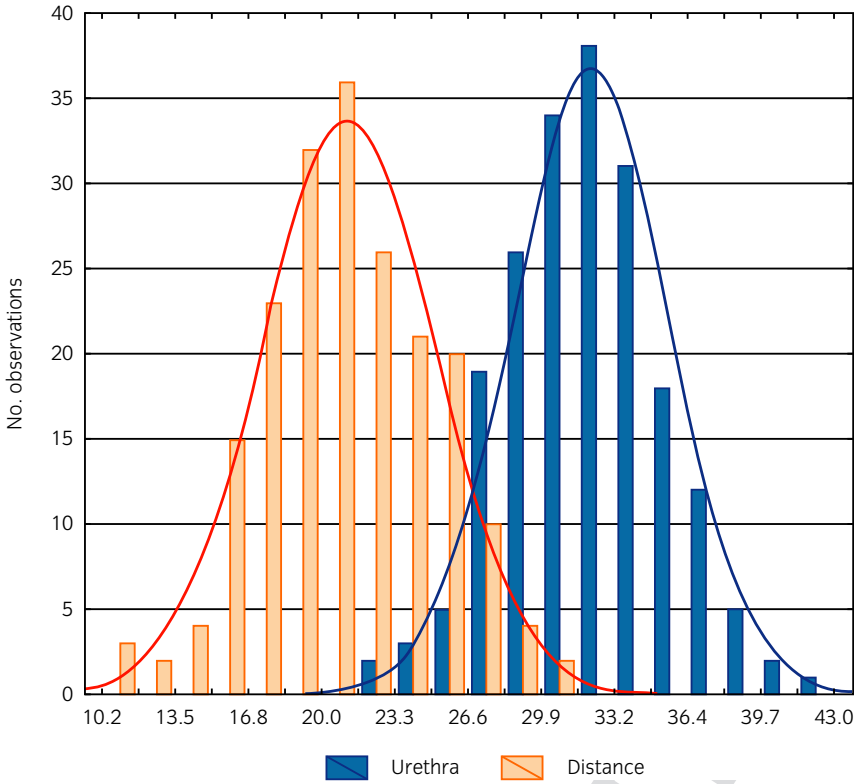

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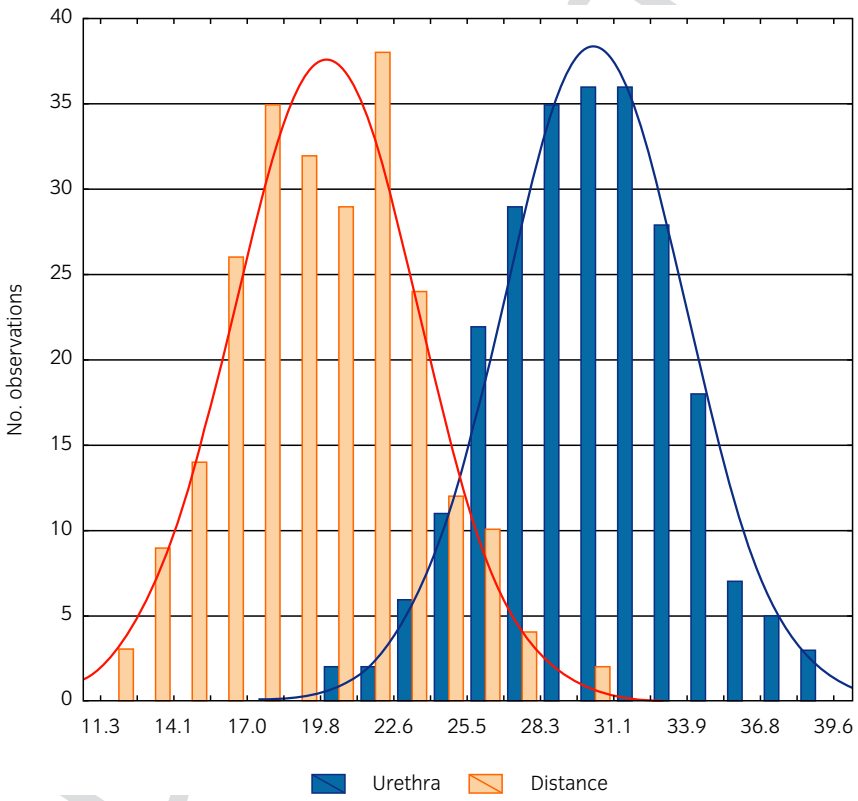

Fig. 6 Xxxxxxx.

Adverse events included two cases of bladder perforation during the surgery, five cases of overactive bladder syndrome (three in the overweight/obese group), as well as four cases of recurrent lower urinary tract infections (all in the overweight/obese group).

Discussion

Sling procedures are currently the gold standard of SUI treatment. The objective overall cure rate is high and satisfactory. In a meta-analysis published in 2017, it was shown that both

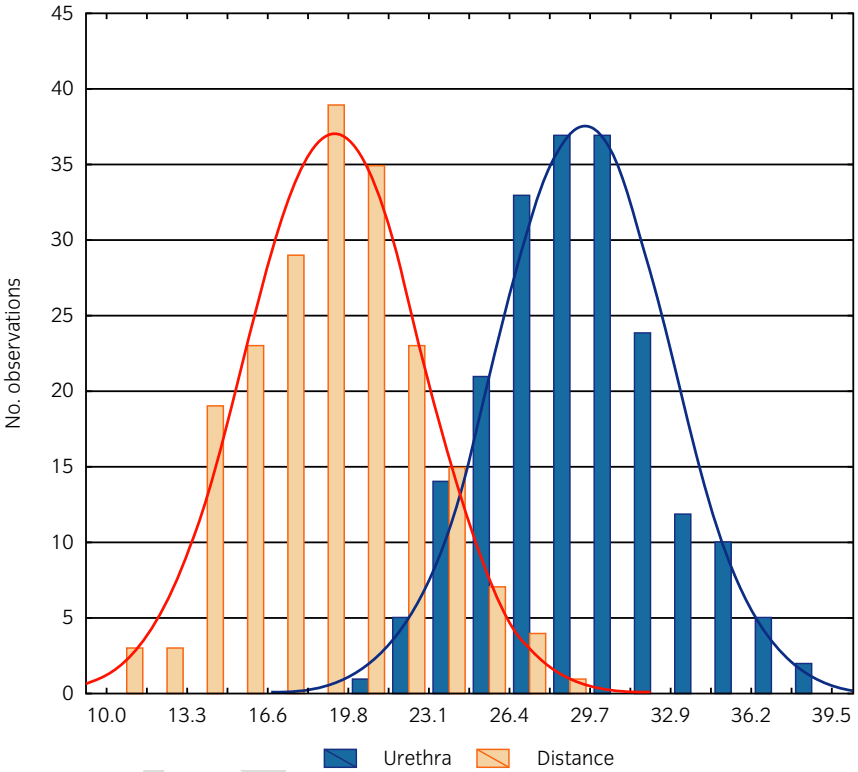

Fig. 7 Xxxxxxx.

Table 1 Mean results of 1-h pad test and percentage of negative (≤2 g) cough test and 1-h pad test before and 6 months post-surgery

Group	All patients (n = 240)	Overweight/obese patients (n = 174)	Elderly patients (n = 35)	Statistical significance
Mean 1-h pad test before surgery (g)	90.6 ± 82.8	90.28 ± 82	111.7 ± 91.7	NS
Mean 1-h pad test 6 months after the surgery (g)	1.2 ± 7.8	1.77 ± 9.7	5.58 ± 20.6	NS
Percentage of negative (≤2 g) cough test and 1-h pad test 6 months after the surgery	93.9	88.5	91.4	NS

Data are given as g/% ± SD.

techniques of sling implantation – retropubic and transobturator – are similarly effective. Objective and subjective cumulative cure rates for TVT and TOT were 61.6% (95% CI 58.5–64.8) and 76.5% (95% CI 73.8–79.2), and 64.4% (95% CI 61.4–67.4) and 81.3% (95% CI 78.9–83.7), respectively.[16]

The authors of a Cochrane analysis showed that there is evidence that at up to 1-year observation the rate of subjective cure of TOT and TVT is high and similar (RR 0.98, 95% CI 0.96, 1.00; 36 trials, 5514 women; moderate quality evidence) ranging from 62% to 98% in the TOT group, and from 71% to 97% in the TVT group.[17]

Nevertheless, certain patients suffer from recurrent or persistent SUI after the surgery. Currently, when ultrasound is a promising tool in the diagnosis of sling complications, it has been shown that most of the complications are connected with suboptimal sling location, and can be visualized using a short, easy and cheap imaging modality – pelvic floor ultrasonography. In our previous work, we showed that sling position too proximal to the bladder neck is often connected with persistent SUI.[5] Similar results were published by other authors using different ultrasound techniques.[6,18]

As the proximal sling position seems to be suboptimal for the best clinical results, there is an ongoing discussion regarding whether the proximal location of the sling is connected with tape "migration" or caused by primary incorrect location. It is extremely important from the clinical point of view. Assuming that the tape location is stable, it is obvious that the proximal position of the sling is connected with inappropriate technique and should be diagnosed immediately after the procedure.

The present study for the first time shows a stable sling location in the mid-term observation after the TVT procedure. We also determined that the sling does not shift its position depending on the patient's age or weight.

Treatment of persistent SUI is the subject of many clinical trials. There are different approaches to solve the problem, including second sling implantation, sling incision or sling excision with postponed second sling implantation.[19,20]

It should be stressed that repeat suburethral sling implantation without excision of the failed one is usually not as effective as the primary procedure. It was shown that women undergoing repeat sling procedures have a nearly twofold

increase in the odds of treatment failure than those undergoing a primary surgery.[21] The repeated sling implantation might also cause complications influencing patients' quality of life, such as overactive bladder de novo, urinary retention, pelvic plain syndrome and others. In contrast, there is some evidence that repeated sling after a failed sling excision might have similar effectiveness as the primary procedure.[20,22] Still, such protocol requires two or more further surgeries, which is hardly acceptable for patients.

It also must be considered that sling excision can lead to complications, such as hemorrhage, hematomas, fistulas, diverticula and urethra or bladder injuries.[23–25] What is more, complications after sling procedures, including persistent SUI, often lead to litigation. Food and Drug Administration warnings caused partial withdrawal of these procedures, mainly in the USA.[26,27]

All these observations imply that clinicians should consider early diagnosis of suboptimal tape placement. Due to the fact that the proximal (close to the bladder neck) sling position is connected with worse clinical effectiveness of the procedure, and taking into account the possible complications of repeated sling surgeries or sling excision and our observation of stable sling position after implantation, we suggest that it should be recommended to provide early visualization of sling location (up to 7 days post-procedure) and early sling removal in case of its suboptimal position. Early sling removal is a simple and safe procedure allowing second sling implantation several weeks after the first attempt. This procedure could help avoid difficult and risky procedures, such as late sling excision.

Conflict of interest

None declared.

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