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Article *in* Neurourology and Urodynamics · September 2014

DOI: 10.1002/nau.22658

Neurourology and Urodynamics 34:741–746 (2015)

Do Different Vaginal Tapes Need Different Suburethral Incisions? The One-Half Rule

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Aim: Despite a wide array of vaginal tapes to treat stress urinary incontinence (SUI), evidence suggesting that both patient characteristics and tape positioning influence outcomes, and differing tape insertion pathways (retropubic vs. transobturator), it remains unclear if the same incision location is effective for all tapes. The aim of the study was to compare outcomes using two different surgical incision locations when inserting a transobturator vaginal tape (TOT) to treat SUI. **Methods:** We compared patient characteristics, tape positioning, and surgical outcomes in 123 women undergoing a TOT procedure who were randomly assigned to have the surgical incision begin at 1/3 of the sonographically-measured urethral length (similar to the traditional retropubic approach) or 1/2 of the urethral length. **Results:** It was feasible to place the tape according to intention in 99.2% of the study cohort. The overall cure rate was higher when the incision site began at 1/2 the urethral length (83.6%) than 1/3 (62.9%) ($P = 0.01$). In the subgroup analyses, only patients with normal urethral mobility had significantly different cure rates (85.7% vs. 55.2%, $P = 0.02$). No significant differences in cure rates were observed between the other mobility categories of the study groups—hypermobility was consistently associated with high cure rates and hypomobility with low cure rates. **Conclusions:** When surgically treating SUI with a TOT, incision at the mid-urethra using the 1/2 rule is recommended as it leads to better outcomes for most patients, particularly those with normal urethral mobility. *Neurourol. Urodynam. 34:741–746, 2015.* © 2014 Wiley Periodicals, Inc.

Key words: one-half rule; pelvic floor sonography; retropubic TVT; stress urinary incontinence; transobturator tape (TOT); urethral mobility

INTRODUCTION

When Ulmsten initially described his tension-free vaginal tape (TVT) technique for treating stress urinary incontinence (SUI), he identified the mid-urethra (high pressure zone) as the desired location for tape placement.[1] In order to accomplish this objective, he began the surgical incision 1 cm from the external urethral orifice. Ethicon, Inc. adopted this strategy which was incorporated into their manual of instructions (cookbook).[2]

It has been widely assumed that this incision location (10 mm from the external urethral orifice) would be the same for all women and all vaginal tapes currently on the market. However, Ulmsten's technique was originally developed using technology available over two decades ago that involved radiomorphologic and urodynamic studies. Recent studies utilizing advanced, dynamic medical technology (i.e., 3D/4D ultrasound) found that variations in anatomical/physiological characteristics of women (i.e., urethral length, height of the vaginal sulci, and mobility of the urethra) influence the success of the SUI outcome and the occurrence of postoperative complications.[3–12]

The 1/3 rule, an adaption of Ulmsten's original technique, has been largely successful at positioning the TVT at the critical high pressure zone by taking into account the patient's urethral length and the proximal ventrocranial shift towards the mid-urethra of the TVT under pressure.[4,6,9] According to this approach, the site to begin the suburethral incision is calculated using the following formula: distance of the distal end of the vaginal incision from the external urethral orifice = 1/3 of the sonographic urethral length. It is not clear, however, if the transobturator tapes (TVT-O/TOT), a newer generation and the second most widely used tape, have the same movement pattern under pressure as the TVT.

We hypothesized that it is unlikely the tapes would behave alike given the inherent differences in the approaches (retropubic vs. transobturator) and the anatomical/physiological constraints resulting from the dissimilar pathways of the tapes. TVT strings are placed in a ventrocranial (more vertical, U-shape) and TOT strings are placed in a ventrocaudal, (more horizontal, H- shape) direction.[13] Sonographic visualization of transobturatoric tapes in vivo showed no or a decreased shift along the urethra towards the bladder neck than what was found with the retropubic tapes. As a consequence, achieving the desired high pressure zone under pressure may require placing the transobturatoric tape more proximally and using a different incision location/strategy.

The primary aim of our study was to compare SUI outcomes in two groups of patients undergoing a TOT procedure using differing surgical techniques: (1) the 1/3 rule which uses a similar distal incision site to the traditional approach (TVT-O cookbook) while also accounting for variations in the urethral

Eric Rovner led the peer-review process as the Associate Editor responsible for the paper.
Potential conflicts of interest: Nothing to disclose.
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Received 22 January 2014; Accepted 24 June 2014
Published online 30 August 2014 in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/nau.22658

length, or (2) the 1/2 rule, a newly proposed technique which begins the incision more proximally at the mid-urethra.

MATERIALS AND METHODS

We included in the study, women with clinically- and urodynamically-proven stress urinary incontinence who were undergoing a TOT procedure at one of two tertiary urogynecological centers. SUI was determined using objective and subjective criteria, previously described by Kociszewski et al.[4,6,9,14] Patients were excluded from the study if they had previous incontinence surgery or they were not available for a 6-month follow-up visit (i.e., transportation, employment, or personal constraints). All eligible patients were informed of the purpose of the study and written consent to participate was obtained (local ethical review board approval—Ek Kt. TGAA003 and EC 051205).

Preoperative data collection included documentation of comprehensive medical history and patient characteristics. Urethral length and mobility were measured using introital ultrasound performed in a standardized manner using GE Voluson 730 (GE Healthcare, Chalfont St. Giles, UK; vaginal scanner, 4.0–9.0 MHz, 160° beam angle) and a Toshiba Aplio ultrasound system (vaginal transducer, 3.6–8.3 MHz, 160° beam angle). These assessments were carried out, as described in a previous publication, with the patients in a semi-sitting position and a standardized bladder filling volume of 300 ml.[15] The urethral length was measured from the bladder neck to the distal end of the hypoechogenic urethra (ending at the hyperechogenic urethral papilla). Urethral mobility was determined via vector analysis.[16] Urethral mobility was divided into three categories based on linear dorsocaudal movement (LDM) with vertical descent: hypomobile ($\leq$5 mm), normal mobility (>5 mm and <15 mm) and hypermobile ($\geq$15 mm).[3,17]

Patients were randomly assigned to one of two transobturator tape insertion technique groups—1/3 rule or 1/2 rule. The four urogynecologists involved in the study performed the TOT (Gynecare TVT™ Obturator, Ethicon, Somerville) procedures according to the manufacturer's instructions. However, to reduce postoperative groin pain, the exit point was made close to the ramus inferior of the pubis.[18] The incision location was chosen with respect to the urethral length (one-third and one-half rule). The 1/3 rule technique was done by starting the suburethral incision at 1/3 ultrasonographically measured urethral length (distance of the distal end of the suburethral incision from the external urethral orifice). For example, the incision would start at 10 mm from the external urethral orifice in a woman with a 30 mm long urethra. Using the 1/2 rule, the incision would begin at 15 mm.

All patients were put under local/analgosedation and a single injection of the antibiotic ceftriaxone (2 g) was given at the start of the procedure. Intraoperative urethrocystoscopy was performed to confirm an intact bladder and urethra. For proper positioning of the tape, a cough test was used with 300 ml of saline in the bladder. Following standard postoperative procedures, first voiding was attempted after 2 hr. If sonographically-measured residual volumes were greater than 200 ml, catheterization was done.

During hospitalization, assessments of the tape position and complications (1–2 days) were conducted. Postoperative evaluation of treatment outcome was done at the 6-month follow-up visit and it included patients' reports, clinical findings, pad test results, and pelvic floor sonography (see detailed ultrasound description above).

Real-time ultrasound imaging was used (video documentation) to observe the dynamic interaction between the TOT and the urethra. To accomplish this, the position of the bladder neck and urethra was used to track the shape changes of the tape at rest and during straining. Values obtained when measuring the maximum excursion during the Valsalva maneuver were used to categorize patients into three groups (modified from).[4] Urethral encroachment was defined as either the presence of a C-shaped tape or an impression on the posterior urethral wall at the junction of the tape.[4,19] The three categories of tape dynamics were defined as follows:

Group I: When observed at rest, the tape lies parallel to the urethral lumen. During the Valsalva maneuver, the tape becomes C-shaped or shows transient urethral encroachment indicating urethral compression.

Group II: Both at rest and during the Valsalva maneuver the tape runs parallel to the urethral lumen. The tape does not become C-shaped under pressure and there is no urethral encroachment.

Group III: The tape is C-shaped when observed at rest and maintains this same shape during the Valsalva maneuver (continual urethral encroachment).

Additional sonographic measurements done at rest and during straining included: (1) the position of the TOT along the urethra (mid-tape as reference point) and expressed as percentage of entire urethral length; and (2) the proximity of the tape to the urethra determined as the shortest distance between the two.

Data on postoperative complications such as groin pain, de novo urge and voiding dysfunction were also gathered for each study participant. The primary outcome assessed—SUI treatment success—was defined as a patient with a negative postoperative cough test, a negative 1-hour pad test (<2 g difference), and the degree of subjective suffering improved to a VAS score of 0 or 1. For purposes of this study, if patients did not meet all of these conditions, the treatment was considered unsuccessful.[6,9]

Statistical Analysis

Using a significance level alpha = 0.05 and a power of 80%, the required sample size was a minimum of 57 patients for cure rates of 60% and 85%, respectively (nQuery Advisor 7.0). With regard to statistical analyses, the primary outcome was coded as a binary variable with treatment success versus treatment failure. Statistical tests were performed and graphic representations were generated using STATISTICA 10.0.1011 (StatSoft, Inc. 2013). Pearson's Chi Square test was used for binary variables, and the Mann–Whitney–Wilcoxon test or the independent samples *t*-test were used for continuous variables (based on Shapiro–Wilk tests of normality). Logistic regression tests were performed using the backward stepwise (likelihood ratio) method. Results were considered to be significant at a *P*-value of <0.05.

RESULTS

Of 127 women with SUI who were assessed for inclusion in the study from 2/2006 to 10/2008, 123 were enrolled. Three women were not available for a 6 month postoperative visit and one woman declined participation in the study. Sixty-two women were randomly selected for surgical treatment using the 1/3 rule incision technique and 61 were treated using the 1/2 rule. All 123 patients were clinically assessed 6 months following surgery.

The mean age of the study cohort was 60.6 (±9.7) years. The mean BMI was 27.4 (±4.2), with 74.8% of patients overweight (≥25) and 22.0% obese (≥30). Ninety-two study participants had a history of at least one spontaneous delivery and 17 had caesarean deliveries. The study participants had a median of two children (IQR 1–3). Additional preoperative assessments were as follows: the mean maximal urethral closure pressure (MUCP) was 36.2 (±13.7) cmH_2O; the median sonographic urethral length was 30.3 mm (IQR 27.7–34.2); the mean measurement of urethral mobility was 15.0 mm (±6.6) (57 normal mobility, nine hypomobile, 57 hypermobile); 38 (30.9%) women had mixed incontinence that was successfully treated for OAB symptoms before surgery; and 66 (53.7%) of the women had at least one previous gynecological surgery (eight had two previous surgeries). Baseline values were similar for the two groups, with no statistically significant differences detected (Table I).

Thirteen patients (10.5%) experienced complications within the first few days after surgery: six patients had OAB dry (frequency urgency symptomatic), five complained of groin pain and two had voiding dysfunction. When assessed at 6-month follow-up visits, these postoperative complications had resolved in eight patients. Of the five women with longer-term postoperative complications, two reported persistent OAB dry symptoms, one had groin/thigh pain, one had pain at the level of the vaginal sulcus and one experienced voiding dysfunction. Logistic regression analyses for the development of postoperative complications showed no association with tape incision site technique ($P = 0.16$), tape-urethra distance ($P = 0.59$), urethral mobility ($P = 0.52$), tape position ($P = 0.84$), or likelihood of cure ($P = 0.65$).

Of the entire study cohort of 123 women, 73.2% were cured of SUI after TOT insertion. The cure rate was notably higher ($P = 0.01$) in the patient group with the TOT placed using the 1/2 rule (83.6%) than the 1/3 rule group (62.9%) (Fig. 1). Subgroup analyses indicated that urethral mobility may have had an influence on the surgical outcome. The difference in the mean urethral mobility between those women who were cured (16.7 mm ± 5.8) and those who were not cured (10.4 mm ± 6.3) were statistically significant (mean difference 6.2; $P < 0.001$; 95% CI [3.8–8.7]). Thus, patients with more preoperative urethral mobility had a higher likelihood of being cured than patients with low urethral mobility. The cure rates were high in women with a urethral mobility ≥15 mm (hypermobile) in both study groups (96.4% one-half group; 79.3% one-third group). Although the difference in the cure rates was not statistically significant ($P = 0.10$), the rate in the one-half group was notably higher. The location of the incision did not impact the outcome for patients with a hypomobile urethra, as all nine patients had unsuccessful results. Conversely, patients with a normal urethral mobility (> 5 mm and < 15 mm) had a higher cure rate when the incision site was determined using the 1/2 rule than the 1/3 rule (85.7% vs. 55.2%, respectively; $P = 0.02$) (Fig. 2).

When measured at rest, tapes inserted with the 1/2 technique were found in the target range of 45–65% of the urethral length in 98.4% of the study sub-group, and tapes inserted with the 1/3 technique were found in the 60–80% target range in 100% of women in that sub-group. The median

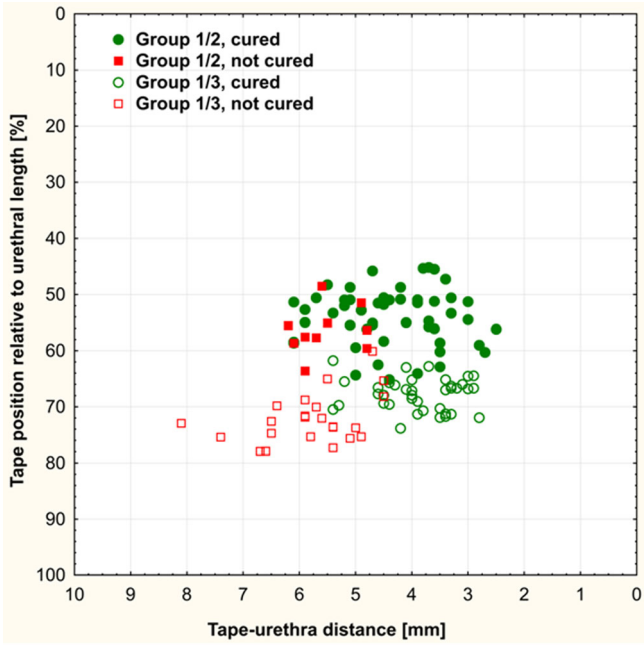

Fig. 1. Outcome at 6 months after TOT insertion according to the 1/2 or the 1/3 incision technique, showing tape position relative to urethral length (%) and tape distance from the urethra (mm). The TOT was positioned closer to the mid-urethra in women who were cured (60.2%, IQR 52.6–67.3) than in women who were not cured (70.0%, IQR 59.8–74.9) ($P < 0.001$), and the cure rate was higher in the 1/2 group than the 1/3 group (83.6% vs. 62.9%, respectively, ($P = 0.01$)).

TABLE I. Baseline Values for Patients With a TOT Placed According to the 1/3 and the 1/2 Incision Site Rule

Patient characteristic	1/3 rule (n = 62)	1/2 rule (n = 61)	*P* Value
Age—yr. (mean ± sd)	60.7 ± 9.4	60.5 ± 10.0	0.88
BMI - kg/m^2 (mean ± sd)	26.9 ± 4.1	27.9 ± 4.2	0.20
Parity - no. (%)			0.95
0	9 (14.5)	4 (6.6)	
1	16 (25.8)	22 (36.0)	
2	21(33.9)	23 (37.7)	
3	14 (22.6)	8 (13.1)	
4	1 (1.6)	4 (6.6)	
5	1 (1.6)	0 (0)	
Maximal urethral closure pressure cmH_2O—(mean ± sd)	38.2 ± 14.5	34.1 ± 12.6	0.10
Urethral length—mm (median, IQR)	31.1 (27.8–33.9)	30.0 (27.6–34.4)	0.44
Urethral mobility—mm (mean ± sd)	15.4 ± 7.3	14.5 ± 5.7	0.46
Mixed incontinence—no. (%)	22 (35.5)	16 (26.2)	0.33
Previous gynecological surgery—no. (%)	32 (51.6)	34 (55.7)	0.65

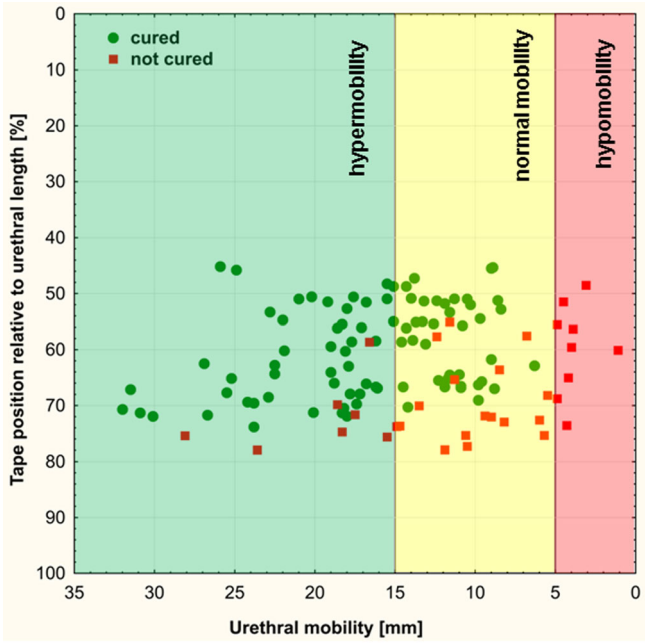

Fig. 2. Outcome at 6 months after TOT insertion, showing tape position relative to urethral length (%) and urethral mobility (mm). The mean urethral mobility was 16.7 mm (± 5.8) for women who were cured compared with 10.41 mm (± 6.3) for those who were not cured ($P < 0.001$). For women with a hypermobile urethra (urethral mobility ≥15 mm), the incision site technique did not appear to influence the cure rate ($P = 0.10$). Whereas, patients with a normal urethral mobility (> 5 mm and <15 mm) had a higher cure rate when the TOT was inserted according to the 1/2 rule ($P = 0.02$). All nine patients with a hypomobile urethra had unsuccessful results independent of the incision technique used.

position of the tape at rest along the urethra was 54.7% (IQR 50.7–58.11) in the 1/2 rule group and 69.2% (IQR 66.6–72.1) for patients operated according to the 1/3 rule ($P < 0.001$) (Fig. 1). Under straining, the median position of the tape along the urethra was fixed or showed a small ventrocaudal shift (55.2% IQR 50.8–59.7 1/2 rule; 73.1% IQR 70.0–75.7 1/3 rule). For patients who were cured of SUI, the TOT was located closer to the mid-urethra when measured at rest (60.2%, IQR 52.6–67.3) than in women who were not cured (70.0%, IQR 59.8–74.9) ($P < 0.001$).

Within the 1/3 rule group, a statistically significant difference was detected in the median tape position along the urethra in cured patients (66.9%, IQR 65.6–69.9) and those who were not cured (72.9%, IQR 69.4–74.9; $P < 0.001$). However, in addition to having a higher overall cure rate, no significant difference in median tape positions was observed between cured (53.3%, IQR 50.3–57.7) and not cured patients (56.9%, IQR 54.0–58.7) in the 1/2 rule group ($P = 0.17$). When assessed at the 6-month follow-up visit, none of the tapes were positioned at the level of the bladder neck or dislocated within 45% of the urethral length.

No significant difference was found in the median tape-urethra distances between the two study groups (1/3 rule group 4.5 mm [IQR 3.6–5.6]; vs. 1/2 rule group 4.6 mm [IQR 3.8–5.4]; $P = 0.76$). However, a statistically significant difference in the median tape-urethra distance was detected under straining (1/3 rule group 3.5 mm [IQR 2.9–5.0] vs. 1/2 rule group 2.9 mm [IQR 2.5–3.8]; $P < 0.001$). In addition, differences were observed in the distance measurements made at rest between patients who were cured of SUI (4.0 mm, IQR 3.4–4.7) and those who were not cured (5.7 mm, IQR 5.2–6.3) ($P < 0.001$) (Fig. 1).

With regard to tape-urethra dynamics, none of the patients showed signs of permanent/continual tape encroachment (Group III). Morphological changes in the tape showing a flat tape at rest and a C-shape during straining (transient urethral encroachment) were observed in a total of 77 patients (Group I). Of these 77 patients, all patients were cured of SUI (28 from 1/3 group and 49 from 1/2 group). Lastly, 46 patients met the criteria as having tape-urethra dynamics described for Group II. This group included all 33 study patients who were not cured and 13 patients who were cured (11 from 1/3 group and 2 from 1/2 group).

DISCUSSION

Ulmsten's seminal findings on the etiology of female incontinence indicated that the surgical treatment of SUI should aim to support the middle third of the urethra (high pressure zone) during straining.[1,2] However, there is evidence to suggest that vaginal tapes behave differently in vivo and not all vaginal tape varieties should be inserted in the same manner. Our findings show that when inserting a TOT, beginning the incision at 1/2 the urethral length was more likely to result in a successful outcome than at 1/3 of the urethral length—similar to the standard technique for classical retropubic TVT.[9] One important conclusion of this study, which is consistent with earlier studies, is that patient characteristics (i.e., urethral mobility) ought to be assessed and appropriately matched with the particular functionality of the tapes.[3–12,20]

The influence of the tape's behavior on the method in which the tape should be surgically inserted has not been widely debated or investigated. As a consequence, limited evidence exists to demonstrate variations in tape shifting patterns under pressure. Nevertheless, we noted during previously conducted ultrasound studies that the TOT and TVT behave differently under increasing abdominal pressure.[13,21,22] We found that the TVT tends to move ventrocranial while the TOT remains either in the same position or to a less extent it shifts ventrocaudal. Assuming this limited movement of the TOT,[19,23] we reasoned that higher placement with the surgical incision beginning at the mid-urethra would provide the necessary reinforcement to the critical high pressure zone.[1,24]

This study's findings did indeed support this notion, as we observed a higher cure rate in patients with the TOT inserted using the 1/2 rule than the 1/3 rule. The TOT was positioned more proximally to the mid-urethra in women who were cured than in those who were not cured. Furthermore, no dislocation of the TOT was detected at the 6-month follow-up visits. Specifically, none of the tapes were lying within 45% of the urethral length, indicating no sliding upwards towards the bladder neck occurred in our study population. Consequently, this sliding action which is widely assumed as inevitable, may be an unwarranted concern for practitioners. Nevertheless, further investigations utilizing longer follow-up periods would be advised since the length of this study may have hindered its ability to detect sliding action or some other unexpected event that could have developed over a longer period of time.

Similar to earlier studies, we found that urethral mobility plays an important role in surgical outcomes following vaginal tape insertion procedures.[12,20,25] For women with a hypermobile urethra—one of the main indications for treatment with a TOT—the likelihood of success is generally high. Although we found no statistically significant difference in the successful outcomes for these women when using different incision sites, the cure rate was higher in the 1/2 group. The

relatively low sub-group sample size may have limited our ability to detect at true difference. Nevertheless, the slight shift of the TOT under pressure seemed to be compensated by the higher urethral mobility such that the middle third of the urethra could be stabilized in both groups. Incision at the mid-urethra (1/2 rule) appeared to be relevant when treating women with normal urethral mobility.

Furthermore, none of the women in the study with a hypomobile urethra had a successful outcome. The prognosis for patients with a hypomobile urethra seems to be poor if a TOT is used. This is likely due to the different anchoring of the tapes which results in the TOT pulling in a ventrocaudal, horizontal direction while the TVT pulls in a more ventrocranial, vertical direction. The consequence for patients with a hypomobile urethra is insufficient support by the TOT of the critical zone of the urethra, assuming it is inserted in a tension-free manner. For patients with a hypo- or immobile urethra, higher continence rates could be achieved by applying more tension when inserting a TOT.[19] However, in exchange for this increased tension, the patient may run a higher risk of developing obstructive complications (voiding dysfunction, OAB symptoms).[4,8,9] Given this inconsistency in the literature, we believe a prudent approach to treat women with a hypo- or immobile urethra would be to insert a TVT.[5]

Sonographically measuring urethral mobility is recommended before initiating treatment to determine the most suitable technique. In cases where mobility is unknown, the 1/2 rule would be the method of choice. This technique helps to position the TOT to provide adequate support to the critical high-pressure zone in women with a normal and hypermobile urethra. These two sub-groups make up the largest proportion of patients.

Urethral mobility is not the only measurement that can be used by practitioners to make decisions concerning surgical strategies. Although the actual length of the patient's urethra may not directly influence the likelihood of surgical success, it does factor into the initial insertion strategy. According to Kociszewski et al., the urethral length in women ranges from approximately 15 mm to 55 mm.[4,26] Given this sizeable range, care must be taken when identifying the high pressure zone as the desirable distance of the tape to the external urethral orifice varies among patients. Another factor which has been shown to influence the success of a tape insertion procedure is the tape distance from the urethra.[6,9] Most unsuccessful cases in both study groups had tape-urethra distances of greater than 5 mm. Results from other studies have not supported this conclusion, though.[27] One important distinction between these investigative studies is that while they were similar, the point of reference (LSM vs. pubic symphysis) to measure the tape distance was different. This key difference limits comparability between these findings. Consequently, the plausibility of such a relationship between the tape position and the surgical outcome should not to be dismissed.

Similar to other research groups,[19,23] we observed that the location of the TOT during straining showed only slight changes in contrast to the previously documented shifting behavior of a TVT.[4,6] Real-time ultrasound imaging and morphological findings facilitate a better understanding of the intensity of the interaction between the urethra and the tape. In our study, dynamic urethral interaction or kinking was observed in 86% (77/90) of the cases of study patients who were cured of SUI and it did not occur in any of the 33 patients who were not cured. The C-shaped angles that were noted during straining with this newer generation of vaginal tapes were consistently $>120^\circ$ and no longer $<90^\circ$ as previously reported for the retropubic TVT.[4]

We believe the mechanism of continence stems from transient compression (not a permanent indentation) of the tape into the urethra. A tension-free inserted tape should be aligned parallel and with adequate distance to the posterior urethral wall. The dynamic interaction between the tape and the urethra depends on multiple factors including the tape position along the urethra (at the level of the high pressure zone during straining), urethral mobility (hypo-/normo-/ hypermobility of the urethra), and tape-urethra distance (proximity of the tape). Further investigation is needed to assess if any of these factors play a more important role in achieving continence or whether they are all mechanically and inextricably interconnected.

Fortunately, contemporary and widely available medical technology (i.e., ultrasound) facilitates pre-operative identification of patient characteristics and design of individualized treatment plans. Similarly, the behavior of tape can be monitored intra- and postoperatively.[19] Not only does this type of active monitoring have clear advantages for treatment management for individual patients, it improves our ability to differentiate tape behaviors as the pool of tape varieties continues to diversify.

CONCLUSIONS

In summary, our findings indicate that outcomes differ based on the location of the incision, yet attributes of the patients such as urethral length and urethral mobility may be more important when selecting the most suitable treatment option. Although tape varieties share the same objective— support to the critical high-pressure zone—their behavior differs. This interplay between the tape and patient characteristics has clinical relevance and ought to be investigated further. When surgically treating SUI with a TOT, incision at the mid-urethra with a 1/2 rule is recommended as it leads to better outcomes for most patients.

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