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Role of intrinsic sphincter deficiency with and without urethral hypomobility on the outcome of tape insertion

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AIMS: Intrinsic sphincter deficiency (ISD) is a known risk factor for therapy failure after tension-free vaginal tape (TVT) insertion. The purpose of this study was to investigate if the severity of ISD alone or other factors such as urethral mobility and tape localization influence outcomes.

METHODS: One hundred and nine women with urodynamically determined ISD, a TVT insertion, and a 6-month follow-up visit were included. Urethral length, mobility, and tape localization were evaluated by pelvic floor sonography. Patients were classified into three urethral mobility groups (hypomobile, normomobile, hypermobile). Surgical outcome was assessed by a combination of objective and subjective criteria.

RESULTS: Therapeutic success rate after TVT insertion was 81.6%. The severity of ISD did not associate with therapy failure. But urethral mobility ($P < 0.0001$), relative tape position ($P = 0.0003$), and tape-urethra distance ($P < 0.0001$) differed between cured and not cured patient groups. Patients with a relative tape position toward 1/2 of urethral length had a higher cure rate. Significantly different cure rates ($P = 0.0003$) were found for hypomobile (67%), normomobile (76%), and hypermobile (100%) urethras. For ISD patients with a hypomobile urethra, highest cure rates were obtained for tape-urethra distances between 2.5 and 3.5 mm.

CONCLUSIONS: The reduced cure rate for ISD patients was due to the subgroup with a hypomobile urethra. A prospective study is needed to confirm that slightly shorter tape-urethra distances and a relative tape position more toward the mid-urethra will lead to better outcomes for this patient group.

KEY WORDS

cure rate, midurethral sling, one-third rule, pelvic floor sonography, stress urinary incontinence, tension-free vaginal tape

Abbreviations: ISD, intrinsic sphincter deficiency; IQR, interquartile range; LDM, linear dorsocaudal movement; MUCP, maximal urethral closure pressure; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; TOT, transobturator tape; TVT, tension-free vaginal tape.

Edyta Właźlak and Volker Viereck contributed equally to this work.

Patients were recruited at Cantonal Hospital Frauenfeld, Switzerland and at Lutheran Hospital Hagen-Haspe, Germany; data collection and manuscript writing was done at Medical University of Lodz, Poland; data collection, statistical analysis and manuscript writing/editing was done at Cantonal Hospital Frauenfeld, Switzerland.

1 | INTRODUCTION

Twelve¹ to 40%² of all patients with stress urinary incontinence (SUI) are affected by intrinsic sphincter deficiency (ISD), that is defined as an urodynamic maximal urethral closure pressure (MUCP) of ≤ 20 cm H₂O.³ Various reasons may lead to this poor urethral closure mechanism, such as age-related reduction of muscle mass, nerve or muscle

dysfunction, previous surgery, or a neurological disease.^{4,5} Patients with ISD are especially difficult to treat.⁴ Standard tension-free vaginal tape (TVT) therapy of the entire SUI population has a 6-month success rate of 93.1%,⁶ and success rates for 32 months, 7 or 11 years still are considerably high (87%,⁷ 81%,⁸ or 77%,⁹ respectively). In contrast, ISD patients have a 6-month cure rate of only 79% for TVT, and 55% for transoburator tape (TOT) insertion.⁴

How to improve success rates in ISD patients? To find out, this study aims to identify distinguishable characteristics between cured and not cured ISD patients. Does a very low urethral closure pressure associate with treatment failure, or are other factors involved?

To this end, we retrospectively studied treatment outcome of ISD patients operated with TVT and acquired baseline and 6-month follow-up data. Investigated factors that also may affect cure rates were the preoperatively determined urethral mobility, and postoperatively determined tape position relative to the urethral length and tape-urethra distance.

Once factors influencing success rates have been identified, we may be able to propose an improved and optimized treatment for curing ISD patients with TVT surgery.

2 | MATERIALS AND METHODS

2.1 | Patient assessment

All women with clinically and urodynamically confirmed ISD that received a TVT insertion and that completed a 6-month follow-up visit were included. Between January 2006 and December 2012, 109 women (15.6% of all patients with TVT) were eligible at two tertiary urogynecological centers. This retrospective study was approved by the ethical review board.

Data collection included medical history, patient characteristics, and intra- and postoperative complications up to 6 months. Preoperative SUI or stress-dominant mixed urinary incontinence (MUI) were determined as previously described.¹⁰ Therapy outcome was assessed at 6 months.¹¹ Cured patients had a negative cough test, a negative 1-h pad test (<2 g) and a VAS score of 0 or 1. All other women were included in the “not cured” group, even if they experienced improvement.¹¹

2.2 | Urodynamic testing and pelvic floor sonography

Urodynamic testing was used to determine the urethral closure pressure and to select patients with ISD, that is, with a MUCP ≤ 20 cm H₂O.³ Measurements were done with a Sedia SE-6 (Sedia AG, Givisiez, Switzerland) or a Duet Logic (Medtronic Deutschland GmbH, Düsseldorf, Germany) with

a microtip catheter.^{10,12} Specifically, measurements were taken with patients at rest in the 45° upright sitting position at 300 mL bladder filling using an eight French Gaeltec® double microtip transducer withdrawn at 1 mm/s, and the transducer was orientated in the 3 o'clock position. Pelvic floor sonography was used to assign the ISD patients to the hypo-, normo-, or hypermobile urethral mobility groups, and to measure urethral length and tape position.^{11–13} Measurements were done with a GE Voluson 730 vaginal scanner (GE Healthcare, Chalfont St. Giles, UK) or a Toshiba Aplio ultrasound system (Toshiba, Tokyo, Japan) as previously described.^{6,11} Preoperative urethral mobility was determined by measuring the linear dorsocaudal movement (LDM), that is, the distance shift between the position of the bladder neck at rest and during straining.¹⁴ Patients were classed into three urethral mobility groups based on their LDM values: hypomobile (≤ 5 mm), normomobile ($5 \text{ mm} < \text{ and } < 15 \text{ mm}$), and hypermobile urethra ($\geq 15 \text{ mm}$).^{11–13} Preoperative urethral length was measured from the bladder neck to the distal end of the hypoechoic urethra. Postoperative relative tape position and the shortest tape-urethra distance measured from the urethra-proximal edge of the tape to the echolucent edge of the urethra were evaluated (Fig. 1).^{6,15,16}

2.3 | TVT insertion

TVT insertion followed the technique by Ulmsten¹⁷ with an adaptation to the urethral length as described previously.⁶ This adaptation takes account of the individual variance of the urethral lengths (from 1.6 to 5.1 cm, $n = 310$; unpublished

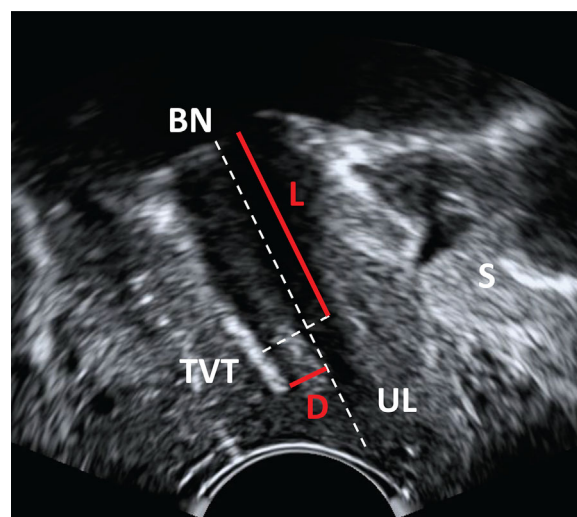


FIGURE 1 Tape localization by pelvic floor sonography with a transvaginal probe. Sagittal view. BN, bladder neck; D, minimal tape-urethra distance (mm), from the closest position of the tape to the echolucent part of the urethra, consisting of mucosa, submucosa, and smooth muscle layers (longitudinal smooth muscle-complex);⁶ L, urethral length from projected mid-tape position to bladder neck (mm); S, symphysis pubis; TVT, tension-free vaginal tape; UL, urethral length (mm) ($L/UL \times 100$: relative tape position [%])

data). The target tape position for highest cure rates was determined between 50% and 70% relative to the urethral length (“relative tape position”) (Fig. 2).⁶ Surgery was performed under local/analgesedation. Urethrocytoscopy confirmed the intactness of bladder and urethra, and the intraoperative cough test at 300 mL bladder filling was used for proper tape positioning.¹¹

2.4 | Statistics

Descriptive statistics were used for baseline characteristics, ultrasound measurements, outcomes, and complication rates. Frequency data were analyzed with the Fisher's exact test and continuous variables were analyzed with the Mann-Whitney *U*-test. Results were considered to be significant at level $\alpha < 0.05$. The primary outcome was coded as a binary variable (cured, not cured). Multiple logistic regression analysis was used to determine the odds ratios of the explanatory variables. Statistical analysis and graphic representations of the data were generated using R 3.2.2 for Windows 7.

3 | RESULTS

3.1 | Patient characteristics

Patient characteristics at baseline are summarized in Table 1. Cured and not cured subgroups did not differ in age, body

mass index, parity and birth mode, but differed in body height ($P = 0.013$) and types of previous gynecological surgeries ($P = 0.009$). Thirty-one percent (34/109) of all patients had a stress-dominant MUI that previously was treated with medication for urgency symptoms. Therapy outcome was not affected by the presence of MUI (Table 1).

No intraoperative complications were reported and there was no difference in complication rates between cured and not cured groups. Twenty-one cases of postoperative complications have been recorded, that included urgency (12×), hematoma (3×), urinary tract infection (2×), voiding difficulties (3×), and residual urine (1×). None of the patients needed a sling mobilization or sling incision.

3.2 | The influence of urethral closure pressure on therapy outcome

The median MUCP of our subpopulation of ISD patients was 16.0 cm H₂O (IQR 12.0-20.0). TVT insertion resulted in a cure rate of 81.6% (89/109), while 18.4% (20/109) of patients were not cured. Treatment failure cannot be attributed to a very low urethral closure pressure alone, since MUCP was not significantly lower in not cured than in cured patients (median MUCP cured vs. not cured: 15.0 cm H₂O [IQR 12.0-20.0] vs. 16.5 cm H₂O [IQR 12.7-20.0]). This means that factors other than MUCP might affect treatment outcome.

3.3 | Other factors that influence therapy outcome

Therefore, we analyzed the influence of the factors urethral mobility, relative tape position, and tape-urethra distance on cure rates. For urethral mobility, preoperative median LDM of all patients was 11.3 mm (IQR 6.4-17.0), of cured patients 12.8 mm (IQR 7.3-18.0), and of not cured patients 5.6 mm (IQR 4.4-9.2) ($P < 0.0001$). The median relative tape position for all patients was 65.0% (IQR 61.4-70.1), for cured patients 64.1% (IQR 60.3-67.5), and for not cured patients 70.6% (IQR 66.4-72.8) ($P = 0.0003$). The median tape-urethra distance for all patients was 4.0 mm (IQR 3.2-4.8), for cured patients 3.6 mm (IQR 3.1-4.4), and for not cured patients 5.5 mm (IQR 4.4-6.3) ($P < 0.0001$). This means that a high urethral mobility, a low relative tape position and a short tape-urethra distance favor cure rate.

3.4 | Relative tape position

The recommended target window for successful TVT placement was defined at 50-70% relative tape position and 3-5 mm tape-urethra distance (Fig. 2).⁶ For all 109 ISD patients, the cure rates were 91.7% (55/60) for TVTs placed inside this window and 69.4% (34/49) for TVTs outside the window (Fig. 2). Patients with TVT positions outside the

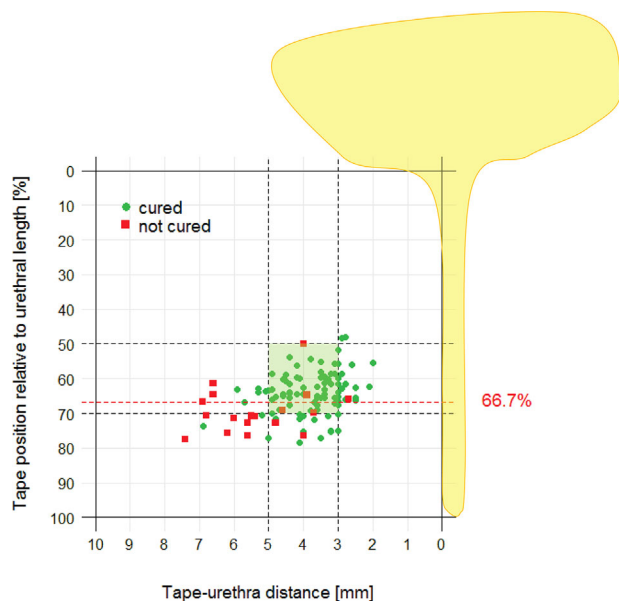


FIGURE 2 Relative tape position (%) versus tape-urethra distance (mm). Results are shown for cured (green dots) and not cured (red squares) patients at 6 months after TVT insertion. The recommended target window for highest cure rates is indicated by the green-shaded area between the black dashed lines (relative tape position 50-70%, tape-urethra distance 3-5 mm). The red dashed line indicates the target relative tape position of 66.7%

TABLE 1 Baseline patient characteristics for all patients with ISD, and for ISD cured and ISD not cured groups

Patient characteristics	All patients with ISD (n = 109)	ISD cured (n = 89)	ISD not cured (n = 20)	P-value
Age—year, median (IQR)	61 (50-68)	61 (50-69)	55 (50-64)	NS ^a
Height—cm, median (IQR)	165 (161-168)	165 (160-168)	168 (165-172)	0.013 ^a
Body mass index—kg/m ² , median (IQR)	28 (25-30)	28 (25-30)	28 (26-30)	NS ^a
Parity—n (%)				
0	8/109 (7%)	5/89 (6%)	3/20 (15%)	NS ^b
1	24/109 (22%)	20/89 (22%)	4/20 (20%)	
≥2	77/109 (71%)	64/89 (72%)	13/20 (65%)	
Birth mode—n (%)				
0	8/109 (7%)	5/89 (6%)	3/20 (15%)	NS ^b
1—spontaneous	90/109 (83%)	76/89 (85%)	14/20 (70%)	
2—C-section/forceps/vacuum extraction	11/109 (10%)	8/89 (9%)	3/20 (15%)	
Type of previous gynecological surgeries—n (%)				0.009 ^b
Patients with no previous operation	62/109 (57%)	56/89 (63%)	6/20 (30%)	— ^c
Patients with previous operations:				
Tape	4/109 (4%)	1/89 (1%)	3/20 (15%)	0.008 ^c
Colposuspension	23/109 (21%)	16/89 (18%)	7/20 (35%)	0.034 ^c
Prolapse surgery w/o mesh	7/109 (6%)	4/89 (4%)	3/20 (15%)	0.045 ^c
Mesh anterior	6/109 (6%)	6/89 (7%)	0	NS ^c
Hysterectomy (vaginal and abdominal)	2/109 (2%)	2/89 (2%)	0	NS ^c
Vaginal irradiation	1/109 (1%)	1/89 (1%)	0	NS ^c
Hysterectomy and colposuspension	2/109 (2%)	1/89 (1%)	1/20 (5%)	NS ^c
Colposuspension 2x	1/109 (1%)	1/89 (1%)	0	NS ^c
Tape and mesh anterior	1/109 (1%)	1/89 (1%)	0	NS ^c
MUI (mixed urinary incontinence)—n (%)	34/109 (31%)	26/89 (29%)	8/20 (40%)	NS ^b

Significance level of $\alpha = 0.05$.

^aMann-Whitney *U*.

^bFisher's exact.

^cLogistic regression with “Type of previous gynecological surgeries”, “Patients with no previous operation” was used as the reference level.

target window have a 4.8-fold higher risk (95%CI: 1.5-18.4) for not being cured ($P = 0.005$).

Sixty-nine patients had a relative tape position <66.7% and 40 patients >66.7%. Cure rates were 91.3% (63/69) versus 65% (26/40) (Fig. 2). Therefore, patients with a relative tape position >66.7% have a 5.5-fold higher risk (95%CI: 1.8-19.7) for not being cured ($P = 0.001$), or, patients with a relative tape position more proximal toward the bladder neck have a higher chance of being cured.

3.5 | Urethral mobility and tape-urethra distance

Therapeutic failure was associated with urethral mobility. The assignment of patients to the three urethral mobility categories (Fig. 3) resulted significantly different cure rates ($P = 0.0003$) between hypomobile 67% (16/24), normomobile 76% (38/50), and hypermobile 100% (35/35) urethras. However, for hypomobile urethras, slightly shorter tape-urethra distances, ideally between 2.5 and 3.5 mm, resulted in the highest cure rates (Fig. 3A). For normomobile urethras,

the optimal tape position was within the recommended target window (Fig. 3B). For hypermobile urethras, even positions outside the target window led to a positive outcome (Fig. 3C).

3.6 | Logistic regression analysis

Multiple logistic regression analysis using all significant variables (LDM, height, types of previous gynecological surgeries, tape-urethra distance, and relative tape position) resulted in a significant association of urethral mobility and tape-urethra distance with the positive outcome of TVT procedure. The odds ratio for LDM was 2.37 (95%CI: 1.32-4.24). Thus, LDM and cure rate were positively associated ($P = 0.003$), and 1 mm increase of LDM resulted in a 2.37-fold higher cure rate. The odds ratio for tape-urethra distance was 0.03 (95%CI: 0.001-0.23). Thus, tape-urethra distance and cure rate were negatively associated ($P = 0.001$), and 1 mm increase of tape-urethra distance resulted in a 0.03-fold lower cure rate. The odds ratio for relative tape position was 0.86 (95%CI: 0.69-1.07) which was not significant ($P = 0.175$), but more distal positions had a tendency toward a negative association.

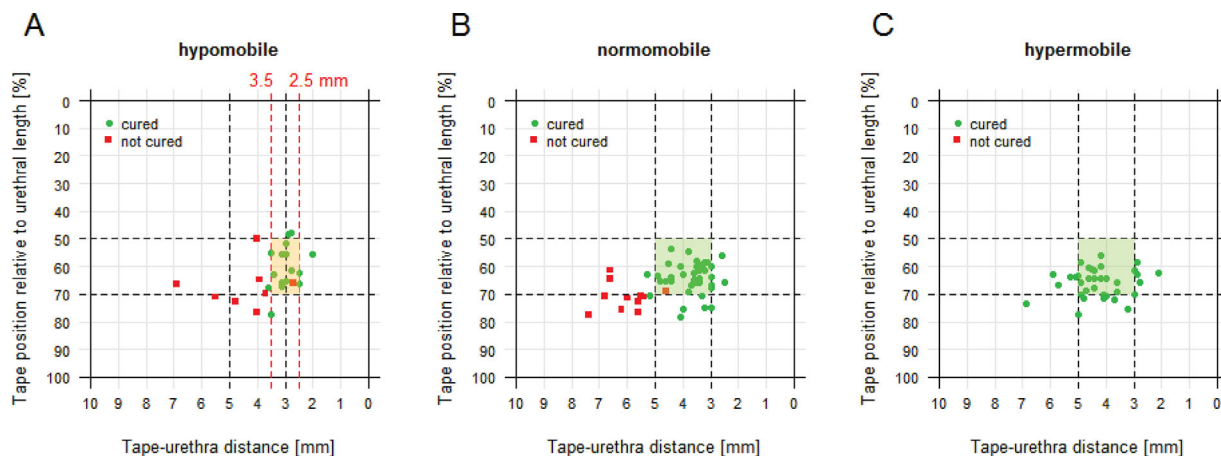


FIGURE 3 Relative tape position (%) versus tape-urethra distance (mm). Comparison of three different urethral mobility groups: (A) hypomobile, (B) normomobile, (C) hypermobile. Results are shown for cured (green dots) and not cured (red squares) patients at 6 months after TVT insertion. (A) The red dashed lines mark the new target tape-urethra distance for ISD with a hypomobile urethra between 2.5 and 3.5 mm, and the new target window is indicated by the orange-shaped area (relative tape position 50-70%; tape-urethra distance 2.5-3.5 mm). (B and C) The recommended target window for ISD with a normo- or a hypermobile urethra is indicated by the green-shaded area between the black dashed lines (relative tape position 50-70%; tape-urethra distance 3-5 mm)

4 | DISCUSSION

For ISD patients, TVT insertion reached the high 6-month success rate of 81.6%. Previously reported cure rates for ISD patients were in the same range, that is, 79%,⁴ 73%,¹ or 73%.¹⁸ However, these cure rates were below the cure rates determined for the entire population with SUI (93.1%).⁶ Our results indicated that these differences were not due to the severity of ISD itself, but due to the higher failure rates of patients with a hypomobile urethra.

ISD patients with a hypomobile urethra only represent a small fraction of the entire ISD population, that is, 22% (24/109) in our study, or 16% (8/49)¹ and 19% (7/37)¹⁸ in previous studies. Even though these fractions are similarly high, our study is more representative because of the higher number of patients included. Cure rates were considerably lower for this subgroup than for the entire ISD population, that is, 67% (16/24) in our study, or 0% (0/8)¹ and 14% (1/7)¹⁸ in previous studies.

The better outcome in our study can be explained by a careful sonographic preoperative assessment of the urethral length and mobility. Over 10 years ago, tape insertions did not account for individual urethral lengths but followed Ulmsten's recommendation with an incision at 1 cm from the external urethral orifice.¹⁷ Furthermore, urethral mobility was determined by clinical vaginal examination under stress condition, but not by sonographical LDM, vertical bladder neck descent,¹⁹ or Q-tip angle measurements.¹³

We found that proper tape position was least critical for ISD patients with a hypermobile urethra, but was crucial for ISD patients with a hypomobile urethra. For this latter subgroup, shorter tape-urethra distances, ideally between 2.5 and 3.5 mm, that is, below the target distance of

3-5 mm, and tape positions more toward the mid-urethra resulted in higher cure rates. This can be explained by the proposed mechanism of action of TVTs. TVTs achieve continence by a dynamic transient compression/kinking at the high pressure zone of the urethra during straining.¹¹ A normo- or hypermobile urethra moves toward the TVT during an abdominal increase of pressure and allows this kind of interaction. But for a nearly immobile, rigid urethra the tape already initially needs to be positioned at the site of action to mechanically stop urine leaking. Therefore, tape localization toward the mid-urethra (high pressure zone) and closer to the urethra seems to be required for a successful treatment of ISD patients with a hypomobile urethra. In agreement with our findings, high cure rates (90%; 45/50) for ISD patients with a fixed urethra were also achieved by adjustable sling insertions that allowed a tape positioning closer to the urethra.²⁰ Likewise, also inelastic slings appear to be successful to treat ISD patients because accurate tension can be applied.²¹ While the cured/improved rate for these tapes was 87.4% (216/247),²¹ results from randomized controlled trials are so far missing. Interestingly, for our investigated ISD subpopulation, these shorter tape-urethra distances did not lead to higher complication rates, particularly not to urinary retention due to overcorrection after sling insertion. We attribute these findings to the special nature of the rigid, immobile ISD urethra. This is in contrast to “normal,” non-ISD urethras where patients with a tape-urethra distance <3 mm were more likely to have voiding dysfunction and required tape mobilization or sling incision.^{15,16}

Similar to our study, treatment with TOT also showed that the combination of ISD and urethral hypomobility had a

lower cure rate than ISD and hypermobility (56.3% [9/16] vs. 82.3% [14/17]).²² However, in another prospective study investigating patients with ISD, TVTs were found to be preferred over TOTs, with cure rates for TVT versus TOT of 79% (53/67) versus 55% (39/71).⁴ The different anchoring of these tapes results in a ventrocaudal, horizontal (TOT) or a ventrocranial, vertical (TVT) pulling direction during straining,^{11,23} and consequently, the important zone of the immobile urethra can be better supported by a TVT than by a TOT. Complication rates for patients with ISD were similarly high as previously reported for all SUI patients.²⁴

A possible study limitation is that the measurement of urethral closure pressure depends on the type of catheter. Comparative studies with microtip, air-charged, or water-perfusion catheters showed that all three methods were reliable, but that measurements between catheters were inherently different. Therefore, the percentage of patients with ISD (MUCP \leq 20 cm H₂O) in a given population depends on the measuring system. Standardization on how to exactly perform urodynamics for the identification of ISD is highly desired.²⁵

5 | CONCLUSIONS

Therapeutic success rate after TVT insertion was lower for ISD patients than for the entire population with SUI. The reduced cure rates could be attributed to the small ISD subgroup with a low urethral mobility. But even in this patient group, surgery was successful for tape positions slightly closer to the urethra, at 2.5–3.5 mm distance, and more toward 1/2 of the urethral length, that is, outside the proposed target tape position for the entire SUI population. A prospective study with a careful preoperative assessment to direct optimal TVT placement may result in better cure rates for ISD patients with a hypomobile urethra.

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