

# Intraoperative maximal urethral closing pressure measurement: a new technique of tape tension adjustment in transobturator sling surgery?

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## ABSTRACT

*Purpose:* Tape tension adjustment is an essential procedure in mid-urethral sling surgery. The goal of this study was to determine if intraoperative maximal urethral closing pressure (MUCP) elevation could be used as a reference value for adequate tape tension adjustment and predict transobturator (TOT) sling surgery outcome.

*Materials and Methods:* A prospective study was performed using MUCP measurements just before tape insertion and just after tension adjustment during surgery. Clinical data including preoperative urodynamic results were collected. The cure rate was determined by questionnaire. Patients were divided into two groups. The MUCP elevation group included patients with a MUCP elevation of more than 10 cmH<sub>2</sub>O before tape insertion; the others were regarded as the non-elevation group. The cure rate and pre- and postoperative clinical variables were compared between the two groups.

*Results:* A total of 48 patients had TOT surgery. The MUCP elevation group (n=19) and the non-elevation group (n=29) were similar with regard to patient characteristics and the preoperative parameters including age, mixed incontinence prevalence, Q-tip angle, peak flow rate, MUCP and the valsalva leak point pressure (VLPP). The mean follow-up period was nine months. The cure rate was significantly higher in the group with MUCP elevation than in the non-elevation group (84% vs. 52%,  $p = 0.02$ ). There was no significant difference in the mean postoperative peak flow rate between the two groups and there was no retention episode.

*Conclusions:* MUCP elevation of more than 10 cmH<sub>2</sub>O just after tape insertion was a prognostic factor.

*Key words:* urinary incontinence; suburethral slings; treatment outcome; urodynamics

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## INTRODUCTION

In 1996 a new surgical technique called the tension-free vaginal tape procedure was introduced by Ulmsten for stress urinary incontinence (SUI) (1). This procedure has become popular for treating SUI. Many studies have reported on a long-term success rate of more than 80% using both objective and subjective assessments (2,3). Although the success rate of the mid-urethral sling is high, there are also many failed procedures. Therefore, identifying the factors that are associated with persistent SUI after surgery is extremely important. Though controversial, the low valsalva leak point pressure (VLPP), low maxi-

mal urethral closing pressure (MUCP), the presence of intrinsic sphincter deficiency (ISD), presence of mixed incontinence, and the presence of a high grade cystocele are thought to be important prognostic factors (4,5).

However, among the studies on the prognostic factors, there is no study on the tape tension adjustment during surgery as a possible prognostic factor. Recently, the tape shortening technique using clips showed a 60-70% success rate in patients with recurrence after a sling operation (6,7). These studies suggest the importance of tape tension in sling surgery. In addition, a tension adjustable sling system, such as the Remeex readjustable sling, was

developed and widely used for repair of SUI (8). Therefore, providing the proper tension during surgery to render the patient continent, is now a focus of study.

Tape tension adjustment is essential for mid urethral sling surgery. However, there have been no methods developed to evaluate the degree of tape tension during surgery. In addition, there is no consensus on the appropriate amount of tension. The amount of tension adjustment has occasionally been determined by the subjective judgment of the surgeon.

We hypothesized that tape tension would influence urethral pressure, which could be measured as the MUCP level in urodynamic testing.

The goal of this study was to determine whether MUCP changes influence the surgical outcome. The MUCP changes were studied before and after placement of the tape and the outcomes were assessed as potential prognostic factors of TOT surgery.

## MATERIALS AND METHODS

From October 2007 to November 2008, the MUCP was prospectively measured just before and after tape insertion in the operating room. A single surgeon performed all TOT operations. The preoperative protocol included a history and physical examination, urinalysis, urine culture, uroflowmetry, PVR urine measurement, Q-tip test, and multichannel urodynamic studies. Urethral hypermobility was defined as when the angle of Q tip test was more than 30 degrees. Written consent was obtained from all patients.

Patients were included in the study if they were female with SUI or MUI (mixed urinary incontinence) and older than age 18. Patients were excluded if they had any urinary tract infection, malignancy, or were pregnant.

TOT procedures were performed as follows. The procedures were performed under spinal anesthesia. After incision and minimal dissection of the vaginal wall, a 6Fr two-channel flexible UPP catheter was inserted to measure the MUCP using a multichannel urodynamic study instrument (Medtronic Inc., Minneapolis, MI, USA). Then, after removal of the catheter, Transobturator tape (Monarc) needles were inserted through out-in technique. After fill-

ing the bladder with 250 mL physiological saline, cystoscopy was performed with the needles still in place.

After cystoscopy examination, a Monarc needle was connected to tape and pulled outside of the previous insertion site. The tension of the tape was adjusted and the catheter was re-inserted to measure the MUCP again. All measurements were completed and the vaginal wound was closed. Operator was blinded to intraoperative MUCP results and did not adjust the tension of the tape after second MUCP measurement.

Patients were discharged from the hospital the morning following the procedure, and were followed up with at one, six, and 12 months and then every year thereafter. The follow-up evaluation included a clinical history, physical examination with a stress test, uroflowmetry, and post-void residual (PVR) measurement.

Cure of incontinence after the procedure was defined as the absence of subjective leakage after coughing, laughing, or other abdominal-straining circumstances, and as the absence of objective leakage on stress cough tests when the patients felt a normal voiding sensation and other term was defined according to recent report (9).

All other cases were considered to be failures. The patients were divided into two groups by the change in the MUCP, i.e. the MUCP elevation group was defined as patients in whom the MUCP was elevated more than 10 cmH<sub>2</sub>O after insertion of the tape compared to before insertion of the tape; the non-elevation group was shown by no change or elevation less than 10 cmH<sub>2</sub>O. Cure rate in the MUCP elevation group was compared to the non-elevation group. In addition, the MUCP changes were compared in patients who had successful procedures and patients who had failed procedures to determine whether it was a possible predictive factor.

Statistical analysis was performed using the Student t-test for continuous data, as well as Fisher's exact test and the chi-square test. Variables that had a p-value less than 0.05 in the univariate analysis were included in the multivariate logistic model. A 5% level of significance was used for all statistical testing and all statistical tests were 2-sided. The statistical analyses were performed using SPSS® 11.0.

**RESULTS**

**1. Patient demographics**

A total of 48 patients, between 32 and 77 years of age (mean 50.3), underwent mid urethral sling surgery with the TOT technique by a single surgeon. No difference in the clinical characteristics was observed between the MUCP elevation group (n = 19) and the non-elevation group. Age, prevalence of mixed urinary incontinence, urethral hypermobility, peak flow rate, preoperative MUCP and leak point pressure were not significantly different between the two groups (Table-1).

ence in the group with a failed procedure (from 40 ± 18 cmH<sub>2</sub>O to 42 ± 22 cmH<sub>2</sub>O) (Figure-2).

**3. Complications**

De novo urgency or urge incontinence was present in one patient in the group with the MUCP elevation group and in seven patients in the non-elevation group. The bladder irritation symptoms were more severe in the MUCP elevation group; however, this difference was not significant. The postoperative peak flow rate and PVR was not significantly different in comparisons between the two groups. No patients developed urinary retention (defined as

**Table 1 - Preoperative clinical parameter between elevation group and non elevation group.**

	MUCP elevation group	Non elevation group	p- value
No. of patients	19	29	
Mean age (years)	49.7 ± 8.7	50.7 ± 9.9	0.72
Prevalence of urgency (%)	32	46	0.06
Prevalence of urge incontinence (%)	31	35	0.56
Prevalence of urethral hypermobility (%)	69	52	0.06
Prevalence of detrusor overactivity (%)	11	14	0.15
Mean MUCP (cmH <sub>2</sub> O)	60 ± 24	66 ± 33	0.16
Mean VLPP (cmH <sub>2</sub> O)	100 ± 15	95 ± 25	0.10
Mean peak flow rate (ml/sec)	25	26	0.70

MUCP: maximal urethral closing pressure; VLPP: valsalva leak point pressure

**2. MUCP changes and cure rate**

The overall cure rate was 65% (n = 35) and the mean follow-up period was nine months (6-15 months). The MUCP was elevated significantly from 36 ± 17 cmH<sub>2</sub>O (before placement of the tape) to 42 ± 18 cmH<sub>2</sub>O (after placement of the tape) in all patients (p = 0.04). The MUCP was significantly elevated in the MUCP elevation group (from 32 ± 15 cmH<sub>2</sub>O to 51 ± 17 cmH<sub>2</sub>O) but not in the non-elevation group (from 40 ± 18 cmH<sub>2</sub>O to 35 ± 16 cmH<sub>2</sub>O).

The overall cure rate was significantly higher in the MUCP elevation group compared to the non-elevation group (84% vs. 52%) (p = 0.02) (Figure-1).

In the group that was cured, the MUCP increased from 34 ± 17 cmH<sub>2</sub>O to 41 ± 16 cmH<sub>2</sub>O after placement of the tape; however, there was no differ-

PVR greater than 100 mL or did not void) or vaginal erosion during the follow-up period (Table-2).

**DISCUSSION**

Since tension-free vaginal tape has been introduced and used widely, many clinical prognostic factors have been reported including ISD, low VLPP, presence of cystocele, and mixed incontinence (4,5). However, there has been little attention focused on the tension of the tape during surgery and the prognostic significance of the tape tension on the surgical outcome.

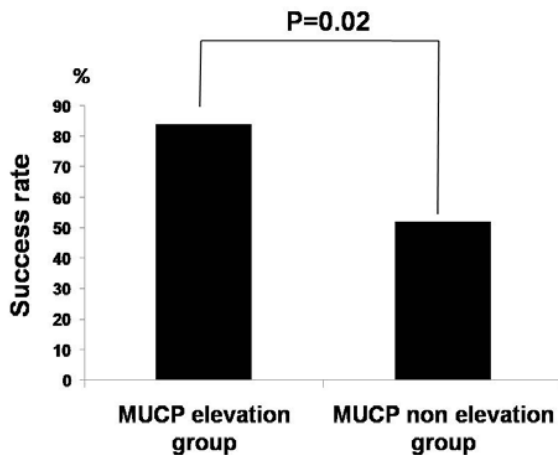
Initially, many surgeons thought it was unnecessary to provide tension on the tape. This was because the mechanism of the mid-urethral sling was

**Table 2 - Postoperative clinical parameter between MUCP elevation group and non elevation group.**

	MUCP elevation group	Non elevation group	P value
Success rate (%)	84	52	0.02
Mean MUCP change (cmH <sub>2</sub> O)	19 ± 16	5 ± 17	0.03
No. of patients with de novo urgency and/or urge incontinence	1	7	0.17
Mean peak flow rate (mL/sec)	18.2 ± 8.8	19.7 ± 9.6	0.52
Mean post void residual (mL)	24 ± 29	29 ± 25	0.46
Episode of Urinary retention	0	0	
Episode of vaginal erosion	0	0	

MUCP: maximal urethral closing pressure

**Figure 1 - Comparison of cure rate between MUCP elevation group and non elevation group.**

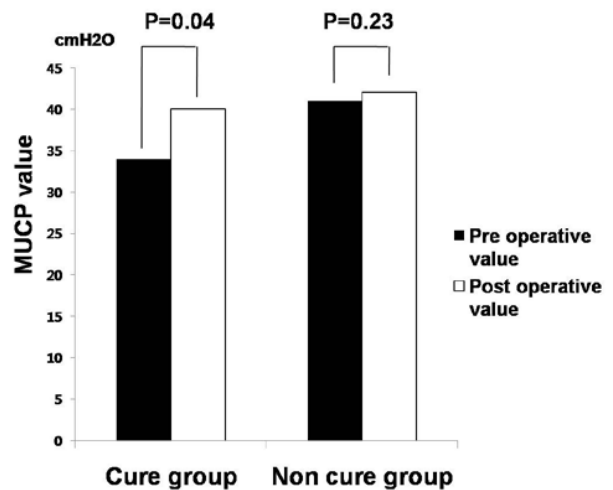


The overall cure rate was significantly higher in the MUCP elevation group compared to the non elevation group (84% vs. 52%) ( $p=0.02$ ).

thought to be based on collagen fibers growing into the tape, which would then fix the tape with mid-urethral tissue rather than tension on the urethra (10).

However, with more experience, many surgeons thought proper tension was needed in the insertion of the tape and that the tension was associated with the surgical outcome. In the case of failed prior mid-urethral sling placement, the tape shortening technique, which shortened the tape to give more tension, had a 60-70% success rate (5-7). In addition, the Remeex system that allows for tape tension adjustments after surgery was introduced and widely

**Figure 2 - The comparison of MUCP change between the cure group and non cure group.**



The MUCP increased significantly in the group that was cured ( $p=0.04$ ); however, there was no difference in the group with a failed procedure ( $p=0.23$ ).

used (8). The latter two methods were based on the concept that tape tension would produce positive outcomes on continence after sling surgery. Good results using these methods suggest the importance of tension adjustment. Although the tension of the tape has been accepted as an important factor, there has been no study addressing the measurement of the tension and its association with patient outcome.

As there is no standard method of tape tension adjustment, it is usually performed in accordance with the surgeon's experience and feeling. Some surgeons use the surgical scissors or right

angle clamp between the tape and urethra and others used a bechop clamp to fold the middle part of tape.

Therefore, the purpose of this study was to determine whether tape tension influences surgical outcome and to determine the reference value of proper tension adjustment. We hypothesized that tape tension would influence urethral pressure, which could be measured as the MUCP level in urodynamic testing. The degree of tension was assumed by the change in MUCP before and after placement of the tape using urodynamic studies in the operating room.

The results of this study showed that patients with an elevated MUCP had a higher cure rate compared to patients without an elevated MUCP. An elevated MUCP above 10 cmH<sub>2</sub>O, after placement of the tape, was associated with a good outcome. Therefore, this factor might be used to help predict patient outcome.

In the non-elevation group, there were patients who showed a decrease in MUCP after tape implantation. So, the mean MUCP was slightly changed.

Similarly, one study reported significant postoperative changes of the MUCP (11). However, another study reported no difference in the MUCP between pre- and post-surgery measurements and no relationship between the outcome of surgery and the UPP (urethral pressure profile) parameters (12). However, in that study, although routine resting UPP had no added value, the postoperative MUCP was also significantly higher in patients with successful outcomes compared to those that had failed surgery (12).

Similarly, the results of this study showed that the mean postoperative MUCP did not differ between patients with successful procedures and failed procedures. The MUCP was decreased in some cases, which made the mean value more similar in the two groups. However, the MUCP was significantly increased in the group with a successful outcome. These findings suggest that the degree of increase in the MUCP rather than the absolute value is the important factor to evaluate during surgery.

The limitations of this study include the following. First, only the UPP and not the URP was measured. The URP may reflect the tension applied to the urethra and further study may show that the value of the URP is an important prognostic factor.

In addition, the cut level of 10cmH<sub>2</sub>O was decided by an analysis that showed a significant difference between the two groups; however, additional studies with more patients are needed to determine the optimal cut-off level.

The patients with MUCP elevation would be expected to have more obstructive symptoms; however, there was no difference in the peak flow rate or residual urine and irritation. One possible explanation is that there was no severe tension that caused residual urine or decreased uroflow in the two groups; even in the group with MUCP elevation. In addition, the number of patients that had urgency or urge incontinence was relatively small.

Although the clinical parameters between the two groups were not significantly different, the prevalence of urinary urgency (32% compared to 46%) was higher in the non-elevation group, and this difference might be clinically relevant.

However, p-value was 0.06. Also, the prevalence of urge incontinence and detrusor overactivity in the urodynamic study were similar between the two groups.

The operator was aware of the baseline MUCP results, and this factor could influence the surgeon's decision during the tape adjustment. However, between the elevation group and the non-elevation group, there is no difference in baseline MUCP. Furthermore, MUCP results before and after placement of the tape were blinded to the operator, and those results did not influence the tape adjustment.

Finally, we performed the operation under spinal anesthesia. The estimated MUCP discrepancy between what was measured during the MUS procedure under spinal anesthesia and the real pressure generated during outcome assessment is unknown. Spinal anesthesia may affect pressure difference during sling surgery. The pressure difference may be a result of the anesthesia utilized. In one study (13), URP was decreased after spinal anesthesia. Similarly, our study showed that the baseline MUCP under no anesthesia is higher than preoperative MUCP under spinal anesthesia. However, the point of our study is that the MUCP difference prior to and after tape insertion is an important prognostic factor, and this is the indirect support needed for proper tension during tape implantation.

Despite these limitations, this preliminary study shows several implications. First, to our knowledge, there is no study about tape tension influencing sling surgery outcome. Our study showed that tape tension, which was indirectly measured by MUCP elevation, is an important prognostic factor. This study suggests that the intraoperative MUCP measurement should be a useful method for deciding on the appropriate tension adjustment and introduces a method for the quantification of the tension using urodynamic studies.

The feasibility of performing urethral closure pressures pre-and intraoperatively may be questioned. However, intraoperative UDS measurement is not so difficult and it may only take few more minutes. We are convinced of the usefulness of the UDS study because the other known prognostic factors, such as low VLPP, cystocele, mixed incontinence, and other factors are almost uncorrectable. However, MUCP elevation can be measured during surgery and can therefore be adjusted.

In this study, the tape tension was not adjusted when MUCP was not elevated more than 10cm-H<sub>2</sub>O. It is another topic and further prospective study will be needed to show the effect of tape tension on surgical outcome.

## CONCLUSIONS

The overall cure rate was significantly higher in patients with MUCP elevation compared to patients without MUCP elevation. The change in the MUCP might be a prognostic factor for patient outcome. The intraoperative MUCP measurement was a useful method for deciding on the appropriate tension adjustment.

## CONFLICT OF INTEREST

None declared.

## ABBREVIATIONS:

**ISD:** intrinsic sphincter deficiency  
**MUCP:** maximal urethral closing pressure  
**MUI:** mixed urinary incontinence  
**PVR:** post void residuals  
**SUI:** stress urinary incontinence

**TOT:** transobturator tape

**URP:** urethral retro-resistance pressure

**UPP:** urethral pressure profile

**VLPP:** valsalva leak point pressure

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