The urethral closure function in continent and stress urinary incontinent women assessed by Urethral Pressure Reflectometry

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THE FOUR ORIGINAL PAPERS ARE


INTRODUCTION

URINARY INCONTINENCE

Urinary incontinence (UI) is a major health issue among women with a prevalence of about 35 % (1). Most patients (70 – 75 %) have stress urinary incontinence (SUI) (leakage in connection with physical effort or exertion, or when sneezing or coughing) either pure or in combination with urgency or urgency urinary incontinence (leakage accompanied or immediately preceded by a compelling desire to void). Treatment modalities comprise conservative aids (lifestyle changes, pelvic floor muscle training and pharmacological therapy) while especially those with significant quality of life problems may require surgical therapy.

The underlying cause of SUI is insufficiency of the urethral closure mechanism during stress events (increased intra-abdominal pressure), whereby the bladder pressure exceeds the urethral pressure. However, the closure function in healthy women is not yet fully understood, neither is the dysfunction in SUI patients. Our incomplete knowledge relates to the complexity of the closure apparatus and inadequate assessment methods (2).

The currently accepted view of the urethral closure function is based on the concept of a urethral sphincteric unit and a support system (2;3).

The sphincteric unit is the main contributor to the permanent closure forces which express the urethral pressure during the resting state (where the abdominal pressure is at its resting value where no voiding and no pelvic floor contraction occurs) (2).

The support system is thought to be the main contributor to the adjunctive closure forces superposed during stress events thus increasing the urethral pressure when the abdominal pressure increases (2;4). As long as the urethral pressure exceeds the abdominal pressure urinary leakage is prevented. Other factors of importance to the closure function are the urethral inner softness, the urethral deformability and the sensory function (4;5).

The sphincteric unit has traditionally been assessed by urethral pressure measurements at one point or at several points along the urethra forming the urethral pressure profile (UPP). The support system has been assessed by the degree of bladder-neck or urethral mobility during stress events measured by the Q-tip test, ultrasound, video-cysto-urethrography and magnetic resonance imaging (MRI) (6;7).

The urethral deformability, the inner softness, and the sensory function have not been conceptualized into measurable parameters.

Due to artifacts and lack of standardization, the conventional methods for assessing the sphincteric unit and the support system have been unable to separate continent and SUI women or measure the severity of the disease. Consequently, we have no reliable clinical parameters for qualitative or quantitative purposes or to detect changes after intervention (8-11).

THE URETHRAL PRESSURE REFLECTOMETRY (UPR)

The urethral pressure reflectometry (UPR) is a method for simultaneous measurement of pressure and cross-sectional area (CA) in the urethra (12). It meets the requirements needed for investigation of pressure in a collapsible tube such as the urethra (13) as only a thin, small, light and flexible polyurethane bag that does not distend or straighten the urethra is inserted. Measurements are not affected by urethral movement; thereby artifacts due to catheter or transducer displacement are eliminated. Hence, UPR circumvents the problems encountered with conventional methods.
The obtained parameters are the urethral opening pressure (the pressure needed to just open the collapsed urethra (13)), the closing pressure, the opening and closing elastance, and the hysteresis, which are sound physical parameters that have previously shown to be of qualitative and quantitative value (12;14). These parameters can be obtained while resting or squeezing, in the supine and erect positions, with high accuracy and test retest reproducibility (15).

OBJECTIVES
MAIN OBJECTIVE
To investigate the urethral closure function by means of the UPR technique in SUI and continent women while resting and during intra-abdominal pressure increase, and to assess if the Tension-Free Vaginal Tape (TVT) operation induces significant changes.

SPECIFIC OBJECTIVES
The main objective was subdivided into the following specific objectives:
- To investigate if the UPR parameters while resting and squeezing change after TVT (study I)
- To develop the UPR technique to allow fast measurements during intra-abdominal pressure increase (studies II and III)
- To assess the urethral closure function by means of the new UPR technique during intra-abdominal pressure increases by straining (pushing down) in SUI and continent women (study III)
- To investigate if the new UPR parameters change after TVT (study IV)

MATERIALS AND METHODS
THE STUDY POPULATIONS
Study I and IV
Twenty-two women with bothersome urodynamically proven SUI scheduled for a TVT operation were consecutively recruited via the outpatient clinic.

Subjects were excluded if they had pelvic organ prolapse (POP) stage 2 or greater, previous surgery for SUI or POP, hysterectomy within the last year before enrolment, detrusor overactivity on filling cystometry, intake of anti-muscarinic drugs within the last 3 months, overt neurological diseases, signs of lower urinary tract infection on urine dipstick, or were pregnant.

Study II
25 SUI and 8 continent women were included. Inclusion criteria were: women on whom UPR had been performed by the step-wise technique and the continuous technique within the same session (in other studies). The participants were recruited via the outpatient clinic and a clinical trial website for investigation in previous studies.

Study III
SUI women
Twenty-six women with bothersome urodynamic proven SUI were recruited consecutively from the outpatient clinic. Exclusion criteria were the same as in study I and IV.

Continent women
Ten continent volunteers with a negative cough stress test and an International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) score of 0 were consecutively recruited via a clinical trial website.

METHODS
All methods and terminology conform to the recommendations of the International Continence Society (ICS) unless otherwise stated. The UPR technique is not described in the ICS standardization report.

In addition to the UPR measurements, the pre- and postoperative assessment in study I and IV, and the assessment in study III included comprehensive medical history, ICIQ-SF, pelvic examination, filling cystometry, uroflowmetry, post-void residual urine measurement, cough stress test, urine analysis, pad-weighing test (2 x 24 hours), bladder diary (2 days), incontinence episode diary (7 days), ultrasound assessment and UPR measurements.

ICIQ-SF: This validated questionnaire was used to assess SUI severity and impact on quality of life, and to detect alterations after TVT operation. Minimal overall score is 0 and maximum 21.

Filling cystometry (Duet Logic, Mediwatch, Rugby, UK or MMS Solar Gold, MEQ, Enschede, the Netherlands) was undertaken using two 5 F transurethral catheters, one for filling the bladder and one for pressure measurements, and a fluid filled rectal catheter for estimation of abdominal pressure. With the patient seated, saline was infused at a medium filling rate (50 ml/min), and the diagnosis of urodynamic stress incontinence was based on the detection of urinary leakage while coughing in the absence of detrusor activity.

Uroflowmetry (Urodyn 1000, Mediwatch, Rugby, UK) was carried out in full privacy with the patient having “a normal desire to void”.

PVR was measured immediately after the micturition using a bladder scanner (Verathon Bladder Scanner BVI 9400, Bothell, WA, USA).

Cough stress test (five forceful coughs) was carried out in the standing position after inserting 150 ml of saline into the bladder via a catheter (10F).

The 2-day bladder diary included records of incontinence episodes, liquid intake, the times of micturitions and voided volumes.

In the 7-day incontinence diary the patient noted every incontinence episode in seven consecutive days.

3D and 4D perineal ultrasound (Voluson E8, GE Medical Systems, Zipf, Austria) was used as biofeedback to ensure strain without voluntary contraction of the pelvic floor muscles.

The TVT procedure (Gynecare, Division of Ethicon and Johnson & Johnson, Somerville, NJ, USA) was carried out using the technique described by Ulmsten et al. (16) under local anesthesia, with no concomitant surgical procedures.

UPR MEASUREMENTS
UPR methodology and equipment; the step-wise technique
UPR has previously been described in details (12). The equipment consists of an empty, thin, distensible polyurethane bag placed in the urethra and connected to a pump and an acoustic transmitter via a PVC tube. The polyurethane bag is inflated by pumping air into it, thereby increasing the pressure and distending the bag. The CA within the bag, and thus the urethra, can then be measured with acoustic reflectometry. Minimal measureable CA is 0.4 mm² and maximum CA is approximately 16 mm². Pressure within the bag can be applied and measured from 0 to 200 cm H2O.

The patient was placed in the supine (lithotomic) position, and the bladder was emptied with a catheter (10F). The UPR polyurethane bag was placed in the urethra using a Ch. 5 baby feeding tube as guide wire, and the PVC tube was anchored to the urethral meatus using Duroderm® plaster. To ensure correct placement of the bag, it was inflated and deflated.
Measurements were conducted while resting and squeezing, in the supine (lithotomic) position and thereafter in the standing position. All measurements were conducted twice and the average of each parameter calculated for use as a study result.

**Measurement while resting**
The woman was instructed to relax during the measurements. Using the pump, the pressure was raised in steps of 5 cm H\textsubscript{2}O from 0 cm H\textsubscript{2}O and until the bag was completely open (Figure 2). The pressure was then decreased in steps of 5 cm H\textsubscript{2}O until 0 cm H\textsubscript{2}O. Each pressure step lasted 3 seconds, during which CA measurements within the bag were recorded. The whole procedure was repeated after a 15 sec pause.

**Figure 1: The UPR measurement**

![Figure 1](image)

1 a–c: the distance in centimeters on the x-axis is the distance along the length of the bag and thus the urethra. The high-pressure zone is seen as the point of minimal cross-sectional area at any given pressure, here shown at three different pressure levels: 10, 65 and 105 cm H\textsubscript{2}O. This represents the component of the urethral closure function producing the greatest pressure on attempting to resist opening of the urethra. The minimal cross-sectional area values at each pressure level were plotted on a graph shown in 1 d.

HPZ: high-pressure zone
Measurement while squeezing
The woman was instructed on how to squeeze i.e., voluntary contraction of the pelvic floor without use of the abdominal muscles, and it was ensured that she squeezed correctly. Measurements were conducted with pressure steps of 10 cm H$_2$O until the bag was completely open, and the patient was asked to squeeze at each pressure plateau and to relax in the pauses when the pressure in the bag increased to the next pressure plateau (Figure 3 A). Squeezing measurements were conducted only while inflating the bag. The whole procedure was repeated after a 15 sec pause.

UPR parameters
The CA was measured at every millimeter along the length of the bag, producing 10 CA profiles per second. At each pressure-step, one mean curve was produced. Profiles at three different pressure levels are displayed in Figure 1 a–c. We only evaluated measurements from the high-pressure zone (HPZ) of the urethra, defined as the position in the urethra where the CA was smallest at a given pressure. The HPZ CA at each pressure level was plotted on a graph shown in Figure 1 d.

Figure 2 shows a pressure/CA graph with two traces: one during increasing pressure (inflation of the polyurethane bag) and one during decreasing pressure (deflation of the bag). The graph shows the opening pressure ($P_o$), the closing pressure ($P_c$), the opening and closing elastance and the hysteresis. The five parameters are defined in the figure.

During squeezing, only $P_o$ and opening elastance were measured.

Modification of the UPR technique
When the pump that controls the pressure in the polyurethane bag is active the noise from the pump may interfere with the acoustic reflectometry measurements. The examination has therefore been made step-wise, which implies that the CA in the bag was measured at a given pressure level, then the pressure was increased to a new level and the CA was measured once again as described above. Such an examination takes at least 90 seconds which is longer than most women can squeeze or strain. Therefore, to measure during squeezing and straining, the squeeze or strain has to be repeated at each pressure level (Figure 3 A). This may lead to inaccuracy as the squeeze or strain may be of different strength each time and the woman may be fatigued.

A full measurement can be completed during only one squeeze or strain if the CA is measured during a continuous pressure change in the polyurethane bag (Figure 3 B).

The UPR technique has been modified so that measurements can now be performed within a time span of seven seconds, hence, measurements during pressure changes are possible. This new “fast” technique is designated “the continuous technique”.

UPR methodology and equipment; the continuous (“fast”) technique
The equipment consists of a computer with an integrated pressure recorder which is connected to a probe (containing an acoustic transmitter and a microphone), a 12 ml syringe and a polyurethane bag via a PVC tube.

With the woman supine the UPR polyurethane bag was inserted in the urethra as described above. Via the syringe air was pumped into the bag thereby increasing the pressure and distending the bag. The syringe was handled by hand. The CA along the length of the bag, and thus the urethra, was measured continuously with acoustic reflectometry, and the $P_o$ was obtained.

Measurements were conducted while resting and during increased intra-abdominal pressure by straining in the supine position.

The abdominal pressure ($P_{ Abd}$) was continuously measured with an air filled balloon catheter (T-dock, Wennonah, NJ, USA) in the rectum.

Measurements while resting
The woman was instructed to relax during the measurements. The pressure in the bag was increased from 0 cm H$_2$O to 200 cm H$_2$O within seven seconds by pressing the piston steadily down and decreased by pulling the piston back again within seven seconds, and the resting urethral opening pressure ($P_{o-rest}$) was recorded.
Figure 3: The step-wise technique and the continuous technique

Figure 3: A shows the pressure inside the polyurethane bag during squeezing using the step-wise technique. The subject squeezes at each pressure level (indicated with an arrow). B shows the pressure and the corresponding minimum cross-sectional area from the squeezing measurement in A. The opening pressure and elastance (slope of the curve) are indicated. C shows a squeezing measurement using the continuous ("fast") technique. The subject holds the squeeze during the pressure increase in the polyurethane bag. D shows the pressure and the corresponding minimum cross-sectional area measured with the continuous technique.

Figure 4: UPR measurements during intra-abdominal pressure increase

Figure 4 a-c: UPR measurements from an SUI woman obtained at three different levels of intra-abdominal pressure. The opening pressures are marked with dots. 4 d: Pressuregram with opening pressures obtained from 10 measurements at different levels of increased intra-abdominal pressure, including the opening pressures from the Figures 4 a-c. The linear regression line of the data was conducted and APIR (slope of the line) and intercept with the y-axis were found. The HPZ pressuregram-LPP is defined as the intercept with the equilibrium line of x=y and can be read from the pressuregram or calculated. The urethral opening pressure at 50 cm H2O abdominal pressure (P_{o Abd 50}) is indicated.

UPR: Urethral pressure reflectometry, HPZ: High-pressure zone, APIR: Abdominal to urethral Pressure Impact Ratio, LPP: leak point pressure.
Measurements during increased intra-abdominal pressure
The woman was instructed to increase the abdominal pressure by straining (pushing down) 10 times at different intensities (to obtain measurements at a broad spectrum of abdominal pressures) and keep the pressure for at least seven seconds. At each strain the pressure in the bag was increased from 0 cm H2O to 200 cm H2O within seven seconds and decreased again within seven seconds. The P0 and the simultaneous P_{Abs} (by the T-dock catheter in the rectum) were recorded.

The UPR parameters obtained by the continuous technique
The related values of P0 and P_{Abs} at the 10 different abdominal pressures were plotted into a HPZ abdomino-urethral pressuregram (Figure 4). Linear regression of the values was conducted, and the slope of the line and the intercept with the y-axis estimated (17).

The slope expresses the effect of the abdominal pressure increase on the urethral pressure and is designated “Abdominal to urethra Pressure Impact Ratio” or “APIR”. The intercept, y-axis, is a mere mathematical parameter as the clinical abdominal pressure will never be 0 cm H2O.

The equation of the HPZ pressuregram line:
\[ P_0 = (APIR \times P_{Abs}) + \text{intercept}_{y-axis} \]

An APIR < 1 implies that the pressuregram line intersects the equilibrium line and that the HPZ pressuregram-LPP can be calculated. An APIR ≥ 1 implies that the pressuregram line does not intersect the equilibrium line at increasing abdominal pressure; the HPZ pressuregram-LPP is “infinite”.

DEFINITION OF CLINICAL OUTCOME
Studies I and IV
Subjective cure: no reported incontinence on ICIQ-SF, improvement: ≥ 50% decrease in post-operative ICIQ-SF score (compared to pre-operative score), and failure: < 50% decrease in post-operative score.

Objective cure: negative stress test and < 5 g leakage at the pad test, improvement: a negative stress test and ≥ 5 g leakage at the pad test, and failure: leakage at stress test.

STATISTICAL CONSIDERATIONS
Power calculations
Study I
Before the study, power calculations showed that 11 patients were needed (power: 90%, two sided P-value 0.05) for the relaxing P0 for the statistical test to detect a difference after surgery, with the assumption of a clinically relevant increase of 5 cm H2O in the resting opening pressure. For the squeezing opening pressure, 19 patients were needed, assuming a clinically relevant change in the squeezing P0 to be 5 cm H2O (power: 90%, two sided P-value 0.05).

Study IV
Before the study, power calculations showed that 21 patients were needed (power: 90%, two sided P-value 0.05) to detect a 10% difference in APIR.

No power calculations were performed before study II and III.

Statistical methods
Studies I and IV
Data were tested with the paired t-test on Microsoft Excel software and presented as mean and standard deviation. A p value ≤ 0.05 was used to define significance in statistical comparisons.

Study II
The coefficient of variance (CV) was calculated as the standard deviation (SD) divided by the mean. The CV was presented in percent.

Studies III and IV
Linear regression of abdominal and urethral pressure data was conducted using the Microsoft Excel software (2007, Microsoft, Redmond, WA, USA).

Study III
Data were tested by the Mann-Whitney U test and presented as median and range (due to the small sample sizes). Correlations between parameters were tested with Spearman’s test. The Statistical Package for Social Sciences version 19 (SPSS 19, IBM, Armonk, NY, USA) was used. Confidence intervals for specificity and sensitivity of the Urethral Closure Equation were calculated using an exact binomial method using R ver. 2.14.1 (open source statistical program available from Comprehensive R Archive Network (CRAN)). Statistical significance was determined at p ≤ 0.05.

ETHICS
The study was approved by The Committees on Biomedical Research Ethics for the Capital Region of Denmark (H-B-2008-002), and informed consent was obtained from all participants.

RESULTS
STUDY I. UPR BY THE STEP-WISE TECHNIQUE BEFORE AND AFTER TVT
Patient characteristics are listed in Table 1. All patients had delivered vaginally only, except one who had had no vaginal deliveries but one caesarean section.

<table>
<thead>
<tr>
<th>Table 1: Demographic characteristics</th>
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<tbody>
<tr>
<td>n = 22</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>54</td>
</tr>
<tr>
<td>Parity</td>
</tr>
<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>Height (cm)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
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</tbody>
</table>

BMI: Body Mass Index

Median follow-up time was 160 days (range: 84—401 days). The subjective cure rate was 82% (18/22), the improvement rate 18% (4/22) and the failure rate 0%. The four improved patients all reported “leakage before reaching the toilet” (0-2 leakage episodes per week) interpreted as de novo urge. Objectively, 100% were cured. The number of incontinence episodes (24h), ICIQ-SF score, stress test and pad test all changed significantly after sur-
Surgery (Table 2). The mean maximum urine flow rate decreased from 31 to 18 ml/sec after surgery (p=0.0002) and the mean PVR increased from 12 to 24 ml (p=0.057).

There was no difference in demographic characteristics or incontinence severity before surgery between cured and improved patients.

The UPR parameters are presented in Table 3.

In the supine position, we found no change in the resting P₀ or Pᵥ after TVT. There was an 18% increase in the opening and closing elastance, respectively, with the patient resting. The hysteresis was unchanged.

The supine squeezing Pᵥ decreased 6 cm H₂O (10%) after surgery, with no difference between cured and improved patients. The supine squeezing opening elastance was unchanged after surgery.

In the standing position, the Pᵥ and P₀ and the opening elastance were unchanged, whereas the closing elastance increased by 11%. The hysteresis was unchanged. The squeezing Pᵥ and elastance did not change in the standing position after surgery.

### Table 2: Clinical outcome measures

<table>
<thead>
<tr>
<th>n = 22</th>
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<tbody>
<tr>
<td>Incontinence (number of episodes/24h)</td>
</tr>
<tr>
<td>ICIQ-SF (score)</td>
</tr>
<tr>
<td>Positive stress test (n)</td>
</tr>
<tr>
<td>Pad test (g/24h)</td>
</tr>
<tr>
<td>Maximum urine flow rate (ml/sec)</td>
</tr>
<tr>
<td>Post-Void Residual urine volume (PVR) (ml)</td>
</tr>
<tr>
<td>Weight (kg)</td>
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</tbody>
</table>

Mean values. ICIQ-SF: International Consultation on Incontinence Questionnaire Short Form.

### Table 3: UPR parameters before and after TVT

<table>
<thead>
<tr>
<th>n = 22</th>
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<tbody>
<tr>
<td>Supine resting</td>
</tr>
<tr>
<td>opening pressure (cm H₂O)</td>
</tr>
<tr>
<td>closing pressure (cm H₂O)</td>
</tr>
<tr>
<td>opening elastance (cm H₂O/mm²)</td>
</tr>
<tr>
<td>closing elastance (cm H₂O/mm²)</td>
</tr>
<tr>
<td>hysteresis (%)</td>
</tr>
<tr>
<td>Supine squeezing</td>
</tr>
<tr>
<td>opening pressure (cm H₂O)</td>
</tr>
<tr>
<td>opening elastance (cm H₂O/mm²)</td>
</tr>
<tr>
<td>Standing resting</td>
</tr>
<tr>
<td>opening pressure (cm H₂O)</td>
</tr>
<tr>
<td>closing pressure (cm H₂O)</td>
</tr>
<tr>
<td>opening elastance (cm H₂O/mm²)</td>
</tr>
<tr>
<td>closing elastance (cm H₂O/mm²)</td>
</tr>
<tr>
<td>hysteresis (%)</td>
</tr>
<tr>
<td>Standing squeezing</td>
</tr>
<tr>
<td>opening pressure (cm H₂O)</td>
</tr>
<tr>
<td>opening elastance (cm H₂O/mm²)</td>
</tr>
</tbody>
</table>

Mean (SD). UPR: Urethral Pressure Reflectometry. TVT: Tension-free Vaginal Tape

**STUDY II. THE UPR CONTINUOUS TECHNIQUE COMPARED WITH THE STEP-WISE TECHNIQUE**

Measurements by the continuous method were well tolerated by the women, easy to perform and could be conducted while resting and straining within 15 minutes all together.

The mean squeezing Pᵥ was 67 cm H₂O by the continuous technique and 64 cm H₂O by the step-wise technique, the difference was not significant (p=0.07). The mean squeezing opening elastance was significantly higher with the continuous technique compared to the step-wise technique. The CV of the squeezing Pᵥ was 6.5% while the CV of the squeezing opening elastance was 14.8%.

**STUDY III. UPR DURING INTRA-ABDOMINAL PRESSURE INCREASE IN SUI AND CONTINENT WOMEN**

Three women were excluded for various reasons; hence 25 SUI patients and 8 continent volunteers were included in the analyses. The two groups did not differ with respect to age, Body Mass Index or menopausal status, but the SUI women had had more vaginal deliveries (Table 4).

The median Pᵥ₀rest appears from Table 5. All SUI women had a Pᵥ₀₀rest ≤ 58 cm H₂O, while the continent women had Pᵥ₀₀rest between 43 cm H₂O and 95 cm H₂O.

The median APIR was 0.72 in SUI women and 1.05 in continent women (p=0.002), but the APIR did not separate SUI and continent women (Table 5). The APIR expresses the effect of the Pᵥ₀₀ increase on the urethral Pᵥ₀.
Of the SUI women, 23 had an APIR < 1 during abdominal pressure increase by strain and their median HPZ pressuregram-LPP was 100 cm H₂O (range 36-580 cm H₂O). The remaining two SUI women had an APIR > 1 resulting in an infinite HPZ pressuregram-LPP.

In 6 of the continent women the APIR was ≥ 1 resulting in an infinite HPZ pressuregram-LPP. The APIR was < 1 in the remaining two continent women resulting in HPZ pressuregram-LPP of 185 cm H₂O and 840 cm H₂O, respectively.

The median P₀-Abs 50 was 67 cm H₂O in SUI women versus 104 cm H₂O in continent women (p<0.0005) (Table 5). This parameter completely separated the two groups of women (Figure 5). The urethral Pₒ at abdominal pressures of 0, 100, 150, 200 and 250 cm H₂O were also calculated and showed significant differences between SUI and continent women.

When the P₀-Rest and the APIR were plotted into a scattergram the SUI women appeared in the lower left part of the scattergram while the continent women appeared in the upper right part (Figure 6). A line could be drawn that separated SUI and continent women. The equation of the line was found; the Urethral Closure Equation (UCE) line:

\[(2 * p * \sqrt{(0.02 * P₀-Rest)^2 + (1.2 * APIR)^2 * 0.5}) - 7.15\]

Sensitivity: 1 (Confidence interval: 0.86-1.0), specificity: 1 (Confidence interval: 0.63-1.0).

SUI women in the study all had negative results when inserting their values into the UCE, while all continent women had positive results.

### Table 4: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>SUI (n = 25)</th>
<th>Continent (n = 8)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53 [38 - 68]</td>
<td>50 [37 - 65]</td>
<td>0.12</td>
</tr>
<tr>
<td>BMI</td>
<td>27 [19 - 36]</td>
<td>28 [20 - 35]</td>
<td>0.69</td>
</tr>
<tr>
<td>Para, total</td>
<td>2 [1 - 3]</td>
<td>1 [0 - 2]</td>
<td>0.18</td>
</tr>
<tr>
<td>Vaginal deliveries</td>
<td>2 [0 - 3]</td>
<td>1 [0 - 2]</td>
<td>0.12</td>
</tr>
<tr>
<td>Caesarean sections</td>
<td>0 [0 - 1]</td>
<td>0 [0 - 2]</td>
<td>0.79</td>
</tr>
<tr>
<td>Post menopausal (per cent)</td>
<td>52%</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>Topic estrogen treatment (per cent)</td>
<td>20%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>ICIQ-SF score</td>
<td>15 [10 - 18]</td>
<td>0 [0 - 0]</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>


### Table 5: UPR measures while resting and during increased intra-abdominal pressure

<table>
<thead>
<tr>
<th></th>
<th>SUI (n = 25)</th>
<th>Continent (n = 8)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>P₀-Rest (cm H₂O)</td>
<td>40 [24 - 58]</td>
<td>68 [43 - 95]</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>APIR*</td>
<td>0.72 [0.35 - 1.05]</td>
<td>1.05 [0.46 - 1.31]</td>
<td>0.002</td>
</tr>
<tr>
<td>P₀-Abs 50 (cm H₂O)*</td>
<td>67 [46 - 83]</td>
<td>104 [85 - 151]</td>
<td>&lt;0.0005</td>
</tr>
<tr>
<td>Urethral Closure Equation*</td>
<td>-1.82 [-3.50 -0.05]</td>
<td>1.18 [0.32 - 2.98]</td>
<td>&lt;0.0005</td>
</tr>
</tbody>
</table>


The correlations between P₀-Rest, APIR, P₀-Abs 50 and the UCE results, and the clinical measures of ICIQ-SF, pad test and number of incontinence episodes per week were calculated (pooled data of continent and SUI women) (Table 6). P₀-Rest showed significant moderate negative correlation with pad test and number of incontinence episodes per week. P₀-Abs 50 and the UCE results showed highly significant strong negative correlation with ICIQ-SF, pad test and number of incontinence episodes per week.

Calculation of the receiver operating characteristic (ROC) curves showed the area below the curve (AUC) to be 1.0 for the measures P₀-Abs 50 to P₀-Abs 100, and for the UCE results.

Correlation tests on the pooled data showed that P₀-Rest significantly decreased with age (controlled for total number of deliveries) (r=-0.35, p=0.05) and with total number of deliveries (controlled for age) (r=-0.61, p<0.0005). APIR did not correlate with age (controlled for total number of deliveries) (r=-0.01, p=0.98) and was not demonstrated to significantly decrease with total number of deliveries (controlled for age) (r=-0.272, p=0.13).
STUDY IV. UPR DURING INTRA-ABDOMINAL PRESSURE INCREASE BEFORE AND AFTER TVT

The 22 women included were the same as included in Study I. One subject was excluded from analysis due to insufficient UPR tracing. Median age of the remaining 21 women was 54 years (range 38-69 years), median parity was 2 (range 1-3), and median Body Mass Index was 28 (range 20-36).

The subjective cure rate after TVT operation was 81% (17/21), the improvement rate 19% (4/21) and the failure rate 0%. The 4 improved patients all reported “leakage before reaching the toilet” (0-2 leakage episodes per week) which was interpreted as de novo urge. Objectively, 100% were cured. ICIQ-SF score, pad test, and number of incontinence episodes per week all decreased significantly after TVT.

The UPR results are presented in Table 7 and Figure 7. APIR increased in all subjects, and mean APIR increased from 0.70 to 1.37 (p<0.0001). Mean $P_{\text{o Abd 50}}$ increased from 66 to 85 cm H2O after TVT and mean $P_{\text{o Abd 100}}$ increased from 103 to 154.

When inserting $P_{\text{o rest}}$ and APIR into the UCE the result was negative in all patients before TVT. After TVT the UCE result had increased in all patients, with a mean increase of 2.96. The result increased to a positive value in 15 of the 21 patients. This was also reflected in the scattergram of $P_{\text{o rest}}$ and APIR where all patients moved upwards after TVT (Figure 8).

Preoperative $P_{\text{o rest}}$ and APIR, respectively, did not differ among cured and improved patients.
Table 7: UPR outcome measures

<table>
<thead>
<tr>
<th>n = 21</th>
<th>Before TVT</th>
<th>After TVT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{\text{rest}}$ (cm H$_2$O)</td>
<td>42.3 (8.2)</td>
<td>42.6 (8.6)</td>
<td>0.77</td>
</tr>
<tr>
<td>APIR</td>
<td>0.70 (0.21)</td>
<td>1.37 (0.43)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>$P_{\text{Abd 50}}$ (cm H$_2$O)</td>
<td>66.3 (9.6)</td>
<td>85.4 (18.4)</td>
<td>0.0001</td>
</tr>
<tr>
<td>$P_{\text{Abd 100}}$ (cm H$_2$O)</td>
<td>101.3 (21.4)</td>
<td>153.9 (39.3)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>UCE</td>
<td>-1.79 (1.06)</td>
<td>1.16 (2.09)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Mean (Standard Deviation), UPR: Urethral Pressure Reflectometry, TVT: Tension-free Vaginal Tape, $P_{\text{rest}}$: Resting urethral opening pressure, APIR: Abdominal to urethra Pressure Impact Ratio, $P_{\text{Abd 50}}$: Urethral opening pressure at 50 cm H$_2$O abdominal pressure, $P_{\text{Abd 100}}$: Urethral opening pressure at 100 cm H$_2$O abdominal pressure, UCE: Urethral Closure Equation.

DISCUSSION
The UPR technique has shown promising results when measurements are performed during resting and squeezing (12). In this PhD study the technique has been further developed to allow measurements during intra-abdominal pressure increase. Thus the studies were conducted partly by the traditional UPR technique and partly by the new (“fast”) technique and have resulted in new urethral parameters, which have gained new insight into the urethral closure function.

The urethral sphincteric unit as measured by the resting urethral pressure has been suggested to represent the permanent closure forces of the urethral closure function (4). UPR measurements showed a statistically significant difference between a $P_{\text{rest}}$ of 40 cm H$_2$O in SUI women and 68 cm H$_2$O in continent women. This is in accordance with data from Klarskov et al who found a $P_{\text{rest}}$ of 40 cm H$_2$O in SUI women and 72 cm H$_2$O in continent women (14). Despite the improved (decreased) variability observed using the continuous technique it does not allow separation of SUI and continent women. Earlier reports of resting urethral pressure measurements using UPP have shown an average MUCP of 39 cm H$_2$O in SUI women and 54 cm H$_2$O in continent women (2), however, with large overlap between groups.

The support system has traditionally been assessed by the bladder-neck mobility or the mid-urethral mobility.

According to the bladder-neck theory, the urethra and the bladder neck are compressed against a supportive layer of structures extrinsic to the urethra, the “Hammock”, during intra-abdominal pressure increase (18). A dysfunctional supportive layer with subsequent decreased resistance is supposed to cause bladder-neck hypermobility which is widely accepted to be associated with SUI (5;6).

According to the mid-urethral theory, the central urethral mobility rather than the bladder neck mobility is important to the continence function. Zacharin suggested “the suspensor mechanism” (a ligamentous complex including the pubo-urethral ligament) to limit the mid-urethral mobility by acting as a central fulcrum between the bladder and the external urethral meatus (19). Hence, when the bladder descends caudally during intra-abdominal pressure increase the urethra is subsequently compressed at its mid-point. Recently, dysfunctional mid-urethral support and subsequent mid-urethral hypermobility has been
reported to be strongly associated to SUI (20;21). Accordingly, dysfunctional mid-urethral support may cause insufficient mid-urethral pressure increase.

The present study indicates that the adjunctive closure forces, which include the urethral support (4), can be assessed by the APIR. APIR is defined as the slope of the HPZ pressuregram line and measures the impact of increase in $P_{\text{abd}}$ on the $P_o$. In all measurements the urethral HPZ was located at the mid-urethra. The finding of a median APIR of 0.72 in SUI women and 1.05 in continent women ($p=0.002$) confirms that the mid-urethral support and pressure is more important to the urethral closure function than the bladder neck.

The APIR values >1 cannot be due to mere compression of the urethra by neighboring structures; respecting the laws of physics only a mid-urethral kink as suggested by Zacharin (19) could induce such a high pressure increase (9). The exact anatomical basis of inefficient mid-urethral support and decreased APIR needs to be further investigated.

The urethral pressure increase during intra-abdominal pressure increase has in the literature been designated “pressure transmission ratio” (PTR) which is misleading as the urethral pressure is not transmitted from the abdomen, but builds up synchronously (9). The PTR has been reported for different parts of the urethra but never precisely for the HPZ. Some investigators have reported decreased values of mid-urethral PTR in SUI women compared to continent women (17;22), while other have found no difference (23).

The $P_o$ at a given $P_{\text{abd}}$ represents the resulting effect of the permanent and adjunctive closure forces at that particular $P_{\text{abd}}$. As an example $P_{\text{abd} 50\text{-}100}$ differed significantly in SUI and continent women and revealed an impaired closure function in SUI women already at this relatively low abdominal pressure level. The difference was so pronounced that SUI and continent women were completely separated (Table 5 and Figure 5).

$P_{o\text{-}\text{rest}}$ and APIR plotted against each other in a scattergram showed complete visual separation of SUI and continent women and allowed us to determine the UCE line: a threshold below which SUI occurred. When entering a woman’s values of $P_{o\text{-}\text{rest}}$ and APIR into the UCE, a negative result indicates a weak urethral closure function pointing towards SUI while a positive result indicates a stronger closure function. Supposedly, there is a grey area around the UCE line where the presence of SUI is dependent on the abdominal pressure level a woman is subjected to.

From the scattergram and the UCE it appears that both $P_{o\text{-}\text{rest}}$ and APIR contribute to the urethral closure function, and that women with low values of both parameters are more likely to experience SUI than women with high values of both parameters. This is in accordance with previous reports of MUCP and urethral support being largely independent predictors of SUI (24). In this study, all SUI women had a $P_{o\text{-}\text{rest}} < 60$ cm H$_2$O. The continent women who had a $P_{o\text{-}\text{rest}} < 60$ cm H$_2$O had an APIR > 1 hence it seemed that women with only one low parameter were able to compensate and remain continent if the other parameter was proportionally high.

Therefore, we suggest that the urethral closure function can be characterized by means of $P_{o\text{-}\text{rest}}$ and APIR. The inner softness is included in $P_{o\text{-}\text{rest}}$ and the urethral deformability is included in the resulting $P_o$ during intra-abdominal pressure increase and accordingly in the APIR. The elastance contributes to the resting closure function but is not comprised in the $P_{o\text{-}\text{rest}}$. We are aware that the urethral pressure represents the resultant contribution of a number of structures and hence provides no precise information of the origin of the pressure (25).

When looking at the ROC curve of $P_o$ at abdominal pressures between 50 and 100 cm H$_2$O and of the UCE, respectively, we found the AUC to be 1, which indicates optimal performance as diagnostic tests (26). To our knowledge, these are the first urethral parameters demonstrating to be robust qualitative and quantitative clinical parameters usable as diagnostic tests in SUI women (2;8;10).

$P_{\text{abd} 50\text{-}100}$ and the UCE results, respectively, showed stronger negative correlation with ICIQ-SF, pad test and number of incontinence episodes per week than did the $P_{o\text{-}\text{rest}}$, APIR, and earlier reported parameters obtained by conventional UPP method (8). $P_{\text{abd} 50\text{-}100}$ and the UCE are therefore quantitative SUI parameters and can be used as SUI severity measures.

$P_{o\text{-}\text{rest}}$ was negatively correlated with age and number of deliveries, respectively, which is in agreement with the reported average MUCP decrease of 15 cm H$_2$O per decade (27;28). Therefore, in the course of time and additional deliveries, respectively, a woman will move towards the left of the scattergram of $P_{o\text{-}\text{rest}}$ and APIR (i.e. towards a weaker closure function). Hence, these parameters potentially may be used to predict the occurrence of SUI in a particular woman following increased age or additional deliveries.

APIR did not decrease with age and was not demonstrated to significantly decrease with number of deliveries. This is in accordance with recent reports that levator ani avulsion caused by deliveries does not seem to significantly influence the mid-urethral mobility (29). However, it contradicts the earlier suggested notion that the urethral support is decreased after vaginal delivery (28) and the commonly held opinion that levator avulsions are related to SUI.

The mechanism of action behind the effect of TVT remains virtually unknown, and there is no robust parameter that has proven to change after intervention. We investigated if the UPR parameters could be used for this purpose.

Mean supine $P_{o\text{-}\text{rest}}$ was unchanged after TVT (paper I and IV) which is consistent with previous reports of supine resting urethral pressure measurements (30-34) and with biomechanical statements (9). Additionally, we found that $P_o$ was unchanged in the erect position, which to our knowledge is new information.

However, the supine opening elastance increased by 18% after TVT, which indicates that the TVT sling increases the resistance against dilation of the urethra and thus somewhat improves the closure function at the resting state. This increased resistance against opening, e.g., for urine flow, probably explains the decreased maximum urine flow rate observed after TVT placement in this study and in previous reports in the literature (35;36).

The hysteresis may reflect the urethral tissue fiber composition. Therefore, scar tissue formation with increased fibrosis after delivery (37) could induce hysteresis. In this study, the hysteresis was unchanged, indicating that the TVT did not induce major fibrosis. This is in accordance with previous reports of minimal inflammatory reaction at two-year follow-up after TVT operation (38).

APIR increased to levels of continent women (or higher) in all patients after TVT, which is in accordance with reports of decreased mid-urethral mobility after TVT (20;33;39-44). Hence, TVT may work by imitating the natural mid-urethral fixation (19) thereby enhancing the mid-urethral support with subsequent decreased mid-urethral mobility and increased $P_o$ during stress.
The increase in APIR to values >1 is suggested to arise by the same mechanism as discussed previously: kinking of the urethra during stress. Mid-urethral kinking after TVT has been visualized by ultrasound and MRI in several studies (20;33;39-44).

Many investigators reported an increased PTR after TVT (31;33;45), while some did not (32;46). The heterogeneity of those results is not surprising as PTR has low reproducibility (3;10).

As TVT virtually only improved the APIR, women with a low pre-operative P_{0_{-abdominal}} did not restore the normal urethral closure mechanism but regained continence by an enhanced APIR which was then able to compensate for the low P_{0_{-abdominal}}. This was visualized in the scattergram of related values of P_{0_{-abdominal}} and APIR before and after TVT (Figure 8) which revealed a mere upward movement of the values after TVT and not a diagonal movement towards the values of continent women (Figure 6).

P_{0_{-abdominal}} increased in all patients, mean P_{0_{-abdominal}} increased from 101 cm H_{2}O to 154 cm H_{2}O which is above the median value of 147 cm H_{2}O in continent women (results not shown).

Likewise, when inserting the parameters into the UCE, all patients achieved a stronger closure function after TVT. Not all patients exceeded the threshold value of a "normal" urethral closure function although they all re-gained continence.

With the presented results, we suggest to use the APIR, P_{0_{-abdominal}}, and UCE as parameters to objectify the urethral closure function changes after intervention.

Until now no parameter has demonstrated to be a robust predictor of TVT failure. Due to lack of failures and the small study population we could not clarify the role of P_{0_{-abdominal}} or APIR as predicting factors, however, it seems plausible that a certain low level of APIR may be predictive of a better effect of TVT than a high level.

The knowledge that urethral dysfunction is caused by a decreased P_{0_{-abdominal}} or APIR and that TVT is able to induce increased APIR may help gynecologists select the proper treatment for a specific patient; however studies are needed to determine other anti-incontinence treatments effect on the urethral closure function.

METHODOLOGICAL CONSIDERATIONS
The UPR method provides advantages compared to conventional urodynamic methods because of the thin and flexible polyurethane bag that allows bending of the urethra during measurements, the reduced risk of catheter-urethral wall interaction due to the luminal pressure measurements, and the measurements in the urethral HPZ.

Until now the pressure in the UPR polyurethane bag has been controlled by a pump with feedback from a pressure transducer. As CA measurements are affected by noise from the pump they could only be obtained during the breaks between the pressure-increases. The technique can be used while resting and squeezing but is inadequate when measuring the urethral opening pressure during stress events. We therefore modified the technique. By the UPR continuous technique, the pressure is increased by hand, hence minimal sound is generated, and measurements can be obtained continuously. This allows measurements during stress events.

Regardless of the technical differences between the step-wise and the continuous technique there was no statistical difference between the mean P_{0}, while resting (results not shown) and while squeezing, measured by the two techniques. The squeezing opening elastance was significantly higher when obtained by the continuous technique compared to the step-wise technique. Therefore, when the elastance is provided, it is important to describe the method by which it is measured. The reproducibility of the continuous technique is somewhat better than previously described for the step-wise technique (squeezing P_{0}, CV of 6.5% vs. 8.5% for the continuous technique and step-wise technique, respectively (15)).

For security reasons, the equipment had a maximum urethral pressure level of 200 cm H_{2}O, which could have limited the reliability of measurements around this level. It furthermore prevented us from using measurements in the erect position where a pressure above 200 cm H_{2}O cm is often needed to open the urethra in continent women. Nonetheless, erect measurements might have been more appropriate when analyzing the urethral closure function.

We measured the urethral P_{0} during intra-abdominal pressure increase by straining well aware that leakage often occurs during faster pressure increases such as coughs. However, the urethral closure mechanism is very complex and the UPR technique does not allow reliable measurement during such a complicated dynamic event as a cough.

The cross-sectional study design of study III, the small number of women included and the SUI-severity of the patients may have limited the study. The results of correlations between P_{0_{-abdominal}} and APIR, respectively, and age and number of deliveries, respectively, should be regarded with caution as the data from SUI and continent women were pooled.

CONCLUSIONS
- The new (“fast”) continuous technique for performing UPR while resting, squeezing and straining is described. The P_{0} is the same while the reproducibility of the parameters seems to be better compared with the traditional technique.
- The novel parameters enabled characterization of the urethral closure function in terms of the permanent closure forces primarily generated by the sphincteric unit (measured by the P_{0_{-rest}}), and the adjunctive closure forces primarily generated by the support system (measured by the APIR).
- The Urethral Closure Equation (UCE) which combines P_{0_{-rest}} and APIR provided a more detailed description of the efficiency of the closure function and the extent and nature of possible dysfunctions in the individual woman.
- Expressing the combined effect of the permanent and adjunctive closure forces at 50 cm H_{2}O abdominal pressure, the P_{0_{-abdominal}} revealed significant deficiencies in SUI women already at this relatively low abdominal pressure level.
- The correlation of SUI with deterioration of the mid-urethral parameters confirms the importance of the mid-urethra area as the continence zone.
- The UCE, P_{0_{-abdominal}} and P_{0_{-abdominal}}, respectively, separated SUI and continent women and showed highly significant negative correlation with ICIQ-SF, pad test and number of incontinence episodes per week. Consequently, they can be used as SUI diagnostic tests and severity measures.
- The P_{0_{-rest}} was unchanged after TVT, whereas the resting opening elastance increased 18%. Accordingly, at the resting state the TVT somewhat improves the closure function by increasing the resistance against the dilation of the urethra, which probably explains the decreased maximum urine flow rate after TVT.
- The APIR increased in all patients after TVT, which indicates that the adjunctive closure forces were increased while the...
permanent closure forces were virtually unchanged, regardless of the pre-operative dysfunction  
- \( P_{o-Abd}\text{50} \) and the UCE demonstrated a more efficient urethral closure function and decreased SUI severity in all patients after TVT. Therefore they may be used as outcome measures after treatment

PERSPECTIVES AND FUTURE RESEARCH

PERSPECTIVES
- The new (“fast”) UPR technique enables characterization of the individual urethral closure dysfunction based on deterioration of \( P_{o-rest} \), APIR, or both
- This characterization may allow individual tailored treatment and thereby lead to improved outcome
- \( P_{o-Abd}\text{50} \) which combines the permanent and the adjunctive closure forces, has shown to be a simple and very efficient parameter to distinguish between continent and SUI

FUTURE RESEARCH:
The following issues remain to be further clarified:
- Change in \( P_{o-rest} \), APIR, \( P_{o-Abd}\text{50} \) and UCE induced by pelvic floor muscle training and other conservative and surgical anti-incontinence treatments
- Change in \( P_{o-rest} \), APIR, \( P_{o-Abd}\text{50} \) and UCE caused by pregnancy and childbirth, both vaginal and caesarean section
- Change in \( P_{o-rest} \), APIR, \( P_{o-Abd}\text{50} \) and UCE by the course of time
- The origin of the urethral pressure while resting and during increased intra-abdominal pressure by combining UPR measurement with imaging
- UPR measurements during coughing
- Simultaneous UPR and cystometry

SUMMARY
Stress urinary incontinence (SUI) occurs when the bladder pressure exceeds the urethral pressure in connection with physical effort or exertion or when sneezing or coughing and depends both on the strength of the urethral closure function and the abdominal pressure to which it is subjected. The urethral closure function in continent women and the dysfunction causing SUI are not known in detail. The currently accepted view is based on the concept of a sphincteric unit and a support system. Our incomplete knowledge relates to the complexity of the closure apparatus and to inadequate assessment methods which so far have not provided robust urodynamic diagnostic tools, severity measures, or parameters to assess outcome after intervention.

Urethral Pressure Reflectometry (UPR) is a novel method that measures the urethral pressure and cross-sectional area (by use of sound waves) simultaneously. The technique involves insertion of only a small, light and flexible polyurethane bag in the urethra and therefore avoids the common artifacts encountered with conventional methods. The UPR parameters can be obtained at a specific site of the urethra, e.g. the high pressure zone, and during various circumstances, i.e. resting and sneezing.

During the study period, we advanced the UPR technique to enable faster measurement (within 7 seconds by the continuous technique) which allowed assessment during increased intra-abdominal pressure induced by physical straining.

We investigated the urethral closure function in continent and SUI women during resting and straining by the “fast” UPR technique. Thereby new promising urethral parameters were provided that allowed characterization of the closure function based on the permanent closure forces (primarily generated by the sphincteric unit, measured by the \( P_{o-rest} \)) and the adjunctive closure forces (primarily generated by the support system, measured by the Abdominal to urethral Pressure Impact Ratio (APIR)).

The new parameters enabled a more detailed description of the efficiency of the closure function and the extent and nature of a possible dysfunction in the individual woman.

The Urethral Closure Equation (UCE) and urethral opening pressure at an abdominal pressure of 50 cm H\text{2}O (\( P_{o-Abd}\text{50} \)) respectively, which combine the permanent and the adjunctive closure forces, could separate continent and SUI women and thus appear to be excellent diagnostic tests. Moreover the parameters showed highly significant negative correlation with ICIQ-SF, pad test and the number of incontinence episodes per week and are therefore valid as urodynamic severity measures.

UPR in SUI women before and after TVT demonstrated a more efficient urethral closure function after the operation. The \( P_{o-rest} \) was unchanged suggesting that the sphincteric unit was virtually unaltered and hence the permanent closure forces unchanged.

However, the resting opening elastance increased by 18% indicating that at the resting state the TVT somewhat improves the closure function by providing increased resistance against the dilation of the urethra, which probably explains the decreased maximum urine flow rate found after TVT in this and previous studies.

The APIR increased in all patients after TVT suggesting that the support system was re-established and thus the adjunctive closure forces improved, regardless of the type of pre-operative dysfunction. The new UPR parameters may be used as outcome measures after treatment.

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