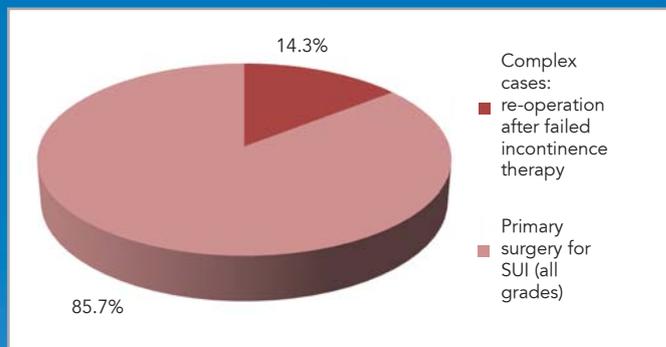
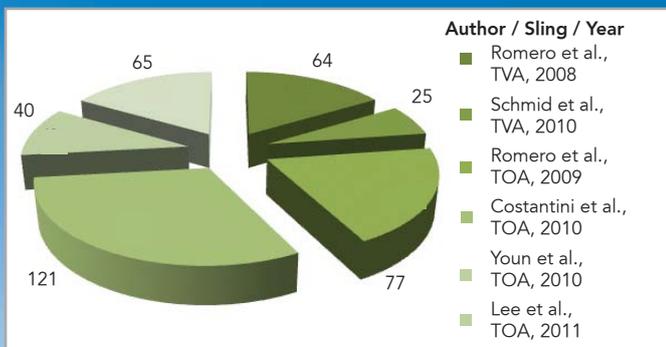


# TVA / TOA Adjustable Slings for Female Incontinence

## Clinical Results

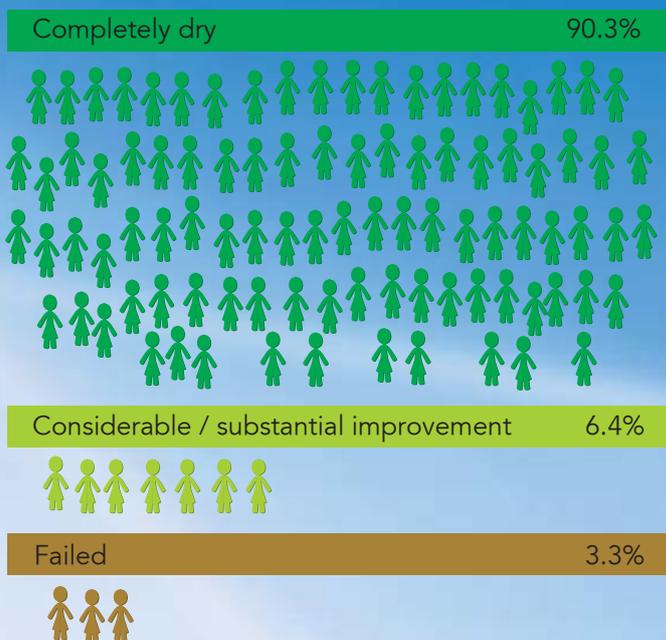
### Studies



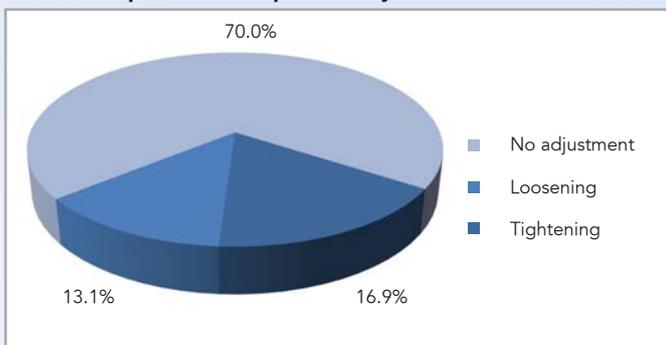
### 392 patients treated



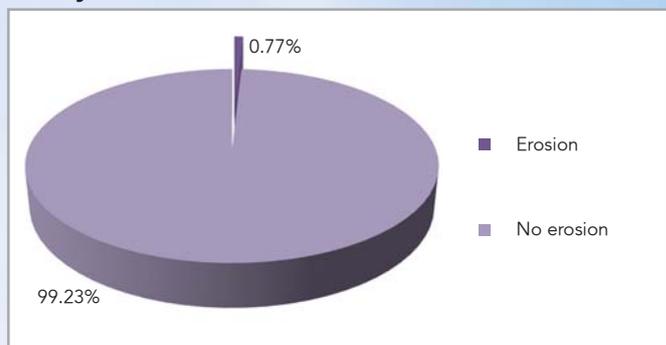
### Results



### 30% of patients required adjustment



### Very low erosion rate: 0.77%



Publication	No. of patients	Follow-up	Erosion (n / %)
 <b>Romero et al., 2008:</b> Transvaginal adjustable tape: an adjustable mesh for surgical treatment of female stress urinary incontinence <i>Int Urogynecol J Pelvic Floor Dysfunct.</i> 2008 Aug;19(8):1109-16. Epub 2008 Mar 20.	64 TVA	12 - 60 months	0
 <b>Schmid et al., 2010:</b> An Adjustable Sling in the Management of Recurrent Urodynamic Stress Incontinence after Previous Failed Midurethral Tape <i>Neurourol Urodyn.</i> 2010 Apr; 29(4):573-7.	25 TVA	3 - 16 months	0
 <b>Romero et al., 2009:</b> Transobturator adjustable tape (TOA) permits to correct postoperatively the tension applied in stress incontinence surgery <i>Int Urogynecol J Pelvic Floor Dysfunct.</i> 2009 Jul;20(7):797-805. Epub 2009 Apr 24.	77 TOA	12 - 52 months	1 / 1.3%
 <b>Costantini et al., 2010:</b> Transobturator adjustable tape (TOA) in female stress urinary incontinence associated with low maximal urethral closure pressure <i>Arch Gynecol Obstet.</i> 2010 Sep;282(3):277-84. Epub 2009 Oct 28.	121 TOA	13 - 36 months	2 / 1.4%
 <b>Youn et al., 2010:</b> Comparison of TOA and TOT for Treating Female Stress Urinary Incontinence: Short-Term Outcomes <i>Korean J Urol</i> 2010 Aug;51(8):544-9. Epub 2010 Aug 18.	40 TOA	3 months	0
 <b>Lee et al., 2011:</b> Transobturator adjustable tape for severe stress urinary incontinence and stress urinary incontinence with voiding dysfunction <i>Int Urogynecol J</i> 2011 Mar;22(3):341-6. Epub 2010 Oct 8.	65 TOA	6 months	0

#### Romero et al., 2009

*"In conclusion, our results show that persistence of stress incontinence and the development of obstruction after surgery depend largely on the tension applied to the mesh, looser or tighter, during the procedure. They also demonstrate that the transobturator approach (TOA), like the transvaginal procedure (TVA), allows postoperative adjustment of tension thus permitting correction of postoperative incontinence or obstruction. This does not increase surgical complications."*

#### Costantini et al., 2010

*"With this adjustable sling, the obturator route could be an excellent, reliable method of treating patients with urinary incontinence due to MUCP  $\leq$  20 cm H<sub>2</sub>O."*

#### Youn et al., 2010

*"These data suggest that better subjective and objective results and residual urine volume can be obtained in the TOA group than those achieved with the traditional non-adjustable mesh and without significant postoperative complications."*

#### Schmid et al., 2010

*"Detrusor pressure at maximum flow rate (pdet/Qmax) increased significantly as did the maximum urethral closure pressure (MUCP). Patient satisfaction improved significantly."*

*"Adjustable slings in women with stress urinary incontinence might be indicated in difficult situations after surgical failure."*

#### Lee et al., 2011

*"Our results support the use of TOA as an effective modality for the treatment of SUI in women at risk for persistent postoperative SUI or obstructive symptoms."*

## Abstracts

### A.M.I. TVA System

Romero et al., 2008

#### Transvaginal adjustable tape: an adjustable mesh for surgical treatment of female stress urinary incontinence

After transvaginal adjustable tape, approximately 15% of patients still suffer incontinence, and voiding dysfunction is present in a relatively important number of patients. Transvaginal adjustable tape (TVA) permits postoperative readjustment of tension, suggesting that better results could be obtained. Sixty-four incontinent women received TVA. Patients were monitored 1, 6, and 12 months post-surgery and annually thereafter by medical history, cough stress test, flowmetry and post-void residual test (PVR), incontinence quality of life, International Consultation on Incontinence Questionnaire-Short Form, and Patient Global Impressions of Improvement (PGI-I) questionnaires. After adjustment, all patients rendered continent, and none had PVR. On no occasion was vesical catheterization or uretholysis necessary. Mean follow-up was  $40 \pm 12.9$  months. Objective and subjective cure rate were 94% and 56%, respectively.  $Q_{max}$  was  $22.3 \pm 9.9$  ml/s. The PGI-I questionnaire showed 94% of patients to be better or very much better than before. Our data suggest that with TVA tape, better results can be obtained, furthermore, without increasing surgical complications.

Schmid et al., 2010

#### An Adjustable Sling in the Management of Recurrent Urodynamic Stress Incontinence after Previous Failed Midurethral Tape

**Objective** The aim of this prospective study was to evaluate the feasibility and outcome of an adjustable sling system AMI in patients with recurrent urinary stress incontinence after failed suburethral sling insertion.

**Patients and Methods** Twenty-five patients with recurrent urinary stress incontinence treated with an adjustable sling system AMI were analyzed for feasibility and outcome. Patients' incontinence bother was quantified using the Visual Analogue Scale (VAS) from 0 to 10. Multichannel urodynamics and pad tests were pre- and postoperatively performed. Time of adjustment, time of the surgical intervention, and clinical outcome were also recorded.

**Results** Twenty-five patients were treated with the adjustable sling system AMI. Median time of adjustment was 3 days (range 1–8) and a median follow up time of 12 months. Twenty-one out of 25 patients were continent, four patients suffered from persisting incontinence. One patient was put on clean intermittent self-catheterization (CISC). Detrusor pressure at maximum flow rate (pdet/Qmax) increased significantly as did the maximum urethral closure pressure (MUCP). Patient satisfaction improved significantly.

**Conclusion** Adjustable slings in women with stress urinary incontinence might be indicated in difficult situations after surgical failure. As we present a selective group of patients these findings may not apply to other patients with recurrent stress incontinence.

### A.M.I. TOA System

Romero et al., 2009

#### Transobturator adjustable tape (TOA) permits to correct post-operatively the tension applied in stress incontinence surgery

**Introduction and hypothesis** The adjustable transvaginal tape (TVA) has shown to allow adjustment of tension thus permitting correction of postoperative incontinence or obstruction. An adjustable transobturator mesh has been checked.

**Methods** Seventy-seven incontinent women received trans-obturator adjustable tape (TOA). Patients were monitored 1, 6, and 12 months post-surgery and annually thereafter by medical history, cough stress test, flowmetry, post-void residual (PVR), and incontinence quality of life, international consultation on incontinence-short form, and patient global impressions of improvement (PGI-I) questionnaires.

**Results** After adjustment, all patients rendered continent; none had PVR. On no occasion was vesical catheterization necessary. Mean follow-up was  $24.7 \pm 10.3$  months. Objective cure rate was 90% with 6.5% having greatly improved. The PGI-I questionnaire showed 90.7% of patients to be better or very much better than before.  $Q_{max}$  was  $21.3 \pm 7.2$  ml/s. No infection was identified. Vaginal extrusion occurred in one patient.

**Conclusions** Our data demonstrate that the TOA allows post-operative adjustment of tension thus permitting correction of postoperative incontinence or obstruction.

Costantini et al., 2010

#### Transobturator adjustable tape (TOA) in female stress urinary incontinence associated with low maximal urethral closure pressure

**Purpose** To determine the success rate of transobturator adjustable tape (TOA, Agency for Medical Innovations, A.M.I., Austria) in stress urinary incontinent patients with maximal urethral closure pressure (MUCP)  $\leq 20$  cm H<sub>2</sub>O compared to those with MUCP  $> 20$  cm H<sub>2</sub>O.

**Materials and methods** In this retrospective study, all female patients with a diagnosis of stress urinary incontinence underwent TOA, from September 2005 to August 2007. All patients had preoperative multichannel urodynamic tests (cystometry, urethral profile and uroflowmetry). During September 2008, patients were contacted by telephone and the validated short forms of the Urogenital Distress Inventory (UDI-6) questionnaire and the Incontinence Impact Questionnaire (IIQ-7) were administered.

**Results** The chart review identified 146 patients (125 with MUCP  $> 20$  cm H<sub>2</sub>O and 21 with MUCP  $\leq 20$  cm H<sub>2</sub>O) who had undergone TOA and who met the inclusion criteria. Of these, 121 patients (82.9%) were contacted by telephone. Results showed a very good quality of life (score 0–7 in the IIQ-7) in 95.9% of patients. Only two (1.6%) patients had persistent significant urine leakage related to physical activity. In the MUCP  $\leq 20$  cm H<sub>2</sub>O group, 90% of patients could be considered as being very satisfied, with a very good quality of life.

**Conclusion** With the TOA procedure, the obturator route could be used to treat patients with urinary incontinence and also with low MUCP.

# TVA / TOA Adjustable Slings for Female Incontinence

## Abstracts (cont.) - A.M.I. TOA System

Youn et al., 2010

### Comparison of TOA and TOT for Treating Female Stress Urinary Incontinence Short-Term Outcomes

**Purpose** The transobturator adjustable tape (TOA) sling operation is a new procedure that allows for the adjustment of tension after surgical intervention, thus permitting correction of postoperative incontinence or obstruction. The aim of this study was to compare the efficacy and safety of TOA with that of the transobturator tape (TOT) procedure.

**Materials and Methods** Between 2008 and 2009, women with stress urinary incontinence (SUI) underwent TOT (n=63) or TOA (n=40). The preoperative evaluation included history taking, physical examination, voiding diary, stress and 1-hour pad tests, and a comprehensive urodynamic examination. Postoperative evaluation was performed at the 1-week and 3-month postoperative follow-up visits.

**Results** The overall cure rate was 90.0% for the TOA group and 85.7% for the TOT group. The rate of satisfaction was higher in the TOA group than in the TOT group (95.0% vs. 85.6%). Four patients in the TOA group needed reduced tension as the result of urinary obstruction. The tension of the mesh was tightened in 1 patient because of a certain degree of continuing incontinence. The residual urine volume was significantly lower in the TOA group than in the TOT group (7.8 ml vs. 43 ml, p=0.01).

**Conclusions** TOA allowed postoperative readjustment for a number of days after surgical intervention, which allowed for good short-term treatment outcomes. These data suggest that better subjective and objective results and residual urine volume can be obtained in the TOA group than those achieved with traditional non-adjustable mesh and without significant postoperative complications.

Lee et al., 2011

### Transobturator adjustable tape for severe stress urinary incontinence and stress urinary incontinence with voiding dysfunction

**Introduction and hypothesis** This prospective multicenter study was conducted to evaluate the efficacy and safety of an adjustable mid-urethral sling (MUS) using transobturator adjustable tape (TOA) in women with severe stress urinary incontinence or combined stress urinary incontinence (SUI) and voiding dysfunction (VD).

**Methods** One day after placement of TOA, the tension was adjusted. Six months after surgery, changes in several questionnaires and uroflowmetry (UFM) parameters were evaluated.

**Results** Among the 65 women enrolled in the study, 27 (41.5%) required postoperative tension readjustments. At 6 months, the complete cure rate of SUI was 84.4%, and patient satisfaction with the operation was 86.2%. There was improvement in the total scores on several questionnaires. There were no significant changes in postoperative UFM parameters.

**Conclusion** Our results support the use of TOA as an effective modality for the treatment of SUI in women at risk for persistent postoperative SUI or obstructive symptoms.

## The slings - in brief:

- Non-elastic monofilament polypropylene:  
Soft, but firm enough lengthwise to provide the necessary support
- Optimally-sized pores:  
Allow seamless tissue integration, thereby reducing risk of infection
- Integrated sutures:  
Enable two-way tension adjustment up to five days after implantation with active patient participation



## Why adjustability?

- Difficult cases of persisting incontinence or urinary retention can be counteracted post-operatively with no surgical reintervention
- Particularly effective means of treating high-risk groups (e.g. combined SUI and voiding dysfunction), severe SUI, or patients in whom previous suburethral sling implantation has failed