

## RESULTS OF THE URETEX TO® TRANSOBTURATOR TAPE FOR TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

### Hypothesis / aims of study

Nowadays, tension-free transobturator tapes have gained widespread acceptance in the treatment of stress urinary incontinence. However, there is a need for data on specific commercially available meshes. The aim of this study is to describe the performance and complications of the Uretex TO® transobturator tape on stress urinary incontinence in women.

### Study design, materials and methods

A prospective observational study was performed. Between April 2005 and June 2006, 59 women were treated for stress urinary incontinence with the Uretex TO® transobturator tape. This polypropylene mesh was placed tension-free using the outside-in technique. All patients were invited to fill in the Urogenital Distress Inventory (UDI) and Incontinence Quality of Life (I-QoL) questionnaire prior to surgery, 6 weeks postoperatively and 1 year after surgery. Five patients did not respond.

Statistical analysis was performed by using SPSS 16.0. Non-parametric tests (Wilcoxon Signed-Rank tests) were applied because the data were not normally distributed.

### Results

A total of 54 women, aged 37 to 78 (median 50), were included. The median parity was two (range 0-5). Twenty-three women (43%) were postmenopausal and 83% of the women had daily stress urinary incontinence. Urge urinary incontinence was found in 20 patients (37%). Mean operative time was 24 minutes (standard deviation (SD) 6). There were no reports of intraoperative complications. The mean blood loss was 50 mL (SD 93; range 0-500). The subjective cure rate of stress urinary incontinence was 85% and the rest of the women (15%) reported an improvement of the stress urinary incontinence at six weeks. The total UDI-score prior to surgery was 172 (SD 86). Six weeks postoperatively this score significantly decreased to 70 (SD 70; p < .001). The I-QoL questionnaire parameters were significantly improved six weeks postoperatively (65.8% (SD 18.1) vs 91.8% (SD 14.7); p < .001). No further changes occurred in the I-QoL score 1 year after surgery (91.0% (SD 18.5)). Urge urinary incontinence disappeared in 13 women (65%). Two patients (3.7%) reported worsening of urge urinary incontinence. De novo urgency urinary incontinence was found in 4 patients (7%). Five patients (9.3%) reported postoperative complications for which reoperation was indicated. During follow-up, voiding difficulties requiring tape section occurred in two patients (3.7%). Two patients (3.7%) had a partial removal of the tape within one year of the initial operation because of vaginal erosions; one of them had a spontaneous drainage of vaginal abscess before the reoperation. One (1.9%) patient was reoperated at 21 days for persistent vaginal blood loss from wound dehiscence. The defect in the vaginal wall was closed and the TOT stayed in situ.

### Interpretation of results

The results of our study showed that the Uretex TO® transobturator tape is effective treatment for women with stress urinary incontinence. It has a high cure rate and it improves the quality of life significantly. There were no intraoperative complications, but postoperative complications (voiding difficulties, tape erosions and wound dehiscence) warranting subsequent surgery were seen in 9.3% of cases.

### Concluding message

The Uretex TO® transobturator tape is effective treatment for women with stress urinary incontinence. It significantly improves the quality of life in these women. Nevertheless, the rate of postoperative complications warrant further research on this specific type of mesh.

<b>Specify source of funding or grant</b>	NONE
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	No
<b>This study did not require ethics committee approval because</b>	According to the Dutch law (WMO 26/2/1998), there was no ethical approval needed for this study. The code of Good Behaviour on responsible use of information in medical scientific research (reference: Dutch law WGBO/WBP) was followed.
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes