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# MIDURETHRAL TISSUE FIXATION SYSTEM SLING IN TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

## Hypothesis / aims of study

Tissue fixation system (TFS) is a novel, minimally invasive, therapeutic option for women with stress urinary incontinence, called a 'micromethod' for cure of stress incontinence. The TFS uses two small plastic anchors to fix an adjustable midurethral polypropylene mesh sling into soft tissues below the pubic bone. The aim of our study was to evaluate the efficacy and safety of the TFS procedure.

## Study design, materials and methods

Thirty women aged 43-74 years (mean 54.5years) who underwent the TFS procedure at our Department of Gynecology between April and July 2005 were included. Patients' BMI ranged from 21.6 to 44.6 kg/m<sup>2</sup>(mean 29.4 kg/m<sup>2</sup>), parity from 0 to 6 (mean 2.6). Diagnosis of stress urinary incontinence was based on history, physical examination and urodynamic assassement. Main urodynamic parameters were as follows: peak flowrate 7-53 (mean 27.1) mL/sec, first sensation to void 10-222 (mean 112.2) mL, maximal bladder capacity 231-490 (mean 397.7) mL, maximal urethral closure pressure 23-102 (mean 50.1) cmH<sub>2</sub>0. In one patient low pressure urethra was found. The TFS was combined with other procedures such as the suture of vesicovaginal fascia to correct urethral hypermobility (26 cases), total vaginal hysterectomy (3 cases) and anterior bridge and posterior IVS (one case). The procedure was performed under general anesthesia by one surgeon experienced in urogenital surgery. Mean operating time for the TFS alone was 5 min.

According to pelvic organ prolapse quantification (POPQ) system no signs of prolapse (POPQ Ia) were noted in 20 (66.7%) patients, 5 patients (16.7%) presented with degree of prolapse classified as IIa, one (3.0%) as IIp, one (3.0%) as IIc and 3 (10.0%) as IVc. Three patients underwent pelvic surgery in the past: one Burch colposuspension (1998) and two total vaginal hysterectomy (1987 and 1990). The study was approved by the local ethical committee and followed the rules of the declaration of Helsinki.

### <u>Results</u>

The efficacy of treatment was evaluated 8 to 11 months (mean 10 months) after surgery using the cough test and patients' reports. Continence (no urine leakage on any occasion) was achieved in 18 (60%) of women and 8 (26.7%) patients noticed significant improvement (less and minor incontinence episodes). Procedure was ineffective in 4 (13.3%) patients. Among sexually active patients most (92.2%) experienced improvement or no change in sexual function and only (7.8%) reported deterioration of sexual function probably not related to surgery.

No complications such as bladder injury or significant bleeding were experienced during the surgery. None of the patient presented with postoperative urinary retention. In one case the failure of the TFS was discovered on the day after the surgery and the continence was achieved after transobturator tape placement. One patient developed urinary tract infection with staphylococci sensitive to doxycylin and gentamycin. After antibiotic therapy the patient remained continent. As far neither anchor displacement nor tape erosion was observed.

### Interpretation of results

Our preliminary results indicate that efficacy of the TFS may be comparable with other sling methods. The procedure appears to be safe and enables to avoid some complications such as bladder or bowel injury and intraoperative bleeding. Anchors placed during the procedure do not seem to influence negatively patients sexual live or cause unpleasant feeling during intercourse.

#### Concluding message

The tissue fixation system (TFS) appears to be safe and efficient procedure for treatment of stress urinary incontinence. Our observations indicate that it is unlikely that the TFS impairs sexual function of treated patients.

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This clinical trial has not yet been registered in a public clinical

HUMAN SUBJECTS: This study was approved by the Local Ethical Comitee, Lublin, Poland and followed the Declaration of Helsinki Informed consent was obtained from the patients.