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TVT SECUR® - FIRST EXPERIENCES AFTER A FOLLOW-UP OF 17 MONTHS

Hypothesis / aims of study
The aim of our investigation was to evaluate the outcome of the TVT secur® operation, a novel minimal-invasive suburethral sling procedure for the treatment of female genuine urinary stress incontinence, after a follow-up of more than 12 months.

Study design, materials and methods
Between August 2006 and December 2006, 31 patients with urodynamically proven stress urinary incontinence underwent the TVT secur® procedure at our center. In an observational study design patients were re-evaluated retrospectively after a median follow-up of 17,8 months (16-20). Urogynecological history was obtained and patients underwent a clinical stress-test, multichannel urodynamics and answered a standardized questionnaire. If patients were unavailable for re-examination only a telephone interview was performed by a doctor.

Results
24 of 31 patients with a median age of 59.7 years (41-87), mean body mass index of 28.7 kg/m^2 (19.9-39.9) were re-evaluated, 22.6% were lost to follow-up. Evaluation revealed an objective cure rate of 66.6% as defined by negative clinical stress-test, while 33.3% still had leakage on stress-test. Subjective improvement (completely continent and improved) for stress incontinence was 75%, while 25% considered themselves still stress incontinent. Three patients underwent additional successful incontinence surgery (two retropubic TVT®, one abdominal colposuspension). There was no patient with urinary retention, hematoma, bladder injury or infection. Vaginal wound dehiscence was found in 4 cases and could be managed conservatively with topical estrogens.

Interpretation of results
After a follow-up of 17.8 months the minimal-invasive TVT secur® seems a safe and easy to perform incontinence procedure. Compared to retropubic TVT® the outcome of the TVT secur®-procedure seems to result in lower cure rates.

Concluding message
These preliminary results require larger sample sizes and longer follow-up to elucidate the future place of this novel microinvasive mini-sling procedure. In addition more efforts have to be made to filter out suitable and non-suitable patients for mini-sling surgery.

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**retrospective observational study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**