

TVT-SECUR® - System:

One year experience with a minimal invasive suburethral sling for the treatment of stress urinary incontinence.



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EIN UNTERNEHMEN DER VINZENZ GRUPPE

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Objective:

Gynecare TVT-SECUR® (TVT-S) is the third generation of the TVT-system. It is a short laser-cut polypropylene midurethral tape (8cm) and requires no exit points. The TVT-S allows fixation of the sling in the obturator internus muscle ("Hammock"-position) or in the urogenital diaphragm in a retropubic way ("U" - position). The purpose of this study is to describe the efficacy and outcomes with this new system after one year experience in our unit.

Material and Methods:

63 patients were enrolled: mean age 59.2 years (range 39-86), mean body mass index of 27.2 kg/m² (21.4-40.7) and mean parity was 2.0. All of them had a stress urinary incontinence verified by urodynamics.

All patients underwent TVT-SECUR® procedure in the Hammock position, in 1 case in combination with an Amreich II procedure. Anaesthesia was local in a combination with remifentanyl in 1 patient (1.6%) and general in 59 (98%) patients. Mean operation time was 20.7 minutes, average blood loss was 25.1ml (20-80) and average time in the hospital was 3.4 days. After a median follow up of 4.7 months (1-11) patients were evaluated by interview, King's health questionnaire, symptom visual analogue scale (VAS 0-10), physical examination, perineal sonography, stress test, Pad test.

Results:

60 out of 63 cases could be evaluated, 3 were lost of follow up.. Objective cure rates by stress test were the same as subjectively: Over all 42 (70%) of women felt that they were cured, with a negative stress and Pad-test, 14 (23.3%) felt improved and 4 (7%) felt unchanged.

Learning curve: An interim-analysis of the first 20 cases showed an important learning curve: Of our very first 20 cases only 11 (55%) patients could be cured, 5 (25%) improved and 4 (20%) remained unchanged. In the following 40 patients 31 (77.5%) were cured, 9 (22.5%) improved and no one unchanged. Therefore all of the unchanged cases were under the first 20, which shows that after absolving our learning curve the results got significantly better.

Complications: De novo urgency appeared in 4 patients (6.6%), urinary tract infection in 5 (8.3%), post operative residual urine >50ml longer than 3 days in 4 (6.6%), 3 of them settled spontaneously within 18 days. One 85 years old patient had persistant urinary retention, so we had to remove the tape. We did not see any hematoma, bladder or urethral injury, dyspareunia or thigh pains, wound-infection. In one case we found a lateral vaginal erosion 7 weeks postoperatively. 2 patients (3.3%) had unintended tape removal at the time of inserter removal, necessitating in one case the usage of TVT-O in the other case we re-implanted the TVT-Secur. 80% of all complications occurred within the learning curve of the very first 20 cases.

Conclusion:

TVT-S® is a quick, safe and minimally invasive midurethral tape for the treatment of SUI. Our objective cure rates are similar to other midurethral slings with a low complication rate. TVT-S® can also be performed very well in an ambulatory setting.

There is a real learning curve: The system necessitates to be very cautious for adjusting the tension of the tape and for disconnecting the inserter from the tape. Long term comparative data collection, a registry will be required. We are looking forward starting such a registry in Austria in the next weeks.

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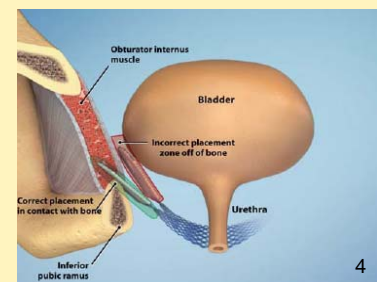
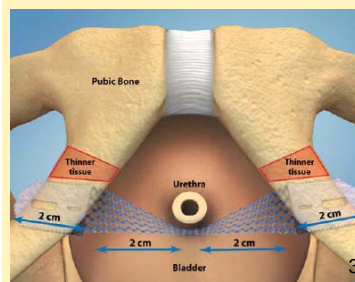
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1, 2 TVT-S tape
3, 4 recommended position
TVT-S needs to be exactly
placed within the obturator
internus muscle



Visualisation of TVT-S in
Hammock position by
perineal sonography

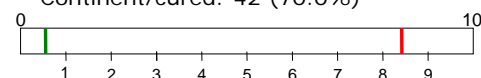
Outcome I n= 60	First 20 cases	Following 40 cases
Cured/ Continent	11 (55%)	31 (77,5%)
Improved	5 (25%)	9 (22,5%)
Unchanged/ Incontinent	4 (20%)	0

Outcome learning
curve

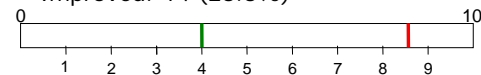
Third Generation – TVT-SECUR

OUTCOME all cases n=60

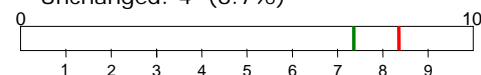
Continent/cured: 42 (70.0%)



Improved: 14 (23.3%)



Unchanged: 4 (6.7%)



Outcome:

Red marks: before
surgery
Green marks: after
surgery