TVT-SECUR®-System: Retrospective data of two years experience in complication risk, outcome, and patient satisfaction.

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Objective:
Gynecare TVT-SECUR® is a third generation minimal invasive suburethral sling for treatment of primary stress urinary incontinence. It is a short laser cut polypropylene midurethral tape (8 x 1,1cm) and requires no exit points. Therefore it may be safer and less painful. The TVT-SECUR® allows the fixation of the sling within the obturator internus muscle ("Hammock" position) or in the urogenital diaphragm in a retropubic ("U") position. The purpose of this study was to evaluate complication rates, efficacy, short term outcome, and patient satisfaction of a two years experience with this system in our unit.

Material and Methods:
118 patients were included, mean age was 59,9 years (range 35- 91), mean body mass index 27,7 kg/m2 (range 19,5- 41) and mean parity was 2,13 (range 0- 8). All of the patients had primary stress urinary incontinence (SUI) verified by urodynamics, all of them underwent TVT-SECUR® procedure in the Hammock position.
51 patients had no previous surgery (42,7%), 28 had previous hysterectomy (23,9%), 19 had hysterectomy and colporrhaphy (16,2%), 1 had posterior IVS, Burch colposuspension and mesh (0,9%), respectively. 17 had any other surgery before (14,5%).
No concomitant surgery had 99 patients (83,9%), concomitant hysterectomy was performed in 6 patients (5%), colporrhapy of posterior vaginal wall in 1 (0.9%), 12 patients had other abdominal surgery (10,2%). We performed local anestesia in a combination with ultra short intravenous analgesia (Ultiva®) in 3 patients (2,5%) and general anestesia in 115 (97,5%) patients. Mean operation time was 18 minutes, average blood loss was less than 100ml (N=117).
We have found that placement of TVT-Secur® must be significantly tighter against periurethral tissues compared to longer suburethral slings in order to ensure a better outcome of continence. We modified the original surgical technique by covering the tape with the inverted end of a forceps when pulling out the metal inserter gently to protect loosening of tension or removal of the tape.
After a median follow up time of 4 months (range 1-13) patients were evaluated by interview, King´s health questionnaire, visual analogue scale (VAS 0-10), physical examination, perineal sonography, and stress test.

Results:
115 out of 118 patients could be evaluated, 3 were lost of follow up.
Complications:
Over-all complication rate was 9/118 (7,6%). We observed 1 patient with a bleeding more than 500ml and haematoma in the cavum Retzii because of disconnection of the inserter with the tape while pushing it into the obturator internus muscle. This complication had to be treated by laparotomy to make a suction of the haematoma. In 2 cases (1,8%) we found a lateral-vaginal erosion postoperatively as a result of wrongful implantation in the very first cases during the learning curve.
4 patients had dyspareunia (3,4%), 2 (1,8%) 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-implantated the TVT-Secur but this patient was not continent at the time of observation. We did not see any urethral injuries, no patient had thigh pains and no one a infection in the area of surgery.
Success: Objective cure rates by stress test did not significantly differ from subjectively felt continence. Of all 115 patients 72 (62,6%) felt cured with a negative stress test, 31 (27%) felt improved and 12 (10,4 %) felt unchanged. The mean improvement of all the patients concerning visual analogue scale VAS was 6 points (mean VAS preoperative 8, mean VAS postoperative 2).
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. Concerning the following 95 patients 61 (64,2%) felt cured, 26 (27,4%) improved and 8 (8,4%) unchanged.

Conclusion:
Our objective cure rates are similar to those reported for other midurethral slings. The over-all complication rate is low (7,6%). 4/7 complications occurred at the very first 20 cases. There were no bladder injuries and no thigh pains. The procedure itself can be also performed in an ambulatory setting .
There is a real learning curve: The system necessitates to be very cautious about adjusting the tension of the tape and about disconnecting the inserter from the tape. Long term data collection, randomized controlled comparative studies to prove equal efficacy to retropubic and transobturator tapes will be required.


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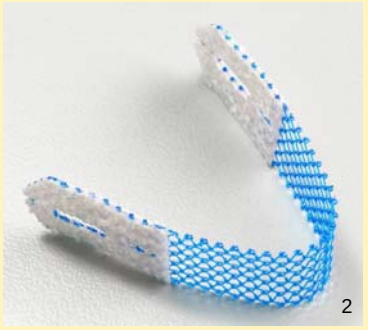
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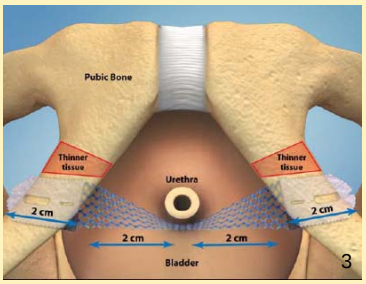

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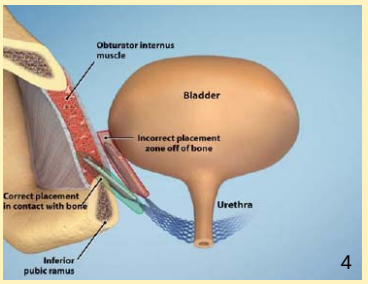

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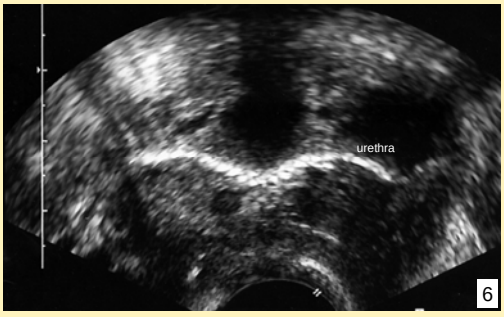

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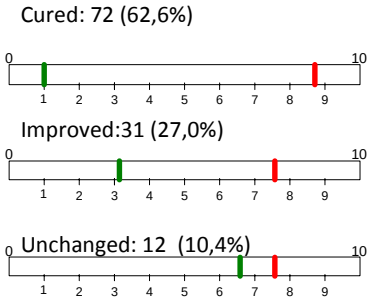
1, 2 TVT-S tape

3, 4, 5 recommended position

TVT-S needs to be exactly placed within the obtuator internus muscle

6 Visualisation of TVT-S in Hammock position by perineal sonography

TVT-Secur® outcome all cases n=115
Success rate: 89,6% VAS (0-10) subj.and obj.



7 Outcome:
Red marks: before surgery
Green marks: after surgery

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