

## ONE-YEAR SURGICAL OUTCOMES AND QUALITY OF LIFE IN MINIMALLY INVASIVE SLINGS FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: TVT SECUR® VS. CUREMESH®

### One-year Surgical Outcomes and Quality of Life in Minimally Invasive Slings for the Treatment of Female Stress Urinary Incontinence: TVT SECUR® vs. CureMesh®

**Hypothesis / Aims of study:** We compared the efficacy and safety of two minimally invasive sling procedures used to treat female stress urinary incontinence (SUI), tension-free vaginal tape (TVT) SECUR® and CureMesh®, and assessed the one-year surgical outcomes.

**Study design, materials and methods:** Sixty women with SUI were randomly assigned to receive either the TVT SECUR (n=38) or CureMesh (n=22) procedures between April 2007 and June 2008. Patients were monitored via outpatient visits one, three months and one-year after surgery. The efficacy of these procedures was evaluated by the cough test or an urodynamic study. At these postoperative visits the patients completed several questionnaires including incontinence quality of life, patient's perception of urgency severity, scored form of the Bristol Female Lower Urinary Tract Symptoms, visual analog scale, and benefit, satisfaction and willingness to undergo the same operation again. The objective cure rate was defined as no leakage using the cough test with a full bladder. The subjective cure rate was evaluated using the self-assessment of goal achievement one-year postoperatively.

**Results:** Average follow-up period was 18.4±2.9 months for TVT SECUR group and 17.8±1.8 months for CureMesh® group (p=0.086). One-year objective success rates were 86.8% in TVT SECUR group (cured in 68.4% and improved in 18.4%) and 90.9% in CureMesh® group (cured in 77.3% and improved in 13.6%), respectively. Patients' subjective satisfactions on the operation were 68.4% and 77.3% satisfactory, 10.5% and 9.1% normal. Urinary storage symptoms were all significantly improved in TVT SECUR group and only nocturia and urgency symptoms were significantly improved in the CureMesh® group.

**Interpretation of results:** The two groups were similar in preoperative characters and urodynamic parameters. The objective cure rates between TVT SECUR® and CureMesh® were similar. All questionnaires showed improved values after surgery. None of the patients suffered complications such as bladder perforation, urinary retention, and erosions.

**Conclusions:** Our study shows that the TVT SECUR® and CureMesh® procedures are both safe and simple to perform, with no difference in efficacy. Comparative studies with long term follow-up are warranted to determine the true efficacy of these procedures.

#### References

1. Molden SM, Lucente VR. New minimally invasive slings: TVT Secur. *Curr Urol Rep* 2008;9:358-61.
2. Tartaglia E, Delicato G, Baffigo G, Signore S, Corvese F, Perla A, et al. Third-generation tension-free tape for female stress urinary incontinence. *J Urol* 2009;182:612-5.

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	Retrospective study was performed
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes