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RESULTS OF A PROSPECTIVE OBSERVATIONAL STUDY ON FUNCTION AND SAFETY OF THE TOT-SAFYRE® (TOT/S), A COMPOSITE SILICONE-POLYPROPYLENE SLING SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study: There is good evidence to date that the original TVT method is highly efficacious and safe (1). However, for other devices on the market, varying in material, mesh texture and surgical approach (transvaginal vs. transobturator) data on efficacy are mostly subjective and safety, predominantly anecdotal (2). It was the aim of this study to examine efficacy and safety of TOT/S, a composite sling consisting of a macroporous polypropylene mesh and two lateral self-anchoring silicone columns, that allow postoperative readjustment.
Study design, material and methods: In a prospective observational study between 11/05 und 1/06, 79 out of 108 consecutively operated women (2 surgeons) with TOT/S were controlled for efficacy and safety of the method based on a questionnaire, the validated patient's global impression of severity and improvement scale (PGIS/I) (3) and a gynaecological examination by two different examiners blinded to each other.
Results: Average age was 61.1 (range 39-85), average time from operation was 20.4 mths (range 12-33). 83.3% of all pts considered their preoperative SUI as severe or very severe. Postoperatively, 59.5% of the patients subjectively had no leakage at any time anymore. 89% of the pts stated that their incontinence had improved: 'Very much' (47,9 %), 'much' (31,5%%), or 'little' (9,6%) while 6.8% showed no change or worse (4.1%). 12.6% of the pts. had developed an overactive bladder syndrome. 7.6% (53/79) of the sexually active women complained of pain during intercourse and 1 partner had felt discomfort during sexual intercourse since implantation of the sling. Vaginal mesh erosion was found in 8,8% (7/79), 3 being entirely asymptomatic. In 5 pts the mesh was removed, 2 pts refused further surgery. In a further 13.9 % of the pts the mesh could be palpated as a rough structure within the vaginal mucosa. In 47% of the pts the lateral silicone column which at the time of the initial surgery was placed, so to be covered by lateral muscular tissue, could be palpated medial to the pubic bone thus indicating dislocation.
Interpretation of results: This study shows that the TOT/S results are comparable to the 2-year data on the TVT, based on subjective continence and subjective patients's satisfaction rate (1). The TOT/S erosion rate of 8.8% (6.4% if calculated on the basis of all patients treated) seems to be increased compared to data currently available in the literature on the TVT but matches an erosion rate of 6.2 % out of 129 pts, recently published on another TOT procedure. Whether the TOT procedure in general or the silicone column dislocated beneath the vaginal mucosa, as found in this study, is the major reason remains unclear.
Concluding message: This study underlines that especially new devices and procedures need to be clinically assessed, because patient's subjective evaluation of efficacy alone is not sufficient to detect material related complications.

1. Am. J. Obstet. Gynecol. 2004; 190: 324
2. Obstet. Gynecol. 2005; 106: 713
3. Am. J. Obstet. Gynecol. 2003 Jul; 189: 98

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