

## DE NOVO STRESS URINARY INCONTINENCE (DE NOVO SUI) FOLLOWING ANTERIOR MESH APPLICATION: RESULTS OF THE TILOOP TOTAL 6-STUDY (NCT01084889)

### Hypothesis / aims of study

The purpose of this study is to assess the influence of anterior pelvic prolapse reconstruction with a titanised polypropylene mesh on the rate of stress urinary incontinence (SUI) postoperatively. This analysis includes both the cases of successfully treated pre-existing SUI and the cases of de novo- SUI after mesh-based colposuspension.

### Study design, materials and methods

This prospective multicenter observational study examines the influence of anterior pelvic prolapse reconstruction with a titanised polypropylene mesh on rate of erosion and patients quality of live. This subgroup analysis examines the impact of anterior mesh repair on the occurrence of stress urinary incontinence following anterior mesh implantation. At last 287 patients suffering from a symptomatic prolapse of the anterior vaginal wall (POP-Q-grade 2 or higher) were included between April 2010 and December 2012. Age  $67 \pm 7$ , range 44-88 y., median 69 y.; BMI  $27 \pm 4$  kg/m<sup>2</sup>, 17-63, median 26; birth  $2.1 \pm 1$ , range 0-8, median 2. Nine centres in Germany participated in the trial.

The study used a titanium coated polypropylene mesh with six anchoring arms (Tilooop Total 6, pfm medical AG). The procedure of colposuspension and apical fixation at the Ligg. sacrospinalia was performed in a standardized way in all centres. QoL questionnaire data were evaluated before surgery and furthermore to follow up data 6 and 12 months postoperatively, combined with a clinical examination. Currently, 238 patients have completed the 6 month follow up, 166 patients the 12 month follow up.

In addition to the implantation of the anterior Tilooop mesh, every other medically indicated surgical prolapse procedure was simultaneously allowed, for example, posterior colporrhaphy.

The results in view of de novo-SUI-appearance are compared to SUI- rates after classical procedures for pelvic organ prolapse (1,2).

### Results

287 patients could be included in the study. In February 2013, 238 patients have completed their 6 months follow up, 166 patients have completed the 12 months follow up. Considering the cases without SUI preoperatively and de-novo-SUI six months later only, a de-novo-SUI-rate results of 31.3% corresponding to the questionnaire data and of 18.9% corresponding to the medical anamnesis.

On the other hand, the anterior mesh implantation leads obviously to a lot of cases of successful treated pre-existing SUI. Taken as a whole, so there is a increase of continent patients after six months from 61.0% to 65.1%.

### Interpretation of results

However, the data also show that the patients reflect their own state of health according to situation (QoL questionnaire or doctor patient's talk) differently what complicates an unambiguous quantification of the clinical findings.

### Concluding message

The number of de novo-stress urinary incontinence following anterior mesh application correlates with the published data after classical procedures for pelvic organ prolapse (1,2). However, the simultaneously observed decline of incontinence cases in the whole study group is surprising and should be provided for the patients with pre-existing stress incontinence at the operation planning.

### References

1. Int Urogynecol J (2009) 20:235 - 245, doi: 10.1007/s00192-008-0734-4
2. Int Urogynecol J (2012) Jul 17, doi: 10.1007/s00192-012-1882-0

### Disclosures

**Funding:** disclosures: none **Clinical Trial:** Yes **Registration Number:** clinicaltrials.gov-Identifier: NCT 01084889 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** 1.Ethikkommission, Landesärztekammer Baden-Württemberg, Germany 2.Ethikkommission, Sächsische Landesärztekammer, Germany **Helsinki:** Yes **Informed Consent:** Yes