

## VAGINAL MESH REGISTRY: RESULTS OF THE AUSTRIAN UROGYNECOLOGY WORKING GROUP

### Hypothesis / aims of study

In 2006 we set up a voluntary nationwide registry for vaginal meshes for the correction of prolapse to gather data on the safety and perioperative and postoperative complications associated with these procedures. We present the preliminary results.

### Study design, materials and methods

All 90 gynecology units in Austria were invited to participate in the registry. 21 centers using meshes participated between 2006 and 2009. The registry was open for all vaginal mesh operations and systems performed between 2006 and 12/2009. A one-page, 23-item questionnaire addressed the relevant urogynecologic history, dyspareunia, previous gynecologic surgery, stage of prolapse as well as surgical details (isolated vs. concomitant surgery, mesh type and position, intra- and perioperative complications, transfusion requirements, pain perception on the day of discharge). Data were collected preoperatively and we attempted to obtain 3 and 12-month postoperative follow-up. At 3 and 12 months patients had a gynecologic exam and were asked about bladder and bowel symptoms and sexual function. Patient and physician scored their subjective satisfaction with the outcome. Demographic and clinical data were analyzed using descriptive statistics.

### Results

We collected data on 696 procedures with 11 different systems. 585 operations (84%) were done with Prolift devices (Gynecare/EWHU). 357 (51%) patients had no previous pelvic floor surgery; 279 patients had concomitant operations. 445 (64%) received an anterior or posterior mesh augmentation whereas 251 (35%) received mesh in both compartments.

A total of 27 (4%) intraoperative complications were reported: 16 (2%) major bleeding (>300ml), 7 (1%) bladder injuries, 2 (0.3%) rectal injuries and 2 (0.3%) vaginal perforations. Eight patients required RBC transfusion (2-26 units). The median postoperative hospital stay was 5 days (1-24). 50 (7%) patients scored >3 on a Visual Analogue Pain Scale on the day of discharge.

Preliminary follow-up data are as follows: We have data on 391 patients (56%) at 3 months and 235 (34%) at 1 year. Mesh erosions were found in 55 (14%) and 28 patients (12%) after 3 months and 1 year, respectively. 12 and 11 patients had mesh excision at 3 months and 1 year, respectively.

Preoperatively 145 (40%) of 367 sexually active women reported dyspareunia. At 3 months and 1 year 18 (5%) respectively 23 (6%) sexually active women reported dyspareunia.

Patient and physician dissatisfaction after 3 months and 1 year was 6 (1%) / 15 (2%) and 7 (1%) / 11 (2%) respectively.

### Interpretation of results

The results of this registry are more likely to reflect community practice than series in large and specialized centers (external validity). The major limitation of this registry is its voluntary and unaudited nature and the low follow-up rate. The true complication rate associated with vaginal mesh systems for correction of prolapse is likely higher than that recorded here.

### Concluding message

In our registry vaginal mesh operations were associated with 4% intraoperative adverse events. The low follow-up rate to date precludes conclusions regarding outcomes.

<b>Specify source of funding or grant</b>	<b>no funding</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>No</b>
<b>This study did not require ethics committee approval because</b>	<b>It did not require it</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>