Sexual function after implantation of partially absorbable transvaginal meshes – the ProViS study

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I personally have no financial relationships to disclose.
Study Rationale

- Potential risk of de novo dyspareunia caused by transvaginal meshes
- Partially absorbable meshes:
  - half being absorbed within 84 days
  - probably less impact on sexuality
Study Hypothesis/Objective

There is no worsening of the vita sexualis after compared to prior to the implantation of a partially absorbable transvaginal mesh.
Study Design

- Prospective, multicentre, post-marketing study
- Single-arm design with intraindividual comparison
- Statistical analysis by paired t-test
Patients

- Pelvic organ prolapse stage 2 or higher (according to ICS-POPQ)
- Sexual intercourse $\geq 2x$ within last 4 weeks

To reach statistical power we aimed to include 125 patients. Due to the withdrawal of the study product from the market we had to stop recruitment after inclusion of 11 patients.

- 1 patient refused to fill in questionnaires after 12 months.
Methods/Interventions

- Implantation of a partially absorbable TVM
- anterior, posterior, anterior+posterior or total mesh
- Before and 12 months after surgery:
  - validated German version of the Female Sexual Function Index Questionnaire (FSFI-d)\(^1\)
  - validated German version of the Australian Pelvic Floor Questionnaire (PFQ)\(^2\)

\(^1\)Berner M et al (2004), \(^2\)Baessler K et al (2010)
Methods/Interventions

➢ 12 months after surgery:

➢ level of satisfaction with the surgical outcome by
  ➢ Visual Analog Scale (VAS)
  ➢ Patient Global Impression question (PGI)³ and
  ➢ the question “Would you have that operation done again?”

³ Bullens PH et al (2001)
Results

Fig. 1: Alteration of FSFI-d total score (the higher the score, the less sexual problems).

Non-inferiority margin of -3.3 is not exceeded and the 95% confidence interval does not cross the zero line. Thus, there is not only no deterioration of sexuality (p=0.00055), but statistically even an improvement (p=0.0171).

--- Mean; --- 95% confidence interval; --- Zero Line; ---. Non-inferiority margin.

(note: For illustration purpose a small random deviation was added to prevent overplotting)
Fig. 2: Alteration of FSFI-d subscore pain (the higher the score the less dyspareunia).

Non-inferiority margin of -1 is not exceeded, but the 95% confidence interval crosses the zero line. Thus, dyspareunia does not deteriorate ($p=0.0038$). The graphically noticeable tendency towards improvement is not statistically significant ($p=0.12$).

--- Mean; --- 95% confidence interval; . . . . Zero Line; . . . . Non-inferiority margin.

(note: For illustration purpose a small random deviation was added to prevent overplotting)
Results

Fig. 3: Alteration of the PFQ subscore sexuality (the lower the score the less sexual problems).

The 95% confidence interval does not cross the zero line. Thus, there is a statistically significant improvement of sexuality (p=0.0186).

___ Mean; _ _ _ 95% confidence interval; 
_ _ _ _ _ _ _ _ _ Zero Line; _ _ _ _ _ _ Non-inferiority margin.

(note: For illustration purpose a small random deviation was added to prevent overplotting)
Results

Sexuality

- Sexual function is better and Dyspareunia is less common after mesh implantation than before surgery.
- Function of all pelvic floor compartments is improved (data for subscores bladder, bowel and prolapse not shown).
Results

Fig. 4: PGI

“Compared with how you were doing before your recent pelvic floor operation, how would you rate your situation during the last 12 months?”

(1 = much better, 5 = much worse)
Results

“How satisfied are you with the result of your operation?”

Average satisfaction is 5.7 on a VAS from 0 (completely satisfied) to 100 (totally unsatisfied).
Results

Patient satisfaction

- Patient satisfaction (PGI, VAS) is high.
- All patients would have the operation done again.
Conclusions

- Implantation of transvaginal meshes does not seem to worsen sexual life.
- Our study even implies a tendency towards improvement in sexual function after mesh-supported surgery in women with pelvic organ prolapse.
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