

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



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I personally have no financial relationships to disclose.**



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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



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Study Hypothesis/Objective

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



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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.



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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

¹Berner M et al (2004), ²Baessler K et al (2010)



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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)



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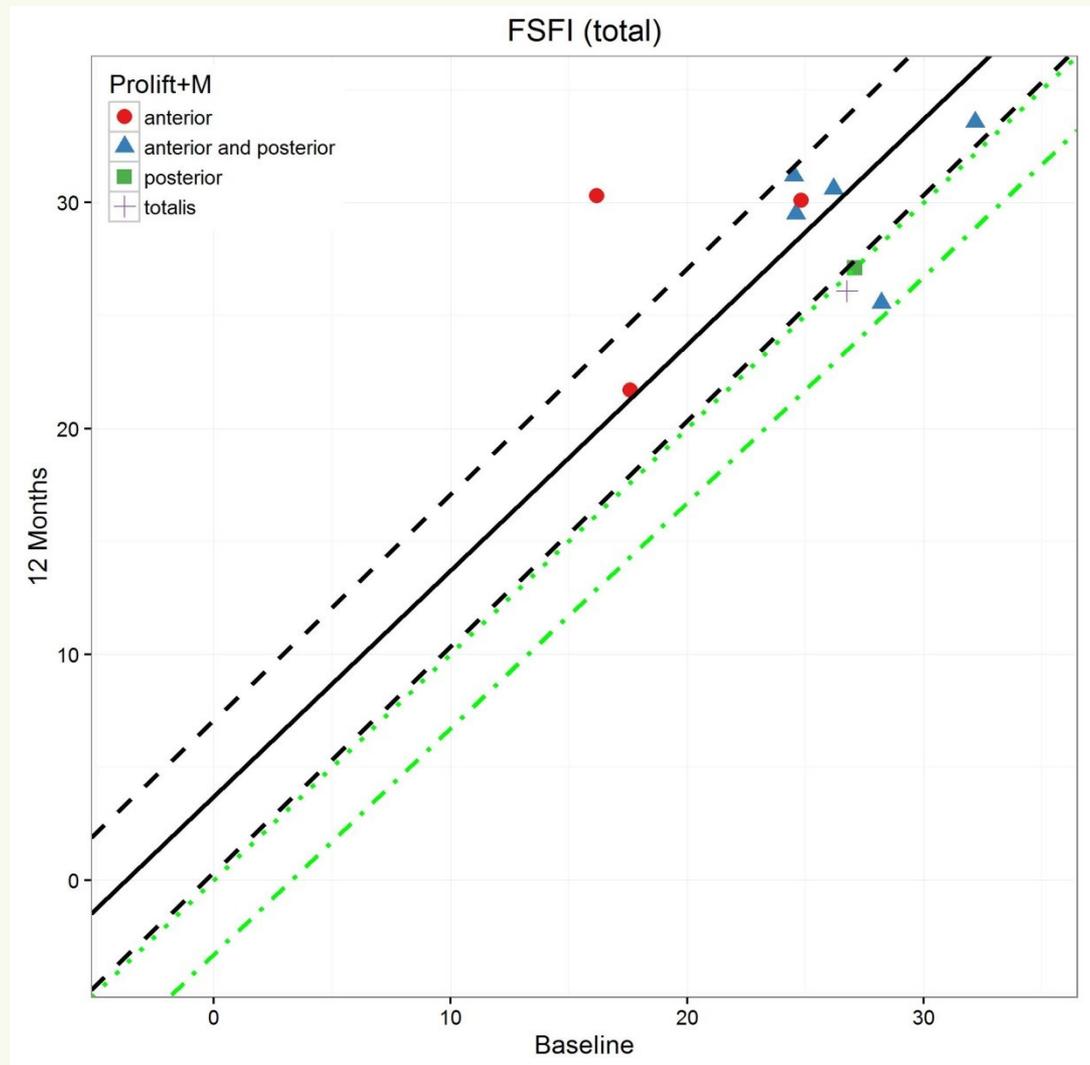
Results

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)



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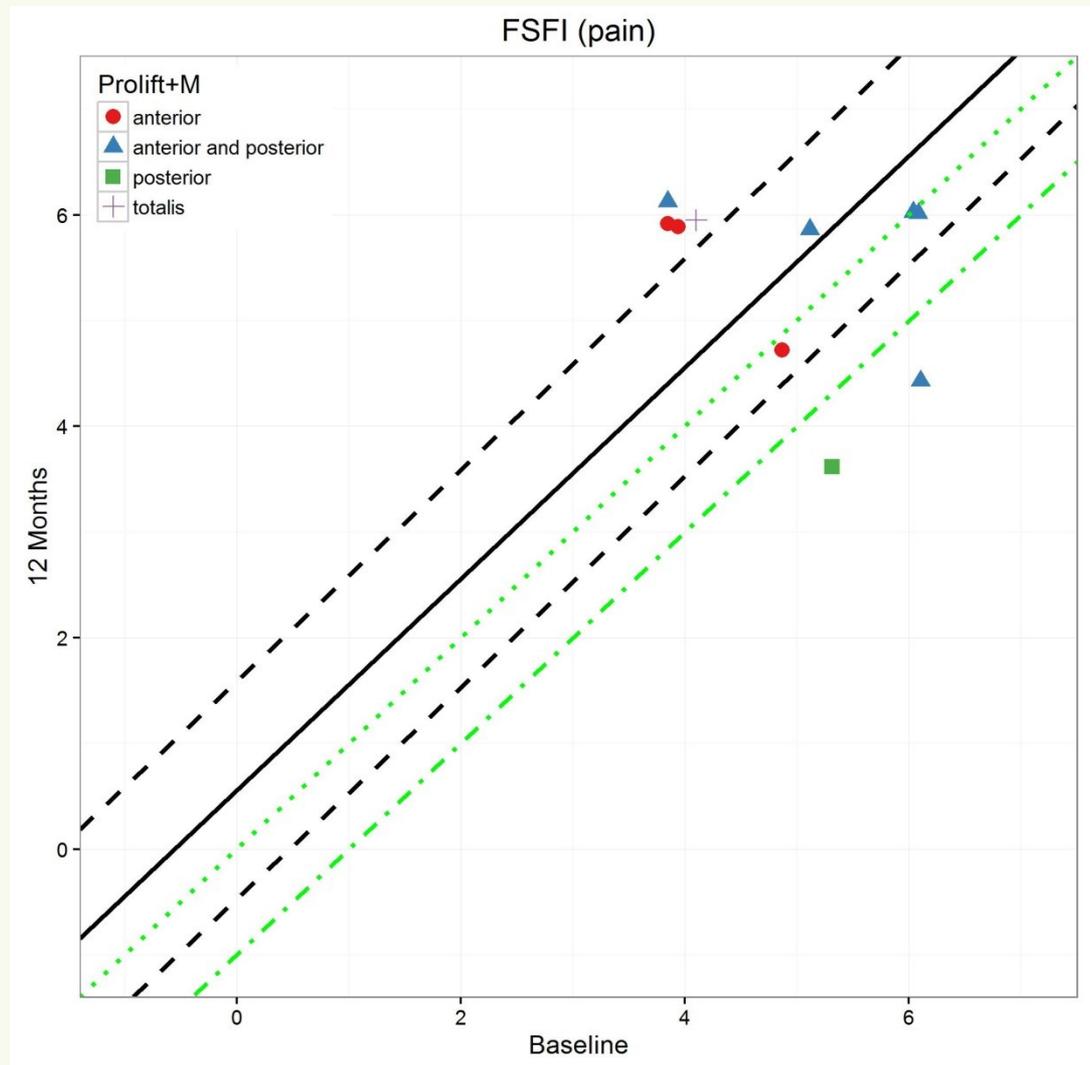
Results

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.

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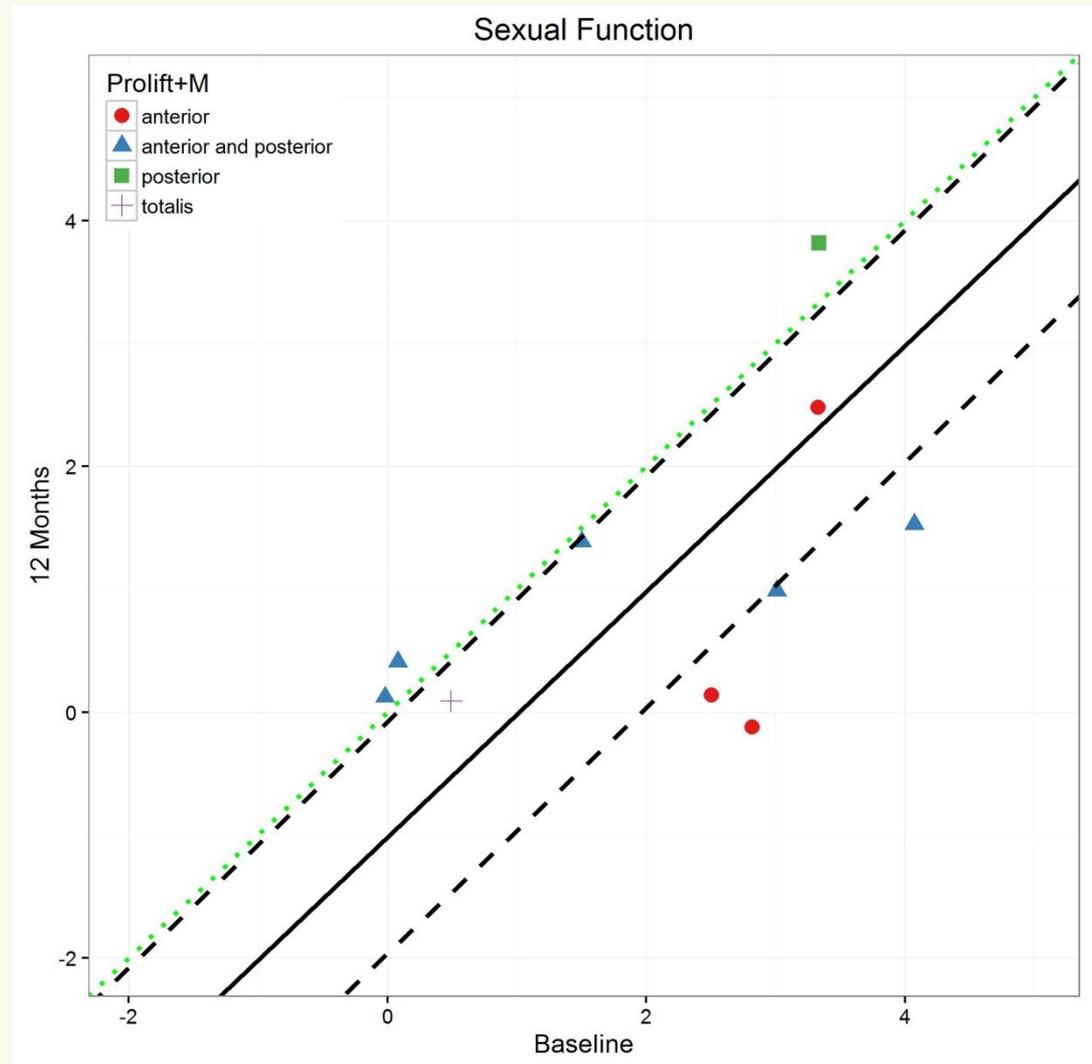
Results

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.

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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).



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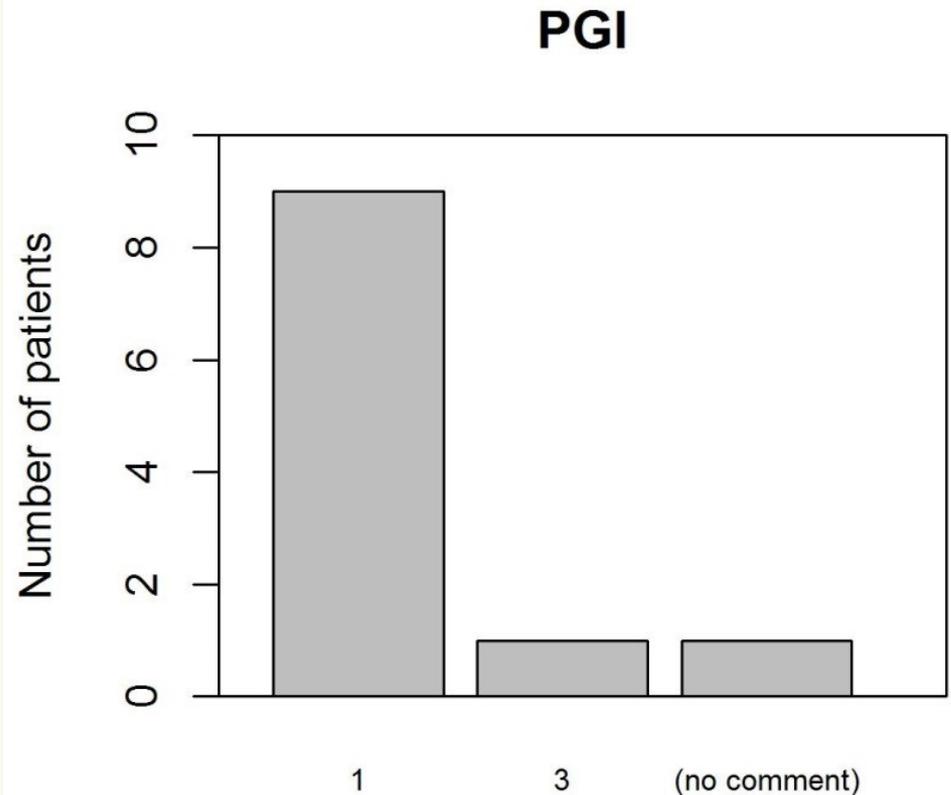


Results

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)



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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).



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Results

Patient satisfaction

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



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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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