

Study summary

Anchorless implant for the treatment of advanced anterior and apical vaginal prolapse

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Surgical treatment of advanced anterior wall and apical vaginal prolapse using the anchorless self-retaining support implant: long-term follow-up

› Gil Levy, Anna Padoa, Naama Marcus, Anat Beck, Zoltan Fekete, Mauro Cervigni, *Int Urogynecol J.* 2022 Jan 13: 1–9

Method

70 patients with a cystocele POP-Q \geq stage 2, with or without apical prolapse, were treated with a self-retaining support (SRS) implant in the prospective, multicentre SRS-I (n = 20) and SRS-II (n = 50) studies. The SRS Implant is an anchorless, single-incision system consisting of a titanised mesh that is held taut by a frame. The present publication shows the long-term follow-up of the SRS-I and SRS-II studies.

Endpoints (measured 2 weeks and 6, 12, 24 and 36 months postoperative)

- › Anatomical improvement (POP-Q measurement of points Aa, Ba and C)
- › Adverse events
- › Improvement in Quality of Life: Pelvic Function Distress Inventory-20 (PFDI-20) subdivided into the Pelvic Organ Prolapse Distress Inventory-6 (POPDI-6), Urinary Distress Inventory-6 (UDI-6), Colorectal-Anal Distress Inventory-8 (CRADI-8) and Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire-12 (PISQ-12)

Results

Objective success rate of 94.3%* / Subjective success rate of 95.7%**

Median follow-up period: 38.4 months (12.5–51.3 months)

No intraoperative complications

No chronic pelvic floor pain

No re-operations due to a recurrent prolapse

No mesh erosions

* POP-Q stage 0 or 1 (Ba \leq -2 cm) at last follow-up

** Results are based on question 3 of the PFDI-20: "Usually have a bulge or something falling out that you can see or feel in your vaginal area?"

- › No dyspareunia (PISQ-12)
- › One case of frame erosion (1.4%); in two cases, partial resection of the frame without any complications (2.8%)
- › Insertion of a transobturator tape in two patients (2.8%) after development of de novo stress urinary incontinence
- › Temporary urinary retention in two patients (2.8%), one case of delayed voiding dysfunction (1.4%)
- › Concomitant interventions: vaginal hysterectomy (14%), incontinence tape (20%), posterior colporrhaphy (21%)
- › 27% postoperative worsening of the posterior compartment prolapse in patients who did not undergo a concomitant posterior colporrhaphy; four patients were symptomatic
- › Response to the PFDI-20 by 67 patients at the last follow-up: significant improvement of 61.5 points (clinically significant improvement \geq 45 points)

Table 1: POP-Q measurements of points Aa, Ba and C pre- and postoperative (last follow-up Ø = 38.4 months)

Variable	Preoperative n = 70	Postoperative n = 67 (* p < 0.05)
Anterior compartment		
Point Aa	2.0 cm (-1 to 3 cm)	-2.9 cm (-3 to -1 cm)*
Point Ba	3.1 cm (-1 to 6 cm)	-2.8 cm (-3 to -1 cm)*
Apical compartment		
Point C	0.4 cm (-8 to 6 cm)	-6.9 cm (-10 to 1 cm)*

Figure 1: POP-Q measurements pre- and postoperative (last follow-up Ø = 38.4 months)

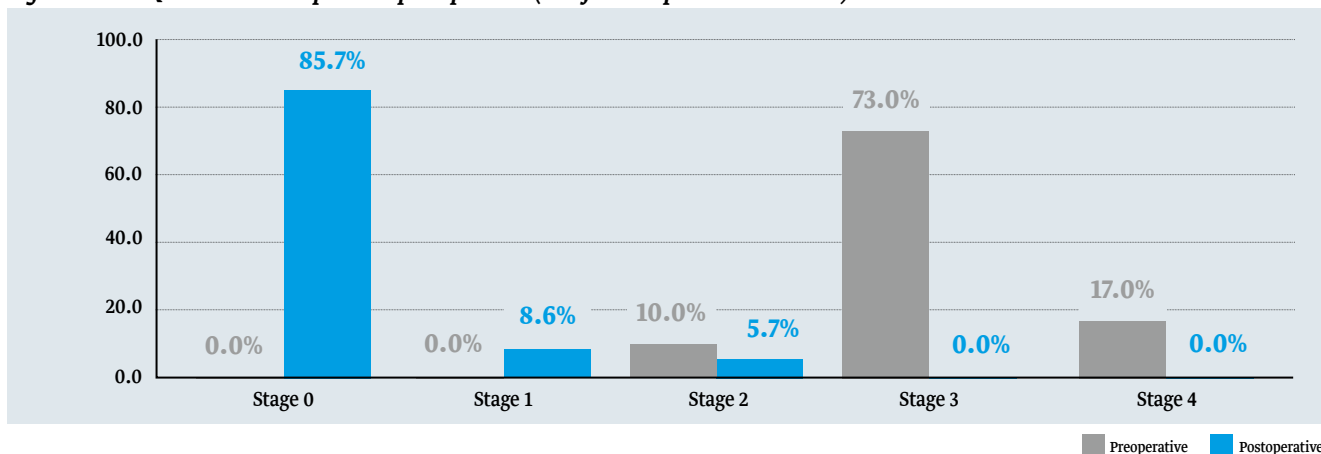


Table 2: Scoring of questionnaires on quality of life PFDI-20 and PISQ-12 pre- and postoperative (last follow-up Ø = 38.4 months)

Questionnaire	Preoperative	Postoperative	Difference (* p < 0.05)
POPDI-6	41.4	10.4	31.0*
CRADI-8	24.1	16.1	8.0*
UDI-6	40.3	17.7	22.6*
Total PFDI-20	105.8 (n = 70)	44.3 (n = 70)	61.5*
PISQ-12	31.2 (n = 43)	32.8 (n = 26)	1.6

Conclusion

The long-term results of the SRS Implant show excellent subjective and objective success with minimal risk of complications or the need for re-intervention. The SRS Implant is a safe and effective treatment option for patients with symptomatic anterior and/or apical prolapse.

References



Additional information:
www.pfmmedical.com/meshimplants-professionals

PubMed:
<https://pubmed.ncbi.nlm.nih.gov/35022836>

Contact

Should you have any questions our Regulatory and Clinical Affairs Team will be glad to advise you.

✉ pms@pfmmedical.com ☎ +49 (0)2236 9641-99 272

pfm medical gmbh
 Wankelstraße 60
 50996 Köln
 Germany

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