

A NEW TROCAR-FREE PROCEDURE FOR VAGINAL PROLAPSE REPAIR USING MESH AND A VAGINAL SUPPORT DEVICE: 1 YEAR ANATOMIC, FUNCTIONAL AND DEVICE PERFORMANCE RESULTS

Hypothesis / aims of study

The GYNECARE PROSIMA® Pelvic Floor Repair System (Ethicon, Somerville, NJ) is a surgical kit designed to treat pelvic organ prolapse. This kit includes mesh implants and a vaginal support device (VSD). The rationale behind the development of this procedure is to reduce the potential complications attributed to trocar mediated anchoring of mesh in the pelvis and the desire to buttress the suspended organs of the pelvic floor during periods of increased intra-abdominal pressure in the early post-operative period. Compared to native tissue repairs, the risk of recurrent prolapse may be reduced by augmenting surgery with mesh implants and supporting the vagina with a VSD for 3 to 4 weeks after surgery. Consistent with orthopedic wound healing principles, the VSD acts as an intra-vaginal splint to support vaginal tissue and the mesh during tissue incorporation. The VSD potentially reduces the adverse impact of changes in intra-abdominal pressure and also avoids the need for mesh fixation by trocars or sutures into the sacrospinous ligaments. A balloon is attached to the VSD and used instead of the traditional vaginal gauze pack. The aim of this study is to report the anatomic and functional outcomes of surgery, and the performance of a vaginal support device (VSD) and balloon following vaginal surgery for prolapse using the PROSIMA system.

Study design, materials and methods

Women from 11 sites in Europe (5), United States (5) and Australia (1) with symptomatic prolapse (POP-Q Stage II-III) were invited to participate in this prospective, single-arm study. Approximately 135 subjects were enrolled to allow for follow up of at least 118 women at 1 year.

The monofilament, polypropylene mesh grafts were inserted through sagittal incisions into the vesicovaginal and / or rectovaginal planes and extended without fixation over the obturator internus muscles and bilateral sacrospinous ligaments, respectively. The VSD can be modified into a large, medium or small size. At the completion of surgery an appropriately sized VSD with attached balloon was placed in the vagina and sutured in place to prevent dislodgement. The balloon was inflated with air. At 24 hours following surgery the balloon was deflated and removed. Outcome measures obtained at baseline, 6 months and 1 year post-operatively included the POP-Q exam for assessment of anatomic support, the short forms of the Pelvic Floor Distress Inventory (PFDI-20), the Pelvic Floor Impact Questionnaire (PFIQ-7) and a Patient Global Impression of Change (PGI-C). Patients were asked specific questions regarding sexual activity and dyspareunia. Intraoperative and post-operative adverse events were recorded. The performance of the VSD and balloon was evaluated using visual analogue scales (VAS) assessing discomfort during balloon removal and subjects' awareness, discomfort and acceptability of discharge related to the VSD.

Results

136 women were included with a mean age of 64.3 years (SD 10.5) and mean BMI 28.4 (5.0). Pre-operatively, 53.7% were Stage II and 46.3% Stage III. 25.7% had undergone prior prolapse surgery and 55.9% a prior hysterectomy. 31 (22.8%) had an anterior, 33 (24.3%) a posterior and 72 (52.9%) combined repairs using the PROSIMA system. Vaginal hysterectomy was performed on 16.9% and a mid-urethral sling in 33.1% of subjects. Two inadvertent cystotomies occurred, with mesh placed in one instance. A small, medium or large VSD was used in 41.9%, 32.4% and 25.7% of subjects respectively. Results of subjects' awareness, discomfort and acceptability of discharge associated with the VSD and discomfort during balloon removal are presented in Table 1. In 17 subjects, the VSD was *in situ* for less than the recommended 3-4 weeks.

The anatomic outcomes are reported in table 2. At 1 year the leading edge of the vaginal wall was at ≥ 1 cm above the hymen in 113 (88.3%) women. For those subjects with the VSD *in situ* for less than 21 days, the leading edge of the vaginal wall was at ≥ 1 cm above the hymen in 9 cases (52.9%).

Based on PGI-C, 73.3% patients reported they were "much better" and an additional 15.3% "a little better". All measures of symptoms, quality of life and sexual function showed statistically significant improvement from baseline. At baseline, dyspareunia was reported in 11 / 63 (17.5%) sexually active patients. By 1 year, 9 of these 11 cases reported resolution of dyspareunia. There were 3 reports of *de novo* dyspareunia. 12 (8.8%) patients who not been sexually active at baseline, resumed sexual intercourse following surgery. Analysis of safety included 12 additional "run in" cases (n=148). Mesh exposure occurred in 12 patients (8.1%): 8 resolved following partial mesh excision; 4 were ongoing at 1 year, of which 3 were treated with topical oestrogen and 1 required no treatment. 3 patients elected further intervention for prolapse by one year follow-up: two had undergone combined PROSIMA repair, one of whom required anterior repair, whilst the second case underwent sacrocolpopexy, which then subsequently failed. The third case had undergone an anterior PROSIMA repair, and required repair of her previously untreated posterior compartment.

Interpretation of results

Our results demonstrate good anatomic and functional outcomes 1 year following surgery for pelvic organ prolapse using the PROSIMA system. The VSD was well tolerated by the subjects and, when retained for 3 to 4 weeks, was associated with a trend towards more successful surgery when compared to early removal. The proportion of women reporting either resolution of dyspareunia or resumption of intercourse was encouraging. Comparative studies are needed to help determine the longer-term effectiveness of the PROSIMA system compared to other procedures for pelvic organ prolapse.

Concluding message

The PROSIMA trocar-free transvaginal prolapse repair utilizing mesh implants and early splinting with a custom shaped vaginal support device appears to have a satisfactory safety profile and results in good anatomical and functional outcomes at 1 year in women with Stage II and III prolapse.

Table 1: Subject-reported experience of the vaginal support device (VSD).

Table 2: Anatomic outcomes using mean (SD) quantitative POP-Q values in centimetres.

POP-Q point	Baseline	1 year	Change	P value
Ba	0.4 (2.0)	-1.9 (1.3)	-2.3 (1.9)	P<0.001
C	-3.9 (3.0)	-6.0 (1.7)	-2.2 (2.1)	P<0.001
Bp	-0.4 (1.9)	-2.5 (0.8)	-2.1 (3.5)	P<0.001
Gh	4.1 (1.1)	3.5 (0.9)	-0.7 (1.1)	P<0.001
Pb	3.0 (1.0)	3.2 (0.8)	0.2 (1.0)	P=0.032
TVL	8.2 (1.5)	7.5 (1.1)	-0.6 (1.6)	P<0.001

References

1. Carey M, Slack M, Higgs, P, Wynn-Williams M, Cornish A. Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device. BJOG 2008;115:391-397

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<i>Is this a clinical trial?</i>	Yes

<i>Is this study registered in a public clinical trials registry?</i>	Yes
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<i>Specify Name of Public Registry, Registration Number</i>	ClinicalTrials.gov; NCT00521066
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<i>What were the subjects in the study?</i>	HUMAN
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<i>Was this study approved by an ethics committee?</i>	Yes
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<i>Specify Name of Ethics Committee</i>	Cambridgehire 1 Research Ethics Committee; Ethics Commission Universitäts klinikum
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	Median VAS	Range
VSD awareness *	26.0	(0, 100)
VSD discomfort*	12.0	(0, 100)
Acceptability of discharge**	9.0	(0, 100)
Discomfort of balloon removal	4.0	(0, 68)

*VAS of 0 = best score possible; VAS of 100 = worst score possible.
 **117 (86.7%) of subjects reported vaginal discharge.

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