

SURGERY FOR PELVIC ORGAN PROLAPSE USING MESH AND A NEW VAGINAL SUPPORT DEVICE: A 12 MONTH FOLLOW UP.

Hypothesis / aims of study

To evaluate a novel surgical technique for pelvic organ prolapse using vaginal mesh repair and placement of a vaginal support device at the completion of surgery.

Study design, materials and methods

An observational, prospective surgical trial. Ethics approval was not obtained as this study was considered a clinical surgical audit. Patient informed consent was obtained prior to surgery.

From June 2004 until December 2004, 69 women underwent vaginal prolapse surgery with the new technique. All surgery was performed by one senior surgeon. Women were assessed clinically with POP-Q examination (all stage 2-3) and urodynamics performed on patients with urinary incontinence prior to surgery. 37% of women had undergone prior hysterectomy and 27% had undergone prior prolapse surgery.

All women underwent vaginal prolapse surgery using fascial plication and mesh augmentation with Gynemesh PS mesh (Ethicon, Somerville, NJ). Anteriorly the vaginal epithelium was dissected off underlying fascia and the dissection continued laterally until each arcus tendineus fascia pelvis and paravaginal spaces were reached. A cross shaped piece of mesh was cut and placed over the fascial with the extension arms placed into the paravaginal spaces. Posteriorly the vaginal epithelium was dissected from underlying fascia and the dissection continued to each ischial spine and sacrospinous ligament. A "Y-shaped" piece of mesh was placed over the fascia with extension arms of mesh placed into the tunnels.

47% of women underwent concomitant incontinence surgery and 45% underwent vaginal hysterectomy.

At the completion of surgery an appropriately sized vaginal support device was placed in the vagina and sutured in place to prevent dislodgment. The support device was removed in the consulting room after 4 weeks.

Examination using POP-Q was performed at 4 weeks, 6 and 12 months. The primary outcome measure for success was a POP-Q stage of 0-1. Patient satisfaction, validated symptom and quality of life questionnaires (Prolapse Symptom Inventory & QOL(PSI-QOL)) were administered pre operatively and at 6 & 12 months post operatively.[1]

Results

Average surgical time was 58 minutes (\pm 18 mins).

At the 12 month review 58 women were available for examination with 90% with stage 0-1 prolapse. Of the 6 women with recurrent prolapse all were stage 2 and there were 3 recurrences in the anterior compartment, 4 recurrences in the posterior compartment and no vault or cervical recurrent prolapse.

59 women completed questionnaires with 85% of women describing no awareness of prolapse symptoms at 12 months (compared to 7% preoperatively). Sexual interference due to pelvic symptoms was described by 11% of women (compared to 48% pre operatively). Patient satisfaction with surgery was high with a mean score of 8 out of 10.

Symptom and quality of life data on validated questionnaires comprises symptom domain (PSI) and QOL domain which are scored separately. Lower scores indicate less prolapse symptoms and lower interference of quality of life. See Table 1.

Complications to date include 1 intraoperative rectal perforation. Long term complications include 4 (6%) mesh exposures, 2 of which have been medically managed. Vaginal strictures have been noted in 6 (9%) women and required vaginoplasty or vaginal dilators.

Table 1: Results

	Pre-op Mean	SD	12 month Mean	SD
Prolapse affects Life	0.63	0.22	0.12	0.22
Surgical satisfaction	N/A	N/A	0.80	0.23
Symptoms (PSI)	2.50	0.47	1.61	0.45
QOL	2.06	0.83	0.37	0.62

Interpretation of results

At the 12 month review of this novel surgical approach there is a high anatomical success rate with low complication rate and high patient satisfaction rates.

Concluding message

Following traditional vaginal repair there is a high rate of pelvic organ prolapse recurrence. By reinforcing the vaginal repair procedure with mesh and supporting the vagina with a support device for four weeks following surgery the risk of recurrence may be reduced. The vaginal support device not only supports the vaginal tissues after surgery but also supports the positioning of the mesh.

Reference

[1] Proceedings of the American Urological Association 95th Annual Meeting. J Urol 2000;163:76.

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HUMAN SUBJECTS: This study did not need ethical approval because Clinical surgical audit but followed the Declaration of Helsinki Informed consent was obtained from the patients.