Abstract no. 395

New material for double trans Obturator technique

M. Zargham, M.J. Eslami, M. Yazdani

Urology department of Isfahan University of medical science, Iran

Abstract

Purpose: To assess the safety and efficacy of PVDF mesh in surgical management of pelvic organ prolapse.
Method: One hundred women underwent double TOT procedure in which, a four handed mesh was used to strengthen the attenuated endopelvic fascia and pelvic diaphragm. Patients then went through the follow ups for at least 3 months.
Result: Eighty nine patients enrolled to the study. Based on an average of 22 months of follow up, the success rate for POP was 97%. During the follow up period, the prolapse relapsed in five patients and additional surgery was performed.
Conclusion: This study suggests that even in a 2-year follow-up period, PVDF meshes had a low rate of erosion and can effectively repair the pelvic organ prolapse.

Introduction

Pelvic Organ Prolapse (POP) is characterized by the attenuation of endopelvic fascia and pelvic diaphragm. It reduces the quality of life (QOL) in almost 50%of women after menopause. Using meshes to reinforce endopelvic fascia and to obtain the reconstruction of pelvic floor anatomy and bladder sphincter support in women, began with the Ulmsten's ''Integral Theory' from 1996. FDA notification on high complications associated with transvaginal polypropylene (PP) meshes in pelvic reconstructive surgeries highlights "the need for new material" (1). The objective of this study is to examine the behavior of polyvinylidene fluoride (PVDF) meshes as a new material suggested for treatment of POP (2).

Methods and Materials

•Between 2010-2018 and in 2 hospitals of the urology and urogynecology department of Isfahan University of medical sciences, women with symptomatic stage III or IV POP according to POP-questionnaire were included in the study. One hundred women underwent double trans Obturator technique (double TOT) surgery of symptomatic prolapse of anterior vaginal wall with or without uterine prolapse and stress urinary incontinence by using PR4 Dynamesh kits, 4 hands fashioned PVDF meshes. Of these, upon informed consent, 89 patients were enrolled in the study. In addition to the main surgery addressing cystocele and uterine or vaginal vault prolapse, other surgical procedures were performed for patients with either severe symptomatic enterocele or rectocele or both. For patients with both severe enterocele and rectocele, levatoroplasty surgery, and for those with only severe rectocele, rectocele repair were performed. In this procedure, 4 helical TOT trocars are passed through the Obturator foramen, two of them through the antro-superior angle toward the bladder neck or mid-urethra and the two remaining through the postero-inferior angle to the coxygeo-sacrospineous ligament muscle complex. Finally, mesh hands are extracted by trocars for surgical management of pelvic organ prolapse.

• All surgical procedures were performed by an experienced urogynecologic surgeon (Dr. M. Zargham) based on the surgical technique that will be described later in this poster. To assess the objective and subjective outcomes, all patients were examined with the POP-Q for POP classification. The presence of mesh erosion was checked during vaginal examination. Urinary and vaginal symptoms were assessed using validated ICIQ-FLUTS and ICIQ-VS questionnaires; for urinary incontinence, patients underwent stress test while supine at maximum physiological bladder capacity. All patients were routinely visited at least 1 and 3 months after surgery while some of them even more often.

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Table 1. Patient's baseline characteristics and perioperative data

Age, years Mean ± SD (range)	60.3 ± 9.1 (32-86)
Parity Mean ± SD (range)	4.8 ± 2.3 (0-14)
Cesarean deliveries no. (%)	8 (8.9)
BMI Mean ± SD (range)	27.9 ± 3.6 (18-37)
Menopause no. (%)	75 (84.3)
Risk factors (diabetes mellitus, recurrent UTI, immunosuppression, chronic constipation, PVR>100, hypothyroidism) no. (%)	54 (60.7)
Prior pelvic surgery no. (%) Hysterectomy Pubovaginal sling (anti-incontinence surgery)	 27 (30.3) 1 (1.1)
Concomitant procedures no. (%) Levatoroplasty Rectocele repair	 17 (19.1) 4(4.5)
Positive cough test prior to surgery no. (%)	50 (56.2)
POP preoperational grade no. (%) Grade III Grade IV	 69 (77.5) 20 (22.5)
Hospital stay Mean ± SD (range)	1.7 ± 0.9 (1-4)

Results

Polyvinylidene fluoride (DynaMesh-PR4 soft 07cm*04cm, FEG Textiltechnik, Aachen, Germany) were used with Double Trans Obturator technique. Sixty nine patients (77.5%) presented stage III and 20 patients (20 %) stage IV of prolapse. The mean follow up was 22.9 months (ranged in 4-44 months). Eighty seven patients (97%) had complete resolution of the prolapse (stage 0 or I based on POP-Q) and 64 patients (91%) recovered from stress urinary incontinence (defined as no accidental release of urine after asking to cough). Four patients had vaginal mesh exposure; one after chemotherapy due to bladder cancer, one following vaginal bleeding 3 months after mesh insertion and the other two due to discontinuation of topical estrogen following vaginitis. Of these, 3 patients underwent surgical mesh removal and in 2 of them, symptoms recurred and outpatient treatment was performed. Five patients (5.6%) presented with the recurrence of prolapse after the symptoms were resolved. During the first week after surgery, 18 patients (20.2%) had urinary retention (defined as post-void residual volume (PVR>200ml) and received a urinary catheter. After a month of surgery, urinary retention sustained in only 5 patients (5.6%) needing surgical intervention to remove the obstruction and urinary retention.

Table 2. Outcomes of double-TOT procedure

Follow-up time, month Mean ± SD (range)	22.9 ± 12.3 (4-44)
POP postoperative grade no. (%) Grade 0 Grade I Grade II Grade III	 53 (59) 34 (38.2) 1 (1.1) 1 (1.1)
Prolapse relapse no. (%)	5 (5.6)
De novo / Postoperative stress urinary incontinence no. (%)	2 (2.2) / 8 (8.9)
De novo / Postoperative urge urinary incontinency no. (%)	4 (4.5) / 6 (6.7)
De novo / Postoperative dyspareunia no. (%)	6 (6.7) / 8 (8.9)
De novo urinary incomplete emptying no. (%)	2 (2.2)
De novo fecal incomplete emptying no. (%)	1 (1.1)
Urinary retention no. (%)	5 (5.6)
Mesh exposure no. (%)	4 (4.5)
Pelvic pain no. (%)	10 (11.2)

Discussion

Following the FDA notification of high complications associated with transvaginal polypropylene (PP) meshes, the need for a new material for the pelvic reconstructive surgeries is more than ever. Previous studies have shown the initial satisfactory result for the usage of PVDF rather than PP meshes. However, further studies in different populations and with longer follow ups are needed to confirm the biocompatibility and safety of PVDF meshes as a secure alternative for PP meshes. Our study suggests that in a mean of 2-year follow-up period, PVDF meshes have a low rate of complications and can effectively repair the pelvic organ prolapse.

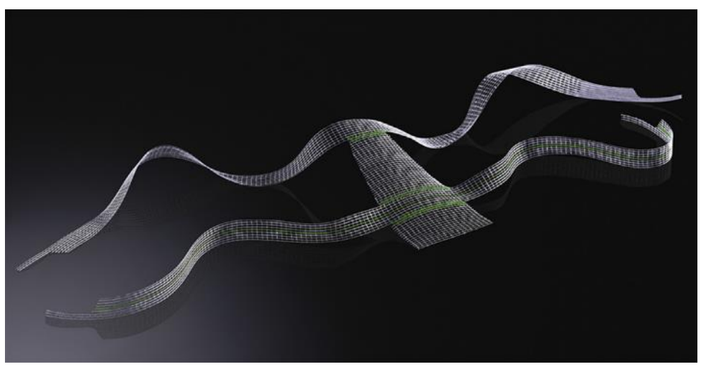

Figure 1. PVDF-mesh (Dynamesh®, PR4), with permission of FEG Textiltechnik (Germany).

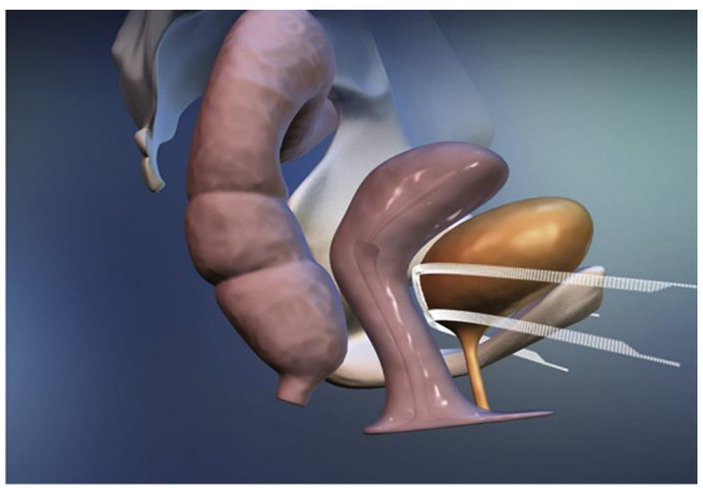

Figure 2. Cystocele repair with anterior vaginal wall insertion of a PVDF-mesh (Dynamesh®, PR4) with permission of FEG Textiltechnik (Germany).

Conclusions

In reaction to FDA warning on mesh associated complications, our study introduces PVDF meshes as an effective and biocompatible material for pelvic organ prolapse surgery.

References

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2- Balsamo R, Illiano E, Zucchi A, Natale F, Carbone A, De Sio M, Costantini E. Sacrocolpopexy with polyvinylidene fluoride mesh for pelvic organ prolapse: Mid term comparative outcomes with polypropylene mesh. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2018 Jan 1;220:74-8.