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ORIGINAL ARTICLE

Transvaginal repair of anterior vaginal wall prolapse with polyvinylidene fluoride (PVDF) mesh: an alternative for previously restricted materials?

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Abstract

Introduction and hypothesis To study the mid-term safety and functional outcomes of transvaginal anterior vaginal wall prolapse repair using polyvinylidene fluoride (PVDF) mesh (DynaMesh®-PR4) by the double trans-obturator technique (TOT).

Methods Between 2015 and 2020, we prospectively included women with symptomatic high-stage anterior vaginal wall prolapse with or without uterine prolapse or stress urinary incontinence (SUI) in the study. The patients underwent transvaginal repair of the prolapse using PVDF mesh in two medical centers. We followed all patients for at least 12 months. We recorded the characteristics of vaginal and sexual symptoms, urinary incontinence, and prolapse stage pre- and postoperatively using International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS), International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF), and Pelvic Organ Prolapse Quantification (POP-Q) system, respectively.

Results One hundred eight women were included in the final analysis with a mean follow-up time of 34.5 ± 18.6 months. The anatomical success was achieved in 103 (95.4%) patients. There was a significant improvement in patients' vaginal symptoms, urinary incontinence, and quality of life scores postoperatively ($p < 0.0001$). Only six patients (5.5%) had mesh extrusion, five of whom were managed successfully. The total rates of complications and de novo urinary symptoms were 21.3% and 7.4%, respectively. Significant pain was reported in 17 cases (15.7%).

Conclusion Our findings show that using PVDF mesh in the double TOT technique for anterior vaginal wall prolapse repair is a safe procedure with high anatomic and functional success rates and acceptable complication rates in mid-term follow-up.

Keywords Cystocele · Pelvic organ prolapse · Postoperative complication · Surgical mesh · Treatment outcome

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Introduction

Pelvic organ prolapse (POP) is a common disease of varying severity among older women, affecting approximately 50% of women with a history of pregnancy, and 20% of them seek medical attention [1]. Given the high burden of the POP, developing a safe and effective treatment strategy is of great importance [2]. Most patients with advanced POP will eventually need surgery [3]. The high rate of failure in traditional POP surgery with native tissue has led to the idea of using synthetic mesh for this purpose since 1990. The size of the mesh, implantation route, and material properties influence the clinical outcome after pelvic reconstructive surgery with mesh [4, 5]. Despite the variety of mesh materials used in POP surgery, the use of polypropylene (PP) meshes has become common throughout the world.

In recent years, greater risk has been reported by using surgical mesh in POP surgeries compared to anti-incontinence surgeries [6]. For instance, the rate of mesh erosion as a major complication in transvaginal POP repair with PP meshes has been reported to be 10 to 19% [7, 8]. This prompted the US Food and Drug Administration (FDA) to warn against the use of surgical meshes [9]. On the other hand, the controversy intensifies when synthetic meshes, despite the high risk of complications such as erosion, provide better pelvic support and a greater postoperative success rate than autologous fascia. As Nguyen and Burchette concluded in their study, not using PP mesh to prevent one case of mesh extrusion would result in surgery for prolapse recurrence in nine [10]. Therefore, studies are underway to find suitable materials in this field.

Polyvinylidene fluoride (PVDF) is a highly non-reactive thermoplastic fluoropolymer that was first described in 2002 for hernia repair by Klinge et al. [11]. Previous animal studies have suggested promising results in terms of tissue response and integration for PVDF [11, 12]. In 2007, Göretzlehner et al. started using PVDF as a new substance in urogynecology [13], and for the first time in 2017, Barski et al. published a report on the short-term efficacy and safety of PVDF mesh for cystocele repair [14]. Moreover, Balsamo et al. compared the outcomes of using PVDF or PP meshes in sacrocolpopexy for patients with POP and showed better anatomic outcomes and fewer storage symptoms and sexual dysfunction in the PVDF arm [15]. Some studies have shown that PVDF has better biocompatibility and causes lower tissue reaction than PP [12]. However, mid- and long-term safety and efficacy of the PVDF meshes have not been established yet. This study aims to investigate the behavior of PVDF mesh as a new material in the surgical repair of high-grade anterior vaginal wall prolapse in mid-term close follow-up.

Materials and methods

This bi-centric prospective study followed the principles of the 1964 Helsinki Declaration and received ethical approval from the institutional research ethics committee (ID: IR.MUI.MED.REC.1399.081). We performed the study between 2015 and 2020 in two teaching hospitals.

Study population

One hundred ninety-six adult women with anterior vaginal wall prolapse were assessed for eligibility. We enrolled the patients with symptomatic stage III or IV prolapse into the study. We explained the benefits and potential complications related to the use of synthetic meshes to the patients. All participants gave informed consent. Exclusion criteria were: pregnancy or planning for childbearing, history of chemotherapy or radiotherapy, infection at the site of surgery, previous mesh insertion at the operation site, or grade IV apical prolapse. Patients might have apical or posterior wall prolapse or stress urinary incontinence (SUI).

Study design

We obtained patients' demographic data and characteristics. We evaluated the vaginal symptoms using International Consultation on Incontinence Questionnaire–Vaginal Symptoms (ICIQ-VS) questionnaire [16], and the most common complaint was having a symptomatic lump or bulge that could be seen or felt in the vaginal area. To quantify the severity of urinary incontinence, we used a validated Persian form of the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) [17].

Patients were examined at lithotomy position for prolapse severity using the Pelvic Organ Prolapse Quantification (POP-Q) system [18]. A cough test was also performed to evaluate SUI. All examinations and surgical procedures were performed by two well-trained and experienced female urologists using the same surgical technique, which will be described.

All patients underwent a pelvic ultrasound and Pap smear to exclude gynecologic pathology. A preoperative urodynamic study (UDS) was performed in patients with a history of anti-incontinence surgery, those with PVR > 150 ml, and patients with neurologic disease. Additional postoperative UDS was not routinely performed. As an additional procedure, we performed transvaginal peritoneal sac closure and levatorplasty for patients with both severe enterocele and rectocele and repaired the rectocele in those with severe rectocele. The minimum follow-up time was 12 months.

Surgical technique

We standardized the surgical procedure before starting the study. For prolapse repair, we performed the double transobturator technique (TOT) using PVDF-mesh (DynaMesh®-PR4, FEG Textiltechnik, Germany). This non-absorbable monofilament mesh sizes 6 × 4 cm and has four arms. After preparation and draping the patient at lithotomy position under spinal or general anesthesia, a urethral catheter was placed. Hydrodissection with normal saline was used to facilitate dissection of the anterior vaginal wall mucosa. The goal of the surgical technique was to adjust each level of the prolapsed organ with DeLancy levels of pelvic support. The operation comprised four steps**:**

Step 1: A midline incision was made, as short and restricted as possible, from 5 cm proximal to the mid-urethra to 3–5 cm distal to the cervix or vaginal cuff. We performed the dissection sharply or bluntly just below the vaginal mucosa and advanced the dissection through the vesicovaginal septum to the pelvic sidewalls: anteriorly up to the middle of the urethra and adjacent to the pubic rami, laterally parallel to the arcus tendinous of the endopelvic fascia, and posteriorly as much as possible near the cervical ring or the uterosacral ligament.

Step 2: For placement of the anterior arms of the mesh, the upper skin punctures were made at the level of the clitoris on genitofemoral folds. Two small helical TOT trocars were inserted through the anterosuperior angle of the obturator space toward the bladder neck (in patients without SUI) or mid-urethra (in patients with SUI) (Fig. 1) using tactile sensation. We did the same on the contralateral side. We performed cystoscopy to rule out bladder or urethral perforation. We tied the anterior arms of the PR4 PVDF mesh to the trocar tips and then pulled them back out of the punctures on both sides.

Step 3: We performed posterior TOT by insertion of two large helical TOT trocars through the inferior punctures, 3 cm inferior and 2 cm lateral to the upper punctures. We touched the ischial spine with the index finger as a landmark for the deepest bony pelvic structure. We guided the trocar with the other hand to enter the pelvic cavity from the posteroinferior angle of the obturator foramen through the coxygeo-sacrospinous ligament (C-SSL) and the muscle complex 1 cm medial and inferior to the ischial spine. The large helical TOT needle tip is configured to allow perpendicular insertion and provide support for the cervical ring as a part of hysteropexy (Fig. 2). We tied the posterior arms of the mesh to the tunneller tips and pulled them back out of the punctures. Then, 2.0 nylon sutures secured the tail of the mesh to the posterior aspect of the cervical ring.

Step 4: Once we extracted all four mesh arms through the skin punctures, we adjusted the mesh gently to elevate the anterior vaginal wall and the prolapsed apex to the level of C-SSL. Afterward, the vaginal mucosa was closed with a continuous 2.0 polyglactin suture without trimming the mucosa.

The urethral catheter and vaginal packing remained for 24 h postoperatively. If the patient's general condition was good and she could urinate without significant post-void residual urine (i.e., > 100 ml), she was discharged home the day after the surgery. Patients received 1 g of IV Ceftriaxone 30 min before the surgical incision, and prophylactic antibiotic (ciprofloxacin, 500 mg, BD) was continued for 3 days postoperatively. We recommended the patients have pelvic rest for 8 weeks following the surgery. Patients with concomitant posterior compartment repair were likely to stay more days in the hospital. In postmenopausal women, we prescribed a topical estrogen cream for daily use from 1 week after the surgery to 3 months, if not contraindicated.

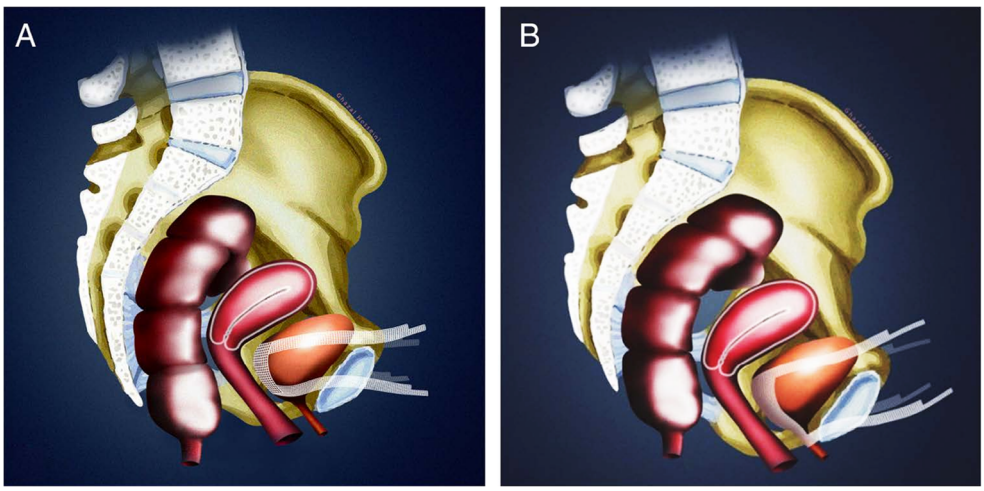

Fig. 1 A. Double TOT technique with PR-4 mesh for treatment of anterior vaginal wall prolapse. Anterior mesh arms are adjusted next to the bladder neck. B. Double TOT technique with PR-4 mesh for treatment of anterior vaginal wall prolapse with concomitant SUI. Anterior mesh arms are adjusted beneath the mid-urethra as an anti-incontinence procedure

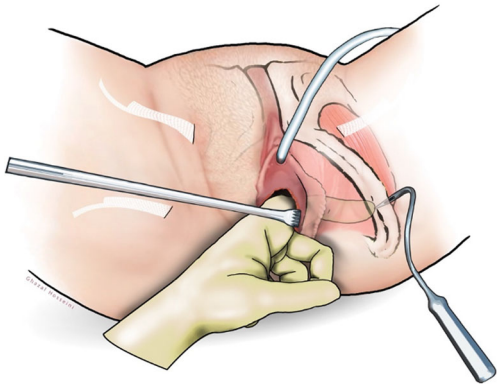

Fig. 2 The route for the posterior tunneler to insert the posterior arm of PR-4 mesh; the three other arms are inserted in the proper site

Outcome assessment

We visited the patients 1 week later to check for early complications. At 4 weeks after the surgery, we assessed the patients by taking a history and performing a physical examination in the lithotomy position for cough test and POP-Q scoring. The pain was measured using the visual analogue scale (VAS), and we considered a VAS score > 6 requiring an analgesic use as significant pain. We repeated the evaluations at 3, 6, and 12 months postoperatively (except for VAS). We asked the patients to complete ICIQ-UI-SF and ICIQ-VS at 12 months.

Complete anatomic success was defined as no anterior prolapse beyond the hymenal ring (Aa and Ba < 0) and cervix above midvagina (C < -TVL/2). The absence of urinary leakage with a negative cough test as well as not using pads except for protection was considered complete success in resolving incontinence.

Statistical analyses were performed using IBM SPSS® statistical software version 23.0 (SPSS, Chicago, IL). Continuous data were presented with mean ± standard deviation, and categorical data were reported as numbers and percentages. After testing data for normality, we used McNemar's test, Wilcoxon signed-rank test, and repeated measures ANOVA to compare the data before and after the surgery. $P < 0.05$ was considered significant.

Results

One hundred fifteen patients underwent double-TOT surgery for anterior vaginal wall prolapse. Seven patients were lost to follow-up, two at the 6-month and five at the 12-month follow-up appointments. Finally, 108 women with a mean age of 61.4 ± 9.2 years were included in the final analysis. Patients' characteristics and perioperative information are shown in Table 1.

The mean operation time was 45.1 ± 12.6 min for the double-TOT procedure only. Concomitant operations including hysterectomy, levatorplasty, rectocele repair, enterocele repair, or posterior colpopexy were performed in 36 (33.3%) patients (Table 1). Two patients required blood transfusion during surgery, both having concomitant surgery besides the cystocele repair. One of them was under treatment with aspirin, and a week before the operation the patient's aspirin was changed to enoxaparin, which was continued for 24 h before the operation. The other one had thalassemia minor but had not taken any anticoagulants.

One-year postoperative anatomic success was obtained in 103 (95.4%) patients. Table 2 shows the mean measures for POP-Q reference points at baseline and postoperative follow-ups. During the postoperative follow-up period, five patients presented with prolapse recurrence (4.6%). We managed three of them (one patient with stage II cystocele and two patients with stage III enterocele) successfully by pelvic physiotherapy and topical estrogen application. We recommended one patient with stage II uterine prolapse for hysterectomy. However, the patient refused the surgery, and we treated her using a vaginal pessary. One patient presented with stage III enterocele 3 months after the surgery, and transvaginal peritoneal sac closure and levatorplasty were performed with a satisfactory result.

Table 3 shows the symptom severities at baseline and 12-month follow-up. The rates of storage and voiding symptoms were significantly reduced after the surgery ($p < 0.0001$ and $p = 0.019$, respectively). The ICIQ-UI-SF and ICIQ-VS scores were significantly improved at 12-month follow-up (p-values < 0.0001) (Table 3). Patients had significantly improved regarding all three domains of ICIQ-VS, i.e., vaginal symptoms, sexual symptoms, and quality of life scores (p-values < 0.0001).

The mean follow-up time was 34.5 (range 12–74) months. Two patients died unrelated to the surgery during the follow-up period. Both had a history of coronary artery disease and died from myocardial infarction: a 60-year-old woman 13 months after surgery and a 52-year-old woman 4 years after surgery. The overall complication rate was 21.3% during the follow-up period (Table 4). Mesh extrusion was seen in six patients (5.5%). In two patients, it was managed with conservative treatment and topical estrogen cream. Another patient underwent outpatient partial mesh removal in the clinic 1 month after the surgery. Only three patients needed mesh excision in the operating room under local anesthesia in which the eroded part of the mesh was removed. In these patients, the procedure was performed 1, 4, and 5 years after the surgery. Except for one patient, mesh extrusion was successfully managed by a single procedure. In the early postoperative period, 17 women (15.7%) reported significant pain needing analgesic use. Three patients complained of self-limiting neuromuscular problems, i.e., paresthesia or pain radiating to the lower

Table 1 Patients' baseline characteristics and perioperative information

Total no. of patient	108
Age (years): mean±SD (range)	61.4±9.2 (34–85)
BMI (kg/m^2): mean±SD (range)	26.5±2 (23–35)
Chief complaint: *n* (%)	
Vaginal mass	78 (72.2%)
SUI	74 (68.5%)
Parity: median (range)	4 (0–14)
NVD: median (range)	4 (0–14)
C/S: *n* (%)	8 (7.4%)
Menopause: *n* (%)	91 (84.3%)
Sexually active: *n* (%)	37 (34.3%)
Risk factors (DM, recurrent UTI, immunosuppression, chronic constipation, PVR>100, hypothyroidism): *n* (%)	52 (48.1%)
Prior pelvic surgery: *n* (%)	
Hysterectomy	31 (28.7%)
Anterior/posterior repair (colporrhaphy)	17 (15.7%)
with suburethral plication	15 (13.8%)
Pubovaginal sling	2 (1.9%)
Burch surgery	1 (0.9%)
Preoperative POP-Q cystocele grade: *n* (%)	
Grade III	79 (73.1%)
Grade IV	29 (26.8%)
Positive cough test: *n* (%)	53 (49.1%)
Operation time (min): mean±SD	
Total	62.7±22.3
Double-TOT only	45.1±12.6
Concomitant surgeries: *n* (%)	
Hysterectomy	1 (0.9%)
Levatoroplasty	31 (28.7%)
Rectocele repair	2 (1.8%)
Posterior colpopexy	2 (1.8%)
Hospital stay (days): mean±SD	2.1±1.4

DM: diabetes mellitus, BMI: body mass index, NVD: natural vaginal delivery, C/S: cesarean section, UTI: urinary tract infection, PVR: post-void residual urine, SUI: stress urinary incontinence, POP-Q: Pelvic Organ Prolapse Quantification system

Table 2 POP-Q points of reference at baseline and 1, 3, 6, and 12 months following surgery (with *p* with p values for repeated measures ANOVA)

	Baseline	Postoperative, 1 month		Postoperative, 3 months		Postoperative, 6 months		Postoperative, 12 months	
	Mean	Mean	*P value*	Mean	*P value*	Mean	*P value*	Mean	*P value*
Aa	+2.1 (−2 to +3)	−2.40 (−3 to −1.5)	< 0.0001	−2.14 (−3 to +2)	< 0.0001	−2.05 (−3 to 0)	< 0.0001	−2.00 (−3 to +1)	< 0.0001
Ba	+5.69 (−1 to +8)	−2.49 (−3 to −1.5)	< 0.0001	−2.19 (−3 to 3)	< 0.0001	−2.08 (−3 to 0)	< 0.0001	−1.95 (−3 to +1)	< 0.0001
C	0.23 (−8 to +9)	−6.40 (−9 to −4)	< 0.0001	−6.14 (−8.5 to −4)	< 0.0001	−5.89 (−8.5 to +1)	< 0.0001	−5.60 (−8 to +2)	< 0.0001
D	−3.17 (−10 to +8)	−8.24 (−10 to −6)	< 0.0001	−7.81 (−9 to −4)	< 0.0001	−7.29 (−9 to +1)	< 0.0001	−7.03 (−9.5 to +2)	< 0.0001

Table 3 Urinary and vaginal symptoms at baseline and 12-month follow-up

	Preoperative	Postoperative (12 months)	*P* value
Storage symptoms (*N*=108)			
SUI: *n* (%)	74 (68.5%)	7 (6.5%)	<0.0001 *
UUI: *n* (%)	33 (30.5%)	9 (8.3%)	<0.0001 *
MUI: *n* (%)	29 (26.9%)	3 (2.8%)	<0.0001 *
Other storage symptoms	30 (27.8%)	8 (7.4%)	<0.0001 *
Voiding symptoms: *n* (%) (*N*=108)	24 (22.2%)	13 (12%)	0.019 *
ICIQ-UI (mean±SD) (*N*=98)	8.79±6.05	0.77±1.87	<0.0001**
ICIQ-VS (mean±SD) (*N*=41)			
Vaginal symptoms	43.31±6.13	7.49±3.75	<0.0001**
Sexual symptoms	43.17±6.15	7.82±4.89	<0.0001**
Quality of life	8.27±0.98	1.6±1.73	<0.0001**

* McNemar's test

** Wilcoxon signed-rank test

extremities. At 12-month follow-up, no patient had significant pain necessitating painkillers.

Four patients presented with acute cystitis during the 1st month after the surgery and received an additional course of antibiotic therapy. A urine culture was negative after 1 week of treatment. Three patients had a significantly elevated PVR postoperatively. One of them had a neuropathic bladder due to spinal canal stenosis, which presented with an underactive bladder needing clean intermittent catheterization (CIC). However, the need for CIC after surgery was reduced. The other two patients developed temporary urinary retention, which resolved 3 weeks later. Eight patients presented with de novo symptoms (Table 4). They all have been managed successfully with conservative treatments with pelvic floor muscle exercise and topical estrogen creams, and none required invasive diagnostic or therapeutic interventions.

Table 4 Postoperative complications

Postoperative complication		Clavien-Dindo
Follow-up (month): mean±SD (range)	34.4±18.6 (7–74)	
Early postoperative complications		
Retention	3 (2.8%)	II
UTI	4 (3.7%)	II
Vaginal hematoma	3 (2.7%)	I
Significant postoperative pain	15 (13.8%)	I
Complications at follow-up		
Mesh extrusion	6 (5.5%)	I, II
Neuromuscular problems	2 (1.9%)	I
Bacterial vaginitis	5 (4.6%)	I
De novo urinary symptoms		
SUI	2 (1.9%)	II
UUI	1 (0.9%)	I
Storage symptoms*	1 (0.9%)	I
Voiding symptoms**	2 (1.9%)	I
Storage + voiding symptoms	1 (0.9%)	I
Prolapse recurrence		
Grade 2	2 (1.9%)	I
Grade 3	3 (2.8%)	II

*Increased daily urine frequency, urgency, or nocturia

**Dysuria, position-dependent micturition, feeling of incomplete emptying, post-micturition leakage, immediate re-void need, splitting of urinary stream, slow and/or interrupted stream, hesitancy, and straining to void

Discussion

Our investigation showed that PVDF is an effective implant material for antero-apical vaginal prolapse repair. Our 1-year objective outcome showed a success rate of 95.4% and a recurrence rate of 4.6%. Overall, vaginal symptom improvement, sexual satisfaction, and quality of life improvement were seen postoperatively, based on ICIQ-VS. Despite performing the procedure in our complex cases where 15.7% of the patients had a history of primary repair failure and 26.8% of them had high-grade or multi-compartment prolapse, the overall success rate was substantial and the overall complication rates were much lower compared to previous reports using PP meshes [15, 19].

In recent decades, PP meshes have been the most widely used implants in slingplasty and pelvic reconstructive surgeries [20]. As noted earlier, vaginal wall repair with native tissue as a safer alternative to synthetic meshes is associated with a high rate of recurrence [21, 22]. However, according to the FDA warning, the transvaginal use of these materials for POP surgeries has shown bothersome complications, and now the use is controversial [23]. In 2002, Kling et al. carried out a morphometric analysis comparing PVDF with PP meshes. They demonstrated a better biostability, less bending stiffness, and minimum host tissue inflammation and fibrosis in PVDF compared to PP, and concluded that "PVDF could be an advantageous alternative to the commonly used materials." They also concluded that the lower tissue reaction in rats implanted with PVDF compared to PP meshes is mainly due to the reduced amount of material with the corresponding reduced surface, i.e., more porosity in PVDF meshes. [11].

Although some authors have reported the use of PVDF meshes in abdominal wall hernia repair [24], there are scars data about applying PVDF meshes in reinforcing the attenuated pelvic fascia. In 2017, Barski and colleagues conducted a preliminary study on 38 cases and claimed that PVDF mesh is safe and effective in transvaginal surgeries of POP in the short term [14]. A year later, Balsamo et al. performed the first comparison of PVDF and PP meshes for open or laparoscopic sacrocolpopexy for POP. Storage symptoms and sexual dysfunction were significantly improved in the PVDF group [15]. In our study, 108 females with high-grade POP underwent the double-TOT procedure with a mean follow-up of 34.5 months. To our knowledge, this is the first prospective study with large sample size and a long follow-up period investigating the efficacy and safety of PVDF mesh transvaginal anterior vaginal wall prolapse repair. At 1-year follow-up, five patients developed prolapse recurrences, which were successfully managed by conservative management, pessary ring placement, or reoperation. These rates are similar to the previous reports of transvaginal cystocele repair with PP meshes [19, 25].

We successfully managed the patient's preoperative vaginal, sexual, and urinary symptoms based on ICIQ-VS and ICIQ-UI-SF. The anatomical success rate at 12 months after surgery was 95.4%. In a study performed by Barski et al. on the efficacy and safety of PVDF mesh in cystocele repair, subjective satisfaction was reported in 87.5% of patients. The rates of prolapse recurrence and mesh extrusion were in line with our results [14]. However, the current study is superior in terms of prospective design, larger sample size, using more specific questionnaires, and longer follow-up duration.

The overall rate of complications was 21.3% in our series. Owing to the structural nature of synthetic meshes, the potential for tissue extrusion has always been considered the main disadvantage, especially in transvaginal POP surgeries. During our long-term follow-up period, there were six (5.5%) patients with vaginal mesh exposure, five of whom were managed successfully with topical estrogen administration or by removing the exposed mesh. In this study, the rate of mesh exposure was lower than in the previous studies using conventional PP meshes in transvaginal POP repairs with an overall mesh erosion rate of 10–19% [7, 8]. We believe that the promising result in reducing mesh exposure besides our surgical modification is caused by the PVDF structure and its biocompatible nature [26].

We suggest two technique modifications to reduce implant extrusion and tissue damage during the procedure. First, we separately sutured the mesh at each DeLancey anatomical level [27] in the pelvis to minimize mesh mobility and migration. Second, we reduced our vaginal wall incision to 3 cm and bluntly dissected the vaginal epithelium at both ends. Then, we passed the tunnellers percutaneously through the anatomical landmarks of the obturator foramen and ischial spine with the guide of the index finger. An intact vaginal epithelium with less scarred tissue may reduce the probability of mesh erosion.

Transient voiding difficulties during the 1st week after surgery is a common complication in patients with transvaginal repair of POP [28]. We reported three (2.8%) patients with bladder-emptying difficulties, one with a history of neuropathic bladder and the other two without a history of voiding disorders. This is expected in POP surgeries regardless of the mesh material, and it may be due to tissue reaction, overcorrection, or retro-pubic or vaginal hematoma at the site of mesh insertion, which can interfere with the bladder neck and cause voiding problems. This can be minimized by using PVDF as a material and double TOT technique versus other types of slingplasty [26, 29].

Pain is the most frequently reported complication of synthetic meshes in POP surgeries and is seen in about two-thirds of patients [30]. It can present as vaginal, abdominal, or buttock pain. Scarring due to the mesh is supposed to have a role in the development of pain, where scar contraction leads to a decreased elasticity and a stiff mesh/tissue compound.

However, in our study, at 12-month follow-up, no patient had significant pain needing analgesic use. Although the definition of pain may vary among the studies, it seems that PVDF meshes produce less scarring owing to higher biocompatibility and thus they cause less pain.

De novo urinary symptoms were found in seven (6.4%) patients. As stated by Rachaneni et al., a good history and clinical evaluation help to determine the best treatment for uncomplicated urinary incontinence and UDS does not improve the outcome of SUI treatment [31], but UDS is indicated in patients with previous anti-incontinence surgery, PVR > 150, or a history of neuropathic diseases. Since not all of the patients routinely underwent a preoperative urodynamic study, patients with occult urinary symptoms were not identified before the surgery. They were likely to present with de novo symptoms after the surgery. However, the rate of de novo symptoms was in the acceptable range (9%) compared to the literature [32].

Using a new material for pelvic floor reconstruction on a large number of patients, relatively long-term follow-up, using intelligible and valid questionnaires, and the prospective nature of the study give superior strength to our research. However, several limitations need to be considered. First, the single-arm design rather than a double-arm study limited our ability to compare the outcomes of PVDF use with any other types of traditionally used materials or to compare the results with non-mesh procedures. However, we reported a very high success rate, minimal recurrence rate, and low complication rate when using PVDF meshes in repairing anterior vaginal wall prolapse. Second, the study population and consequently the procedures performed were not homogeneous. Given that a significant number of patients had SUI in addition to prolapse, and in order not to reduce the number of patients, our study population inevitably became heterogeneous. Finally, our investigation on sexual symptoms was limited since only about one-third of our patients were sexually active. The questionnaire we used for vaginal symptoms did not include dyspareunia. We recommend further studies with larger sexually active subjects to reach a more precise conclusion about the postoperative improvement of sexual symptoms.

In summary, we can conclude that using PVDF mesh in the double TOT technique for anterior vaginal wall prolapse repair is a safe procedure with a high rate of anatomic success and patient satisfaction. In response to the FDA warning, our findings provide worthwhile evidence for a promising alternative synthetic mesh for transvaginal prolapse repair with a low complication rate. However, further steps must be taken to confirm the outcomes in a larger population with a longer follow-up period.

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Authors' contribution MJ Eslami: Data collection and management, Manuscript writing.

M Zargham: Project development, Data collection or management, Manuscript writing and editing.

F Gholipour: Data analysis, Manuscript writing and editing.

M Hajian: Data collection and management, Manuscript writing.

K Bakhtiari: Project development.

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M Eghbal: Data collection.

Z Farajzadegan: Data analysis, Manuscript editing.

Declaration

Conflict of interest for all authors None.

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