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CLINICAL ARTICLE

Long-term functional outcomes following mesh-augmented posterior vaginal prolapse repair

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ABSTRACT

Objective: To assess long-term patient-centered functional outcomes following posterior vaginal wall repair using mesh implants. *Method:* The present prospective telephone interview study enrolled a cohort of women who had undergone posterior vaginal wall repair with mesh between January 1, 2006 and February 28, 2009, at a single center in Israel. Patients were asked to report long-term outcomes, and demographic, clinical, intraoperative, and postoperative follow-up data were retrieved from patients' medical files. Multivariable logistic regression models were used to asses associations between baseline characteristics and long-term outcomes. *Results:* In total, 102 patients were contacted, with 80 (78.4%) at 61–83 months after surgery agreeing to participate. A recurrence of prolapse symptoms was reported by 14 patients (18%) (12 required a corrective procedure), mesh had been removed from two patients owing to erosion/extrusion, and two others had undergone removal of granulation tissue. Long-term, bothersome symptoms were reported by 13 (16%) patients. Parity and previous hysterectomy were associated with lower odds of long-term adverse outcomes, and the location of the apical (C/D) pelvic organ prolapse quantification point and a change in its position following surgery were associated with increased odds of adverse outcomes. *Conclusion:* The long-term adverse-outcome rate was low for patients who underwent posterior vaginal mesh augmentation. These results highlight the importance of apical support for good long-term functional outcomes.

1. Introduction

Rectocele is the most common manifestation of posterior pelvic floor defects, and is often accompanied by constipation and incomplete rectal emptying [1]. Longstanding constipation and increased abdominal pressure can lead to or worsen posterior wall prolapses. Conversely, if not treated properly, rectocele can worsen intestinal syndromes. Advancing age, menopause, perineal surgery, certain congenital perineal defects, and multiparity are risk factors for rectovaginal septum relaxation, changes in the rectal angle, and rectocele [1].

The cumulative risk for requiring pelvic organ prolapse surgery by 80 years of age is 12.6% and the age-specific annual risk has been shown to progressively increase, reaching 3.8 per 1000 women at 70 years of age [2,3]. In the USA, the prevalence of rectocele in women ranges from 12.9% to 18.6% and the average annual incidence is estimated to be 5.7 cases per 100 patient years [4,5].

The aim of surgical rectocele repair is to relieve symptoms that are relevant to the failing anatomic support of the posterior vaginal compartment. Colorectal surgeons frequently operate through an endoanal approach whereas gynecologists usually perform repairs using a transvaginal approach. There are two main methods of transvaginal rectocele repair: the traditional posterior colporrhaphy, and site-specific repair. Both methods can include a biologic graft or synthetic mesh [6].

It has been suggested that mesh augmentation presents no clear advantage in comparison with standard repair [7]. Moreover, transvaginal mesh repair could be associated with adverse outcomes including erosion/extrusion and infection. Additionally, concerns have been raised regarding potential long-term outcomes such as dyspareunia, chronic pelvic pain, and vaginal distortion, which can even occur in the absence of frank extrusion [8,9]. Vaginal mesh erosion and recurrent rectocele incidence rates of approximately 30% and 22%, respectively, have been reported in the literature [10].

Studies of mesh augmentation have mostly assessed anatomical outcomes using pelvic organ prolapse quantification (POP-Q) scores

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and not quality of life [11,12]. Although surgeons tend to focus on anatomical outcomes when defining surgical success, patients are more concerned with functional outcomes [13]. FDA warnings regarding adverse events following transvaginal mesh implantation have led to a call for increased surveillance and reporting of outcomes [14].

The aim of the present study was to assess the long-term functional outcomes of patients who had undergone mesh-augmented posterior vaginal wall prolapse repair.

2. Methods

The present prospective telephone interview study, performed in January 2015, was designed to assess the long-term functional and adverse outcomes among a cohort of women who had undergone posterior vaginal wall repair with mesh implantation at Assuta Medical Center, Rishon LeZion, Israel. The local institutional review board approved the study and oral informed consent for participation was obtained from participants during telephone interviews.

Patients were eligible for inclusion if they who had undergone posterior vaginal wall mesh augmentation for symptomatic posterior vaginal wall prolapse between January 1, 2006 and February 28, 2009. All potential participants were contacted by telephone and asked to participate in the present study.

Prior to surgery, routine history, and general and gynecological physical examinations were performed for each patient. The vaginal examination performed for site-specific prolapse was consistent with the recommendations of the International Continence Society outlined in the POP-Q system. The indication for the primary surgery was symptomatic posterior wall prolapse. Patients underwent a standardized procedure performed by one surgeon (M.N.) and were clinically assessed 1–3 months after surgery in the outpatient clinic. Follow-up continued thereafter with patients' primary care physicians and patients only returned to the study institution if they requested to.

All patients had 1 g of a first-generation cephalosporin administered intravenously 30 minutes before surgery. Iodine antiseptic wash was applied to the surgical site prior to beginning surgery. The surgical technique has been described in detail previously [11]. Briefly, a 50 mL 0.9% saline hydro-dissection was performed at the mid-line of the posterior vaginal wall. A longitudinal incision was made, including the full thickness of the fibromuscular wall of the vagina. A sub-fascial lateral dissection towards the pelvic side wall followed, continuing to the iliac spine and then to the mid-portion of the sacrospinous ligament. The needle guide and the mesh arm used this point thereafter. The other pair of arms was directed through the para-rectal fossa for reconstruction of the posterior compartment. Following this, a partially absorbable mesh implant (Gynecare Prolift; Ethicon, Summerville, USA) was placed and flattened, and the vaginal wall was re-sutured using one layer of running absorbable sutures; the vagina was closed without any resection of vaginal tissue. Additional procedures were only performed if indicated.

Patients who agreed to participate in telephone interviews were asked to provide details of any long-term adverse outcomes, mesh-related complications, and pelvic floor symptoms. Additionally, demographic, clinical, intraoperative, and postoperative follow-up data were retrieved from patients' medical records. The primary outcome was a composite measure of recurrent prolapse (any compartment), stress urinary incontinence (SUI), overactive bladder syndrome (defined as urgency with or without incontinence, usually with frequency, nocturia and dyspareunia), and defecatory dysfunction. The secondary outcome measure was any recurrent surgeries performed.

All statistical analyses were performed using SPSS version 22.0 (IBM, Armonk, NY, USA). Continuous variable data with normal distributions were expressed as mean ± SD; comparisons between groups were made using the Student *t* test. Continuous variables not normally distributed and ordinal variables were presented as medians with inter-quartile ranges and statistical analyses were performed using the Mann–Whitney *U* test. Categorical data were presented as absolute numbers and percentages, and differences were analyzed using the χ^2 and Fisher exact tests, as appropriate. A multivariable logistic regression model was used to evaluate associations between baseline characteristics and long-term symptoms. Variable selection during multivariable modeling was based on clinical and statistical significance. Final parsimonious models were reported. A second multivariate model was constructed to predict repeat operations. A two-sided $P < 0.05$ was considered statistically significant.

3. Results

Of the 102 eligible patients identified from the study institution records, 80 (78%) consented to participate in telephone interviews. Baseline demographic and clinical characteristics of participants in the present study are detailed in Table 1. Almost half the participants had previously undergone a hysterectomy and 36 (45%) had undergone surgery for either a previous pelvic organ prolapse or SUI. POP-Q stage III rectocele was recorded for 76 (95%) patients.

Intraoperative data from posterior vaginal mesh augmentation surgeries are presented in Table 2; all but four procedures were performed under general anesthesia, with the remaining participants receiving regional anesthesia. All patients underwent concurrent procedures; however, only two underwent a concomitant hysterectomy. Treatment with tension-free vaginal tape for SUI was recorded for 37 (46%) patients. Only two patients experienced immediate postoperative complications, which were considered mild (de novo fecal urgency).

Baseline and intraoperative characteristics were also compared between patients who participated in the present study and those who had undergone posterior vaginal mesh augmentation surgery

Table 1
Preoperative patient characteristics (n = 80).[a]

Variable	Value
Age, y	61.53 ± 11.41
Parity	3 (2–3)
Previous hysterectomy	39 (49)
Previous pelvic organ prolapse surgery	24 (30)
Previous SUI surgery	12 (15)
Major health problems	27 (34)
Hypertension	16 (20)
Diabetes mellitus	5 (6)
Rheumatic disease	2 (3)
Malignancy	2 (3)
Hypothyroidism	4 (5)
Asthma	3 (4)
Coronary heart disease	3 (4)
Depression	16 (20)
Other	5 (63)
POP-Q Ba domain	1.50 ± 1.86
Stage	
I	9 (11)
II	22 (28)
III	47 (59)
IV	0
POP-Q C/D domain	4.04 ± 3.03
Stage	
I	2 (3)
II	13 (16)
III	63 (79)
IV	0
POP-Q Bp domain	4.32 ± 1.81
Stage	
I	1 (1)
II	1 (1)
III	76 (95)
IV	0

Abbreviations: SUI, stress urinary incontinence; POP-Q, Pelvic organ prolapse quantification.

[a] Values are given as mean ± SD, median (range), or number (percentage).

Table 2
Intraoperative data from posterior vaginal mesh augmentation surgeries (n = 80).

Variable	No. (%)
Anesthesia	
Regional	2 (3)
General	78 (98)
Concomitant pelvic organ prolapse surgery	
Partial cervical amputation	23 (29)
Hysterectomy	2 (3)
Posterior colporrhaphy	65 (81)
Sacrospinous fixation	80 (100)
TVT for SUI	37 (46)

Abbreviations: TVT, Tension-free vaginal tape; SUI, stress urinary incontinence.

Table 3
Adverse effects occurring during the early and late postoperative period (n = 80).

Outcome	No. (%)
Early postoperative period (1–5 mo)	
Hematoma	1 (1)
De novo fecal urgency	2 (3)
Bladder obstruction symptoms	3 (4)
Late postoperative period (61–83 mo)	
Prolapse symptoms	14 (18)
Anterior	8 (10)
Apical	3 (4)
Anterior and apical	1 (1)
Total prolapse	2 (3)
Defecation problems	1 (1)
Dyspareunia	6 (8)
Mesh erosion/extrusion	1 (1)
Granulation	2 (3)
Dyschezia	1 (1)
Rectal erosion	1 (1)
Recurrent urinary tract infection	1 (1)

who did not participate; no significant differences were observed (data not shown).

Pre-surgery and early post-surgical anatomical measures (assessed using the POP-Q anterior [Ba], apical [C/D], and posterior [Bp] points) are shown in Fig. 1. Following surgery, no POP-Q stage III BP prolapses were recorded and statistically significant ($P < 0.001$) postoperative improvements were observed for Ba, C/D, and Bp POP-Q measures across the entire study population.

Postoperative complications were recorded at 1 month (range 1–5 months) and patients were asked about any complications they had experienced during the telephone interviews conducted at 70 months (range 61–83 months) (Table 3). During early follow-up, only 6 (8%) patients experienced postoperative complications; all were mild and transient. During the interviews, recurrence of prolapse symptoms was reported by 14 (18%) patients; these patients were invited to the study institution for re-evaluation and prolapses were found to mostly affect the anterior compartment. Corrective procedures were required by 12 patients. Anterior pelvic floor compartment prolapse was observed in all 12 patients who required repeat surgeries. Of these 12 patients, two also underwent posterior compartment reconstruction at the same time, indicating two posterior compartment recurrences. Mesh complications necessitated repeated operations in 4 (5%) patients. Mesh removal due to erosion/extrusion was necessary for 2 (3%) patients, 2 (3%) patients underwent surgery to remove granulation tissue from the vagina, and 1 (2%) patient underwent an unrelated surgery owing to endometrial cancer. Long-term, bothersome symptoms other than prolapse that only affected quality of life mildly were reported by 13 (16%) patients. The most common complaint was dyspareunia, which affected 6 (8%) patients (Table 3).

The variables included in the multivariable logistic regression analyses were age; parity; previous hysterectomy; baseline and post-surgical Ba, C/D, and Bp POP-Q point measurements; type of surgery; and follow-up. Parity and having previously undergone a hysterectomy were associated with reduced odds of long-term adverse outcomes, and increasing apical POP-Q C/D point measurements and the change in its position following surgery were associated with increased odds for long-term adverse outcomes (Table 4).

A third multivariate logistic regression model was constructed to analyze associations between repeat operations and recurrent prolapse, after controlling for possible confounders. Only a postoperative change in the position of the apical POP-Q point (C/D) was found to be an independent predictor of increased odds for a repeated operation owing to recurrent prolapse (odds ratio 2.56, 95% confidence interval [CI] 1.08–6.22; $P = 0.033$).

4. Discussion

The major findings of the present study included long-term favorable outcomes, and low adverse-outcome and repeated-operation rates following posterior vaginal mesh augmentation surgery for the treatment of symptomatic rectocele. Only 13 patients (16%) reported long-term, bothersome symptoms other than prolapse. Recurrence of any prolapse symptoms was reported by 14 patients (18%), with

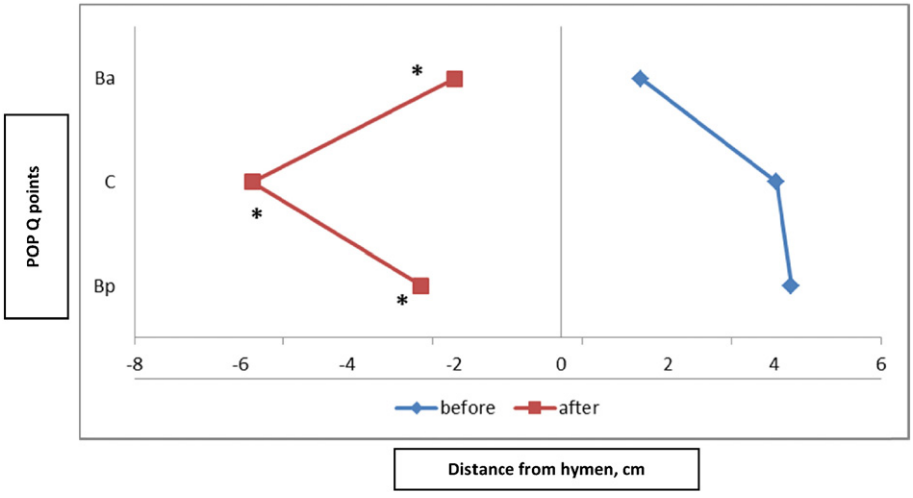

Fig. 1. Anatomical anterior, apical, and posterior POP-Q points (Ba, C/D, Bp) before and after surgery. * indicates a significant difference ($P < 0.001$) between the pre- and post-repair POP-Q point. Abbreviation: POP-Q, Pelvic organ prolapse quantification.

Table 4
Multivariable logistic regression analysis of associations between patient variables with long-term composite adverse outcomes and need for repeated operations.

Variable	Long-term composite adverse outcomes		Repeated operation	
	OR 95% CI	*P* value	OR 95% CI	*P* value
Age at operation	1.00 (0.94–1.05)	0.914	0.97 (0.90–1.05)	0.454
Parity	0.53 (0.29–0.94)	0.031	0.50 (0.19–1.33)	0.187
Patient status post-hysterectomy	0.18 (0.04–0.75)	0.018	0.10 (0.01–0.91)	0.041
Pre-surgery POP-Q domain scores				
Ba	0.71 (0.38–1.35)	0.302	0.78 (0.35–1.76)	0.551
Bp	1.34 (0.37–4.87)	0.661	2.53 (0.66–9.74)	0.184
C/D	2.71 (1.16–6.33)	0.019	2.15 (0.92–5.06)	0.080
Post-surgery change in POP-Q domains scores				
Ba	0.77 (0.49–1.20)	0.249	0.94 (0.55–1.60)	0.817
Bp	0.85 (0.26–2.79)	0.789	2.24 (0.63–8.02)	0.219
C/D	3.32 (1.44–7.67)	0.005	2.44 (1.07–5.57)	0.033

Abbreviations: OR, odds ratio; CI, confidence interval; POP-Q, Pelvic organ prolapse quantification.

most occurring in the anterior compartment; 12 (86%) patients with recurrent prolapse symptoms underwent corrective surgical procedure.

Intra-operative and short-term complications such as bleeding, hematoma, and organ injury during mesh placement have been reported to be associated with synthetic meshes. Adverse long-term outcomes include mesh erosion and surgical failure [6].

In their Cochrane database review examining the surgical management of pelvic organ prolapse in women, Maher et al. [7] retrieved data from three trials that compared native tissue repairs with a variety of total, anterior, or posterior polypropylene meshes for vaginal prolapses in multiple compartments. While no difference in patients' awareness of prolapses was identified between different treatment groups, upon examination, the recurrence rate was higher in the native tissue repair group than in the mesh group (relative risk 2.0, 95% CI 1.3–3.1). The primary mesh erosion rate was 18%, compared with a rate of 9% following secondary correction for mesh erosion. A higher re-operation rate, yet lower recurrence rate, was noted following transvaginal polypropylene mesh repair in comparison with native tissue repair (11% vs 3.7%; relative risk 3.1, 95% CI 1.3–7.3) [7].

In the present study, 16 (20%) patients required further surgery; 12 of these were due to recurrent prolapse (of any compartment). Although comparable to other studies, these rates represent a sustained effect after a median of 70 months of follow-up. Interestingly, in the multivariate logistic regression analysis performed, previous hysterectomy exerted a protective effect against recurrent operations, whereas changes in the C/D POP-Q point following surgery was an independent risk factor for further surgeries.

Re-operation for mesh complications following mesh augmentation is a significant concern for both patients and clinicians. Previous studies have reported reoperation rates owing to mesh complications of 3.0%–7.6% [8,15,16]. A relatively low rate of mesh erosion/extrusion was observed in the present study population; only 2 (3%) patients had mesh removed owing to erosion/extrusion, while 2 (3%) others experienced pelvic pain. Previous studies have reported higher rates of mesh complications [8,15]. High rates (9.0%–16.7%) of de-novo dyspareunia following mesh augmentation have been reported by previous studies [16,17]. Although de-novo dyspareunia was the most common long-term complaint in the current study, it was only reported by 6 (8%) patients, all of whom experienced only mild pain.

Vaginal parity is a known risk factor for recurrent prolapse following pelvic organ prolapse surgery [18]. Surprisingly, the present study found that increased parity was inversely related to the long-term development of adverse post-surgical outcomes. The present study population was highly parous, with a median parity of 3 (range 1–8). It is possible that this finding was incidental; however, it warrants further investigation.

The role of uterine preservation has changed in recent years. It is now commonly accepted that uterine prolapse is not a problem of the uterus but of its ligaments and connective tissue. Hysterectomy itself does not correct the defect and is not adequate treatment for fixation of the vaginal apex [19–21]. Existing data are inconsistent regarding the role of uterine-preserving surgery for pelvic organ prolapse. The question of hysterectomy has also been raised regarding mesh-augmented pelvic organ prolapse repair [22]. Concomitant hysterectomy has been demonstrated to significantly increase the risk of vaginal erosion and studies involving vaginal mesh repair with uterine conservation frequently include both women who have undergone hysterectomy and those undergoing concomitant hysterectomy, making it difficult to distinguish prolapse repair-specific outcomes [21]. High-grade prolapse recurrence rates tend to increase following uterine preservation [23]. In the present study, nearly 50% of patients had previously undergone hysterectomies and two patients underwent concomitant hysterectomy during the index posterior mesh repair procedure. Farthman et al. [19] reported that, after primary prolapse surgery, patients who had undergone a hysterectomy had lower rates of further operations for pelvic organ prolapse or incontinence compared with patients who had undergone uterus-preserving surgeries (13.9% vs 27.0 %). Similarly, Marschalek et al. [20] reported, in a univariate analysis, that patients with recurrent symptomatic prolapse had a significantly lower rate of previous hysterectomy procedures; however, this association was not significant in a multivariate analysis. In the multivariate models constructed in the present study, prior hysterectomy was found to be a significant protective factor for both long-term adverse symptoms and repeated operations. The favorable results in patients who had undergone hysterectomy could be explained by the common practice of performing an apical support procedure (such as McCall culdoplasty or sacrospinous ligament fixation) during hysterectomy. Unfortunately, relevant data from hysterectomy procedures to verify this hypothesis were not available. The favorable outcomes of patients who had undergone hysterectomies, together with the reduced odds of a more severe apical prolapse, as indicated by a higher POP-Q point C/D score, highlights the importance of apical support for long-term outcomes following posterior mesh repair.

A strength of the present study was the inclusion of long-term outcomes that were reported verbally by patients themselves. This reduced the chance of encountering missing data presented by the use of written questionnaires. However, the use of interviews raises the possibility of reporting bias occurring owing to a lack of participant anonymity. All surgeries were performed by one experienced surgeon and this could reduce the generalizability of the results; nevertheless, it diminishes the importance of surgical technique as an influence of outcomes.

The main limitations of the present study were its retrospective design and the lack of validated quality of life questionnaires being administered preoperatively. Although these instruments are accepted as critical components of research, they can require considerable time and significant calculation, and can produce scores that do not have distinct clinical relevance [24]. Although a multiple-question condition-specific quality of life questionnaire evaluating many components can generate total scores that represent an overall measurement a condition, such measurements are limited by the fact that the questions are developed by "experts" rather than from the unique personal perspective of individual patients [25]. Nevertheless, the present study was focused on patient-centered, clinically relevant data.

Not all patients identified through the patient-record search participated in the present study and patients who did not participate could have had different characteristics than those who participated; however, a comparison of baseline and intraoperative characteristics was made, revealing no significant differences with the study participants.

In conclusion, the present long-term follow-up study demonstrated a low adverse-outcome rate among patients who underwent posterior vaginal mesh augmentation surgery for symptomatic rectoceles. These results emphasize the importance of apical support for improved long-term results in patients undergoing posterior vaginal wall surgery with mesh repair.

Conflict of interest

The authors have no conflicts of interest.

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