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Laparoscopic sacrocolpopexy comparing polypropylene mesh with polyvinylidene fluoride mesh for pelvic organ prolapse: Technique description and long term outcomes

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Abstract

Aim: Our aim was to evaluate the feasibility and safety of laparoscopic sacrocolpopexy (LSCP) and compare the long-term outcomes and complication rates of polypropelene (PP) and polyvinylidene fluoride (PVDF), following up within a minimum of 12 months.

Methods: This was a retrospective cohort study using patients who underwent LSCP for POP involving either PP or PVDF mesh between January 2011 and January 2018.

Results: Our study focused on 172 women who underwent LSCP with mesh between January 2011 and January 2018. All procedures were successfully completed laparoscopically, and patients' baseline characteristics were not statistically different in the two groups. Between January 2011 and December 2014, we performed 82 cases of LSC, mainly using PP mesh. Over the last 5 years, since January 2015, we have used PVDF mesh for POP.

Conclusions: LSCP using PVDF mesh was found to provide excellent anatomical and functional outcomes after a median follow-up duration of 41 months, compared with the PP group, which had a median follow-up duration of 54 months. Mesh infection and erosion rates in the PP group were significantly higher than those in the PVDF group. Additionally, rates of vaginal pain and discomfort were significantly lower in the PVDF group when compared with the PP group.

KEYWORDS

laparoscopic sacrocolpopexy, pelvic organ prolapse, polypropelene mesh, polyvinylidene fluoride

1 | INTRODUCTION

The International Urogynecological Association (IUGA) defines pelvic organ prolapse (POP) as the descent of one or more of the pelvic organs (ie, the uterus, vagina, bladder, and bowel) through the genital hiatus.[1] The lifetime risk of undergoing surgery for POP is estimated to be around 20%.[2]

Traditional treatment was based primarily on vaginal and abdominal surgical techniques involving native tissue repair, with or without using mesh. Over the last two decades, however, laparoscopic sacrocolpopexy (LSCP) has been constantly gaining popularity and is regarded as the gold-standard approach by experienced and well-trained surgeons.[3,4] Until now, long-term data has been lacking regarding long-term anatomical results, recurrence, and complication rates after LSCP.

Moreover, a vigorous debate has recently begun about the use of prosthetic material in vaginal and abdominal POP surgeries, as many studies have reported mesh infection,[5,6] erosion, and fistula formation.[7,8] Most of the

meshes used in these studies were made of polypropylene (PP), a material that is associated with an inflammatory and fibrotic reaction.[9] Polymer polyvinylidene fluoride (PVDF) is a nondegradable mesh that was first introduced in 2002 by Klinge et al.[10]

Initial studies involving PVDF have shown higher biocompatibility and reduced reactions and morbidity when compared with PP.[11] PVDF is also visible by ultrasound and magnetic resonance imaging (MRI),[9] which is important during the follow-up period for the anatomical localization of the mesh and also in the case of possible complications. Our study focuses on long-term surgical, anatomical, and functional outcomes when a laparoscopic approach is combined with either PP or PVDF mesh. Our aim was to evaluate the feasibility and safety of LSCP and compare the long-term outcomes and complication rates of PP and PVDF, following up within a minimum of 12 months.

2 | MATERIALS AND METHODS

2.1 | Study design

This retrospective cohort study involved patients who underwent LSCP for POP, using either PP or PVDF mesh, between January 2011 and January 2018. Data were retrospectively collected and analyzed after the Institutional Review Board approved the study.

Patients included in this study were women with symptomatic stage III or IV prolapse, according to the pelvic organ prolapse quantification system (POP-Q), with a minimum follow-up duration of 12 months. Two women in the PP group and one in the PVDF group did not attend their follow-up visits, and their data were excluded. Women who underwent concomitant continence or vaginal surgeries were not included.

Before each operation, a detailed consultation on the surgical technique was conducted with all patients, discussing the implant type and possible complications or recurrences in the future. From January 2011 to December 2014, we used PP meshes, and from January 2014 onward we used PVDF meshes, either PRS or PRR.

2.2 | Surgical procedure

A uniform surgical team (AK and DZ), following standardized surgical steps, performed all procedures. After establishing pneumoperitoneum with a Veress needle, a 10 mm transumbilical trocar was used for a 0° laparoscope, and three 5 mm trocars were inserted suprapubic and iliac, bilaterally. If the patient had a uterus, a total laparoscopic hysterectomy without uterine manipulators was performed as we have previously described.[12]

The anterior vaginal wall was dissected from the bladder to the bladder neck, with the bladder filled with 100 mL of normal saline to help us find the proper surgical plane and bladder integrity. The posterior vaginal wall was dissected down to the levator ani plane. After that, the sacral promontory was identified and the overlying peritoneum was opened while preparing a mesh fixation of about 2 cm. Then, utilizing the advantages of HD laparoscopic cameras, a "tunnel" was created retroperitoneally down to the vaginal wall, without opening the peritoneum. Until December 2014, we used only polypropylene mesh for LSCP. After January 2015, we started using PVDF mesh.

Depending on our preoperative evaluation and intraoperative findings, one of two differently shaped meshes were used. In cases involving either anterior or posterior defects, a flat mesh was used, while in cases where all compartments were affected, a Y-shaped mesh was used. The flat mesh was placed in the affected compartment, either on the anterior or the posterior vaginal wall, and the upper portion of the sacral promontory. The anterior and posterior leaves of the Y-shaped mesh were sutured into the anterior and posterior vaginal walls, respectively, and the third part into the sacral promontory.

The mesh was rolled and inserted through a 10 mm trocar and then opened with the apical portion over the vaginal wall and cranial portion through the retroperitoneal canal towards the sacral promontory. PVDF, compared with PP, demonstrated superior shape stability and easier handling due to its memory effect, aiding the surgeon during this demanding procedure.

PRS mesh was fixed onto both the anterior and posterior vaginal walls with interrupted Ethibond nonabsorbable sutures (made by Ethicon), forming intracorporeal knots and PRP on only the anterior wall. During suture placement, a single vaginal tenaculum was introduced to attain better exposure. Then the cranial portion of the mesh placed through the tunnel was fixed onto the sacral promontory with 3 to 5 tackers (Pro Tack Fixation Devices) in a neutral position to avoid tension. Finally, the hole in the sacral peritoneum was closed using Vicryl 2.0 continuous non-locking sutures.

2.3 | Data collection-assessment

Patients' demographic and medical data were extracted from hospital medical records. After taking a detailed medical history, a physical examination was performed in a gynecological position. All participants were evaluated using POP-Q classification according to a

simplified version by the International Continence Society (ICS).[13] A stress test was performed at maximum physiological bladder capacity before and after prolapse reduction, and additional pelvic and abdominal ultrasounds and urodynamic evaluations were performed in compliance with ICS standards.[13]

Stress urinary incontinence (SUI) was defined the complain of any involuntary loss of urine on effort, physical exertion, sneezing, or coughing and in all cases an urodynamic study was performed to confirm the involuntary leakage of urine during increased abdominal pressure, without detrusor contraction.

Any complain of involuntary loss of urine accompanied or immediately preceded by urgency was defined as urgency urinary incontinence (UUI) and was confirmed with an involuntary detrusor contraction in urodynamic study.

Voiding and storage symptoms were assessed in all patients. Voiding symptoms were characterized as hesitancy, dysuria, post-micturition leakage, slow, or interrupted stream, straining to void and feelings of incomplete bladder emptying. Storage symptoms included urgency, overactive bladder syndrome and daytime urinary infrequency. Anterior prolapse ≥III was defined as when Ba was ≥−1, and posterior prolapse ≥III was defined as when Bp ≥−1, and apical prolapse ≥III when C ≥−1.

Sexual function was validated preoperatively and postoperatively using the questionnaire of the Female Sexual Function Index (FSFI).

After a detailed consultation, informed consent was obtained. Patients with uteri underwent a laparoscopic total hysterectomy, in accordance with our department's strategy. All surgical characteristics were obtained from medical records, and all information concerning intraoperative and postoperative complications was collected. We evaluated all patients postoperatively at 3, 6, and 12 months, and then once every 12 months. Anatomical and functional outcomes were evaluated with anatomical failure/recurrence defined as occurring when POP ≥grade 2 (POP-Q classification) in at least one compartment.

Complications directly related to the insertion of the mesh were described and presented according to IUGA ICS classification code.[14] Severe complications were defined as stage III complications that required an invasive procedure or rehospitalization, according to the Dindo modified classification system. Additional outcomes concerning mesh or surgical complications were recorded.

2.4 | Statistical analysis

Statistical analysis was performed using Fischer's exact test and the nonparametric the Mann-Whitney *U* test when indicated. All calculations were completed using IBM-SPSS version 22.0. A two-sided *P*-value of <.05 was considered significant.

TABLE 1 Study's population characteristics

		PP (n = 82)	PVDF (n = 90)	*P* value (<.05)
Age		61.2 (45-76) y	59.5 (43-79) y	ns
BMI		25.3 (20-34) kg m^2	26.8 (22-38) kg/m^2	ns
Menopausal		60 (73%)	61 (68%)	ns
POP	Stage III	66 (80%)	68 (75%)	ns
	Stage IV	16 (20%)	22 (25%)	ns
Defect	Anterior	45 (55%)	48 (53%)	ns
Defect	Posterior	1 (1.2%)	3 (3%)	ns
Defect all compartments		36 (44%)	39 (43%)	ns
Stress urinary incontinence		17 (21%)	23 (26%)	ns
Urge urinary incontinence		35 (43%)	38 (42%)	ns
Voiding symptoms		68 (83%)	73 (81%)	ns
Storage symptoms		61 (74%)	64 (71%)	ns
Sexually active		49 (60%)	56 (62%)	ns
Sexual dysfunction—dyspareunia		28 (34%)	23 (26%)	ns

Abbreviations: BMI, Body mass index; POP, pelvic organ prolapse.

3 | RESULTS

The population of our study comprised 172 women who underwent LSCP with mesh between January 2011 and January 2019. All procedures were completed laparoscopically and were successful; patients' baseline characteristics are presented in Table 1, while in Table 2 we present surgical characteristics and recurrence of POP. Eighty-two cases of LSC were performed between January 2011 and December 2014 using primarily PP mesh. PVDF mesh was then used for POP starting in January 2015.

In stage III POP cases, PP mesh was used in 66 patients (80%) while PVDF mesh was used in 68 patients (75%). The remaining cases involved stage IV patients, and among them, two in the PP group and five in the PVDF were extremely neglected and displayed eversion greater than 10 cm.

Out of the 82 patients with PP mesh, 45 (55%) had anterior defects, 1 (1.2%) had posterior defects and 36

TABLE 2 Surgical characteristics and recurrence of POP

	PP (n = 82)	PVDF (n = 90)	*P* value (<.05)
Total hysterectomy + LSCP	56	58	ns
LSCP (vaginal vault)	26	32	ns
Operative time Anterior	23 (18-32) min	22 (18-35) min	ns
Operative time Posterior	22 min	21 (17-39) min	ns
Operative time Y shaped	37 (24-59) min	35 (25-53) min	ns
Estimated blood loss	69 (33-320) mL	64 (30-250) mL	ns
Hospital stay	2.3 (1-7) d	2.1 (1-6) d	ns
Follow-up	54 (14-68) mo	41 (12-60) mo	Significant $P < .01$
Recurrence of POP	5	0	Significant $P < .05$

Abbreviations: LSCP, laparoscopic sacrocolpopexy; POP, pelvic organ prolapse.

(44%) had defects in all compartments. Of the 90 patients in the PVDF group, 48 (53%) had defects in the anterior vaginal compartment and 3 (3%) had defects only in the posterior compartment. In these cases, we used the flat mesh (PRP). The remaining 39 patients (43%) had problems in all compartments, and a Y-shaped mesh (PRS) was used.

In the PP group, the mean operative time was 23 minutes for the anterior compartment restoration, 22 minutes in the case of posterior compartment defects and 37 minutes for cases involving defects in all compartments, using Y-shaped mesh.

The mean operative time for the PVDF group, using PRP mesh, was 22 minutes for the anterior compartment and 21 minutes for the posterior compartment. When using PRS mesh for both vaginal compartments, the mean operative time was 35 minutes. The estimated mean blood loss was 64 mL and the mean hospital stay was 2.1 days (range, 1-6).

The median follow-up duration was 54 months (range, 14-108) for patients with PP mesh and 41 months (range, 12-60) for patients in the PVDF group. This is the only parameter in which a statistically significant difference ($P < .01$) between the two groups was observed, as follow-up took longer in PP cases since we have PVDF has been primarily used over the last few years.

Table 3 shows the preoperative and postoperative anatomical characteristics, according to POP-Q classification, in the two groups, and Table 4 shows the postoperative functional outcomes for either persistent or de novo problems.

In the PP group, 12 patients had complications directly related to mesh insertion (shown in Table 5). This included three cases of mesh exposure in the vagina (2AT2S1, 2AT3S1, 2BT3S2) that were treated with vaginal reoperation and one (1AT2S1) that was treated conservatively. Additionally, one case of retroperitoneal ureter compression due to the mesh was observed 12 months after the operation (4CT3S5) and was treated

TABLE 3 Preoperative and postoperative anatomical characteristics according to POP-Q classification

	PP			PVDF		
	Preop	Postop	*P* value	Preop	Postop	*P* value
Aa	+1.3 (−3 to +6)	−2.5 (−3.5 to −1.0)	<.01	+1.7 (−3 to +5)	−2.4 (−3 to −1.5)	<.01
Ba	+3.8 (−2 to +11)	−2.6 (−3 to −0.5)	<.01	+4.2 (−2 to +12)	−2.9 (−3.5 to −2)	<.01
Ap	+2.1 (−3 to +4)	−2.9 (−3.0 to −1.0)	<.01	+2.3 (−3 to +3.5)	−3.1 (−3 to −1.5)	<.01
Bp	−0.8 (−6 to +3)	−2.8 (−3 to −0.5)	<.01	−0.3 (−3 to +7)	−2.9 (−3.5 to −2)	<.01
C	+2.3 (−5 to + 8)	−6.8 (−9 to −4)	<.01	+2.5 (−3 to +9)	−7.2 (−9 to −5.5)	<.01

Abbreviations: PP, polypropylene; PVDF, polyvinylidene fluoride.

TABLE 4 Postoperative functional outcomes for PP and PVDF group either for persistent or de novo problems

	Persistence			De novo		
	PP (n = 82)	PVDF (n = 90)	*P* value	PP (n = 82)	PVDF (n = 90)	*P* value
Stress urinary incontinence	10 (12%)	9 (10%)	ns	4 (5%)	6 (7%)	ns
Urge urinary incontinence	6 (7%)	7 (8%)	ns	3 (4%)	1 (1%)	ns
Voiding symptoms	3 (4%)	0	ns	1 (1%)	0	ns
Storage symptoms	4 (5%)	2 (2%)	ns	1 (1%)	1 (1%)	ns
Sexually active	52 (63%)	61 (68%)	ns			
Sexual dysfunction-dyspareunia	7 (9%)	1 (1%)	<.05	3 (4%)	1 (1%)	ns

Abbreviations: PP, polypropylene; PVDF, polyvinylidene fluoride.

with the placement of a ureteral stent. The recurrence rate of POP was 6% (5 out of 82) in the PP group, with a median follow-up period of 54 (range, 14-68) months, while there have currently been no recurrences or complications reported in the PVDF group, with a median follow-up period of 41 (range, 12-60) months.

Postoperatively, 52 out of 82 (63%) women in the PP group declared themselves sexually active and 10 (12%) complained of sexual dysfunction or dyspareunia. Among them, seven had persistent sexual dysfunction or dyspareunia, and three displayed de novo problems. In detail: in the persistence group 1 woman reported very dissatisfied with overall sexual life on item 16 of FSFI, 4 most times discomfort or pain during vaginal penetration (item 17 FSFI) and 2 most times discomfort or pain following vaginal penetration (item 18 FSFI). In the De novo group with PP mesh two women reported most times discomfort or pain during vaginal penetration (item 17 FSFI) and one woman most times discomfort or pain following vaginal penetration (item 18 FSFI).

In the PVDF group, 61 out of 90 (68%) patients declared they were sexually active, while two (2.2%) reported sexual dysfunction or dyspareunia: one had persistent pain during vaginal penetration almost always (item 17 FSFI) and one a de novo pain following vaginal penetration most times (item 18FSFI). All women were treated conservatively.

In the PP group, we observed a 6% (5 out of 82) recurrence rate and 12% (10 out of 82) rate of vaginal-pain/discomfort. The use of PVDF mesh has excellent outcomes with no serious complications or need for reoperation to date after a median follow up of 41 months.

TABLE 5 Complications related directly to mesh insertion (number and IUGA/ICS code) in the follow up period

	PP (n = 82) 54 (14-68) mo	PVDF (n = 90) 41 (12-60) mo	*P* value (<.05)
Ureter stenosis	1 4C T3 S5	0	ns
Mesh infection	5 1C T2 S1 1C T2 S1 1C T2 S1 1C T2 S1 1C T2 S2	0	Significant $P < .05$
Mesh erosion in vagina	4 1A T2 S1 2A T2 S1 2A T3 S1 2B T3 S2	0	Significant $P < .05$
Fistula formation in vagina	2 4B T2 S2 4BT3 S2	0	ns

Abbreviations: PP, polypropylene; PVDF, polyvinylidene fluoride.

4 | DISCUSSION

LSCP was first described almost 30 years ago and is now performed by the majority of urogynaecological teams as treatment for POP.[15-17] Although the laparoscopic approach is more demanding, it has proven to be as effective as or superior to laparotomy when performed by experienced and well-trained laparoscopic surgeons.[18,19] This competence considers intraoperative and postoperative complications and recovery, which demonstrated similar rates of anatomical and functional outcomes or higher.[19]

The laparoconversion rate ranged from 2% to 8% in various studies.[11,20,21] Our study observed no conversion to laparotomy, which we attribute to preoperative bowel preparation and high surgical competence. All operations

TABLE 6 Studies evaluating mesh exposure after laparoscopic sacrocolpopexy

Study	Pts	Study type	Follow-up, mo	Mesh type	Mesh exposure
Brubaker et al[34,35]	322	RCT	84	17% biological 43% mersiline 39% PP 6% Goertex	23 (10.7%) at 7 y
Culligan et al[36]	115	RCT	60	Porcine dermis PP	1 dermis (1.7%)
Rondini et al[37]	110	RCT	12	PP	2 PP (3.5%)
Tate et al[38]	58	RCT	60	Cadaveric fascia PP	1 Cadaveric fascia (3.4%) 1 PP (3.4%)
Callewaert et al[39]	183	Retrospective Cohort	54 PP 41 PVDF	PP PVDF	2 PP (3.7%) 1 PVDF (2.4%)
Balsamo et al [11]	136	Retrospective case control	94PP 25 PVDF	PP PVDF	1 PP (1.4%) 2 PVDF (3.2%)

Abbreviations: PG, polyglecaprone; PP, polypropylene; PVDF, polyvinylidene fluoride; RCT, randomized control trial.

were performed by the same surgical team with extensive experience in laparoscopic gynecology, who had already performed more than 50 procedures in previous hospital positions. This number is far higher than the minimum of 30 procedures that are required to overcome the learning curve.[22]

In the LSCP literature, the rate of major intraoperative complications ranges from 0% to 10%,[11,23,24] mainly concerning bladder and major vessel perforation. Our study reports no cases of bladder perforation or major vessel injury.

First, during bladder mobilization, we do not use any kind of uterine manipulator, as previously described.[12] The vagina is unobstructed, and when it is necessary during the surgery, the surgeon inserts his left hand into the vagina, and their pointer finger is perfectly oriented to the bladder's surgical margins. We also fill the bladder with 80 to 100 mL NaCl and block the catheter. This makes handling the laparoscopic instruments in a Trendelenburg position more difficult, but in our opinion, it more effectively reveals the correct surgical dissection plane. Moreover, we constantly ensure the integrity of the bladder.

Another important characteristic of our technique is that we do not completely open the retroperitoneum. After finding the sacral promontory, we make an incision about 2 cm in diameter, and then we carefully create a "tunnel" to the vaginal wall. In this way, we minimize mechanical and thermal damage to retroperitoneal structures, consequently reducing intra- and postoperative morbidity. This surgical step would not be feasible without the use of HD laparoscopes, which is another major advantage of laparoscopy that could in no circumstances be implemented in open surgery.

Regarding our strategy for performing a total laparoscopic hysterectomy before sacrocolpopexy, it must be mentioned that we do not use traditional diathermy to open the vagina. In contrast to techniques that involve a uterine manipulator, we use a cold scissor to open the vagina, minimizing tissue necrosis, and improving vascularization of the vaginal vault. Literature reports a mesh exposure rate nearly six times higher when performing a total hysterectomy,[25,26] but our patients' characteristics and long-term outcomes support our approach.

Depending on our preoperative evaluation and intraoperative findings, we decide on the appropriate mesh to use. A straight PP mesh or PRP PVDF mesh is used in cases of predominant defect of the anterior vaginal compartment, and Y-shaped PP mesh or PRS PVDF mesh is used when defects are found in both the anterior and posterior compartments. In this way, the surgeon is able to laparoscopically adapt the mesh to the vaginal wall. Each mesh type comes in varying sizes, so during the operation, the surgeon will determine the appropriate mesh size.

All existing data shows a significantly smaller inflammatory reaction associated PVDF meshes when compared with PP meshes and demonstrates better antimicrobial results, causing better biocompatibility, lower scar-tissue formation, and higher effective porosity.[10,27,28] In our clinic, aspects of the aforementioned studies were confirmed in our data, as we saw no complications directly related to mesh insertion during our follow-up in

the PVDF group, while in the PP group we observed mesh-related complications in 12 patients.

Other critical advantages of PVDF meshes, when compared with the previously-used PP meshes, relates to MRI visibility[29,30] and clearer ultrasound visualization. In our case, with ureter stenosis, MRI visibility would have facilitated our early diagnoses through imaging investigation, excluding any intraoperative injury to the ureter. When PP mesh was used, imaging diagnoses were extremely difficult 12 months post-surgery.

Previous literature has reported the cure rate after LSCP as ranging from 83.8% to 93%,[31-33] and reoperation rates at long-term follow-up as 11% to 16%.[15,24,32] In Table 6, we present several of the more important studies in the literature concerning mesh use in LSCP and mesh exposure rates. Four randomized control trials (RCTs) with large study populations and follow-up periods compare different meshes and implants, and two retrospective studies with long follow-up periods compare PP mesh with PVDF mesh.

One disadvantage of our study is that it is a retrospective study and not an RCT. However, we report a large sample size, especially in the PVDF group, and a long-term mean follow-up of 54 months in the PP group and 41 months in the PVDF group. The difference in the follow-up periods between the two groups is statistically significant and is explained by the fact that we have used PVDF for only 5 years, while PP mesh has been in use for almost a decade. Nonetheless, the follow-up period in the PVDF group is adequate, as all complications appeared within this time period. Additionally, all surgeries were performed in a standardized way over the course of 8 years by an experienced team. We have examined not only the recurrence and reoperation rates but also the anatomical and functional outcomes.

Another limitation of our study is that its retrospective design often underestimates adverse events and causes measurement bias. Moreover, the incidence of adverse events was very small, and we did not observe detailed statistically significant relationships.

5 | CONCLUSION

In this large retrospective cohort study, LSCP using either PP or PVDF mesh was revealed to have excellent anatomical and functional outcomes over a median follow-up period of 41 months, compared with the PP group with a median follow-up period of 54 months. Mesh infection and erosion in the PP group were significantly higher when compared with that of the PVDF group. In addition, rates of vaginal pain and discomfort were significantly lower in the PVDF group when compared with the PP group.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Responsible surgeon, project development, data collection, data analysis, and manuscript writing: AK. Responsible surgeon, project development, data collection, data analysis, and manuscript writing: DZ.

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