



Full length article

Long-term (8.5 years) analysis of the type and rate of reoperation after transvaginal mesh repair (Prolift®) in 349 patients



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ABSTRACT

Objective: Polypropylene meshes have specific complications, and in 2016 the Food and Drug Administration required a Premarket Approval for their use in pelvic prolapse repair, as there was a lack of long-term data.

Our objectives were to determine the long-term reoperation rates and type in our patients after transvaginal mesh repair and to study their risk factors.

Study design: We were able to follow up with 349 patients from a single University Hospital, with phone calls, after a median time of 8,5 years.

The 8.5-year reoperation rates were derived from Kaplan-Meier survival curves.

Results: Our global, long-term reoperation rate, including mesh complications, prolapse recurrence and urinary incontinence after a median follow-up of 8.5 years, was 14.5%.

The mesh-related complication rate (including mesh exposures, infections, and retractions requiring surgery) was 4.3%, the urinary incontinence rate was 5.7%.

The prolapse recurrence rate was 7.2%; mainly found with posterior mesh only (18.5% of reoperations). For total Prolift, the reoperation rate for prolapse recurrence was only 4%. Moreover, 867% of the patients who had an anterior Prolift only or a posterior Prolift only and who were re-operated for prolapse recurrence showed recurrence exclusively in another compartment. In bivariate analysis, only the posterior mesh type was significantly associated with prolapse recurrence versus total meshes.

Conclusion: Despite their market withdrawal, the transvaginal meshes are a safe and efficient option for pelvic organ prolapse surgical management. Low rates of mesh complications can be achieved with cautious dissection and adequate training of surgeons.

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Introduction

Pelvic organ prolapse (POP) is a frequent reason for consultation, especially with the increase in life expectancy and with women spending a third of their life in menopause. They can be strong functional causes of complaint for patients. Indeed, between 30% and 50% of women will present with a perineal trouble in their life, and approximately 6%–18% will need surgery

[1]. Considering the incidence and the high cost of prolapse surgery (over 1,4 billion dollars per year in the USA [1]), optimal treatment needs to be defined. However, traditional surgical procedures using weak native tissues have a high risk of failure, with almost 30% requiring reoperation [1]. The abdominal surgical approach is the standard, but the lower reoperation rate expected for prolapse with this technique [2] has not been consistent and needs to be balanced against the longer operation time, the longer learning curve, and the higher cost [2].

Thus, vaginal synthetic meshes were developed, and it was attractive as a minimally invasive surgery that seemed to provide better anatomic results [3]. Post-operative pain was decreased compared with sacrospinous fixation techniques, and rehabilitation time was shorter [2]. Nonetheless, the meshes also involved specific complication management, such as mesh exposures or rare

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infections. This issue explains the market withdrawal of many vaginal meshes. In 2016, the Food and Drug Administration (FDA, USA) issued a final order to require the filing of a premarket approval application or notice of completion of a product development protocol for surgical mesh for transvaginal POP repair [4]. Still, many studies, even if sometimes inconsistent, demonstrated mesh reliability [5–9]. For example, prolapse recurrence was reported from 4.4% to 33% after prolapse mesh repair [6,10–12], up to 41% with biological meshes [13], and it depended mainly on the definition of the failure (prolapse stage, symptoms, another surgery). Likewise, authors reported that from 2.9% to 23% of cases had mesh exposures [12,14] with 2.6% to 13% undergoing surgical correction [2,14,15] and that global reoperation rates were from 8.5% to 23%. Mesh use is also limited by the lack of long-term studies.

Thus, to fully understand the impact of mesh procedures, new evaluations are required to assess if additional surgeries (as an objective criteria) are needed after them. For this purpose, the joint working group of the International Urogynecological Association and International Continence Society (IUGA/ICS) [16] proposed a standardized terminology as follows to report subsequent procedures to the primary surgery: prolapse surgery at a different site, prolapse surgery at the same site, surgery for a primary procedure complication, and surgery for non-prolapse-related conditions such as urinary or fecal incontinence.

Therefore, the purpose of this study was to analyze the type and the rates of reoperation after Prolift transvaginal mesh repairs in a large cohort of patients after long-term follow-up.

Materials and methods

This study was a retrospective, single center study of 600 consecutive patients who underwent transvaginal mesh repair with Prolift for symptomatic POP with POP-Q stage 2 or more between 2005 and 2009 in Jeanne de Flandre (Lille University Hospital, France).

Patient follow-up data were collected through phone calls from the first author (O.P.) in 2015.

The following information was collected and checked in medical files: age, medical, surgical and obstetric history, stage of POP and compartment involved, type of Prolift, concomitant surgery, intraoperative complications, and the type, place and date of reoperation with the indications for reoperation. Complications requiring surgical intervention were graded according to the Dindo classification system [17] and classified in conformity with IUGA/ICS classification.

Only severe adverse events of Clavien-Dindo classification stage 3a (surgical management with local anesthetic) are reported in this study.

Every patient had a pre-operative consultation with a systematic cough stress test (gynecologic position, bladder full according to the patient) to detect stress urinary incontinence (SUI) or occult urinary incontinence (only revealed after prolapse reduction), and staging of POP was performed according to a simplified version of the International Continence Society (ICS) POP-Q staging system as described by Swift et al [18]. Urodynamic evaluation was performed only when symptoms suggested concomitant SUI. The prosthesis is a pre-cut nonabsorbable, macrosporous, monofilament, soft synthetic polypropylene mesh (Prolift Pelvic Floor Repair System; Ethicon Women's Health and Urology, Somerville, NJ). The surgical procedure was the standardized transvaginal mesh procedure described by the TVM group [19] and previously described by De Landsheere [12]. A concomitant procedure was carried out if necessary, including vaginal hysterectomy or traditional repairs such as sacrospinous fixation or colporrhaphy. In all, an additional surgical procedure was

performed for 118 patients (33,8%). The decision to perform in patients with preexisting SUI a concomitant TVT-O (Tension-free Vaginal Tape-obturator) was based on the severity of symptoms. The sling insertion was carried out alongside Prolift mesh repair according to the technique described by de Leval [20].

The study protocol was approved by the institutional review board of the French College of Obstetricians and Gynecologists (#CEROG-2011-GYN-0201) and received local institutional approval.

Data are presented as numbers (percentage) for categorical variables and mean (standard deviation (SD)) or median [range] for quantitative variables. The normality of the distribution was checked graphically and using the Shapiro–Wilk test.

To assess the selection bias related to patients who were not reachable such a long time after their first surgery, the main patient characteristics were compared using Student's *t*-test or Mann-Whitney U test for quantitative variables and a Chi-Square test for qualitative variables between women included and not included in the study. To evaluate the magnitude of differences between included and excluded patients, we calculated the absolute standardized differences, and a standardized difference higher than 20% indicated meaningful imbalance.

We studied the association between Prolift characteristics and the reoperation rate using Cox regression analysis. Proportional hazard assumptions were examined using Schoenfeld residuals. The 10-year reoperation rates were derived from Kaplan-Meier survival curves. The effect sizes were measured by Hazard Ratios (HRs) with their 95% confidence intervals.

All statistical tests with a 2-tailed α level of 0.05. Data were analyzed using SAS version 9.4 [SAS Institute Inc., Cary, NC 27513, USA].

Results

Study population

Of the 600 consecutive patients who were initially identified, 349 patients were reachable and agreed to participate in this follow-up evaluation (58.2%) (Fig. 1). Patient characteristics are presented in Table 1. We found differences between reachable and non-reachable patients in terms of previous hysterectomy and surgery for SUI, but we found no meaningful differences when examining absolute standardized differences.

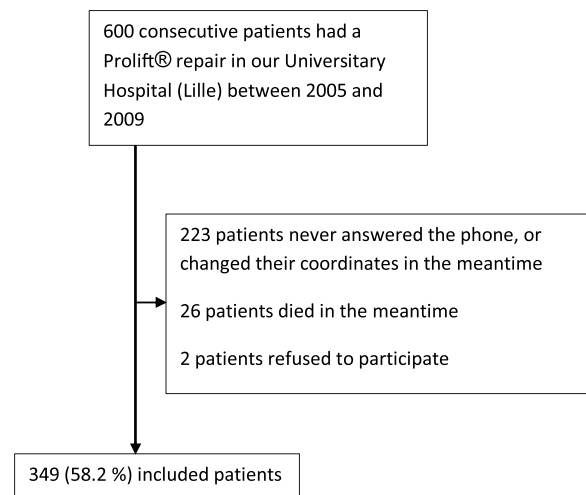


Fig. 1. Flow-chart. Description of our included and excluded patients with reasons for exclusion.

Table 1
Patients characteristics.

	Eligible patients (n = 600)	Included patients (n = 349)	Excluded patients (n = 251)	Absolute standardized difference (%)	P-value
Age, mean (SD)	63.9 (10.2)	63.9 (9.4)	63.9 (11.3)	0.15	0.99
Parity, median [range]	2 [0 to 11]	2 [0 to 10]	2 [0 to 11]	12.5	0.30
Previous surgeries	205 (34.2)	123 (35.2)	82 (32.7)	5.4	0.51
Previous hysterectomy	128 (21.3)	85 (24.4)	43 (17.1)	17.9	0.033
Previous prolapse repair	116 (19.3)	62 (17.7)	54 (21.5)	9.5	0.25
Previous continence surgery	80 (13.3)	46 (13.2)	34 (13.6)	1.1	0.90
Surgeon					
Senior	473 (78.8)	282 (80.8)	191 (76.1)	11.5	0.16
Resident	127 (21.2)	67 (19.2)	60 (23.9)		
Concomitant surgery					
Native tissue prolapse repair (sacrospinofixation, anterior colporrhaphy)	214 (35.7)	118 (33.8)	96 (38.3)	9.3	0.26
Hysterectomy	51 (8.5)	18 (7.2)	33 (9.5)	8.3	0.32
Surgery for SUI	11 (1.8)	10 (2.9)	1 (0.4)	19.6	0.030
Prolift® type					
Anterior only	56 (9.3)	31 (8.9)	25 (10.0)	6.2	0.76
Posterior only	116 (19.3)	65 (18.6)	51 (20.3)		
Anterior and posterior	428 (71.4)	253 (72.5)	175 (69.7)		
Anterior and posterior with uterine preservation	329 (54.8)	185 (53.0)	144 (57.4)	8.8	0.29
Anterior and posterior with concomitant hysterectomy	31 (5.2)	20 (5.7)	11 (4.4)	6.3	0.52
Anterior and posterior with previous hysterectomy	68 (11.3)	48 (13.8)	20 (8.0)	21.1	0.036

Values are number (percentage) unless otherwise indicated.
SD: standard deviation; NA: non-applicable.

Of the 349 mesh recipients included in this study, the mean age was 63.9 years. A total of 85 patients (24.4%) had previous hysterectomy, 62 patients at least one previous prolapse repair, and 46 patients previous urinary continence surgery. 253 patients had total repair (anterior and posterior meshes), and beyond them 53.0% were performed with uterine conservation. Concomitant native tissue prolapse repair was performed on 33.8% of the patients. The median follow-up was 8.5 years [range, 6.7–10.6]. We reported 50 patients who needed a reoperation (10-year Kaplan-Meier estimation: 14.5%), out of which only 7 patients required 2 reoperations and 4 patients required 3 reoperations. The interventions were performed by experienced senior surgeons for 80.8% of included patients; the rest were performed by graduate residents under senior supervision.

Post-operative complications

Table 2 and 3 detail post-operative rates, indications and median presentation times for mesh-related complications, urinary incontinence (Table 2) and prolapse recurrence (Table 3). Fig. 2 shows complication-free probability across time.

15 patients had mesh-related complications, most commonly mesh exposure (2.6%) with a median presentation time of 24 months. Posterior mesh exposure was more frequent (2.5%) than

anterior mesh exposure (2.1%). We also reported one mesh infection at 0.5 months (after total Prolift with concomitant hysterectomy, which justified large mesh excision 2 weeks after mesh insertion) and one symptomatic synechia. One severe rectal compression causing constipation and dyschezia and one severe symptomatic mesh retraction also resulted in wide mesh removal.

The main reoperation indication was not urinary incontinence as it was after 3 years [12] but prolapse recurrence. For the patients reoperated for direct prolapse recurrence, they mainly initially had a posterior Prolift only. However, only 3.1% of the patients who had a posterior Prolift only had been reoperated for direct prolapse recurrence.

We counted 9 secondary hysterectomies with 2 indicated by post-menopausal bleeding. Only one (and it was one of those 2) anatomopathological examination found malignant cells (adenocarcinoma).

Bivariate analysis of reoperation risk factors

The 8.5-year reoperation rate among the reachable patients was 14.3%. In bivariate analysis (Table 4), we did not find any association between the global reoperation rate and patient age, parities, previous surgery (even specifically previous non-prospective prolapse surgeries or previous hysterectomies), concomitant

Table 2
Surgical postoperative complications: mesh related complications and urinary incontinence procedures.

	n (%)	Presentation time, month, median (range)
Mesh related complication	15 (4.3)	24 [0.5 to 93]
Global exposure mesh rate	9 (2.6)	
Anterior mesh exposure	6 / 284 (2.1)	
Posterior mesh exposure	8 / 318 (2.5)	
Mesh infection	1 (0.3)	0.5
Severe painful mesh contraction	3 (0.9)	26.7 - 55.1 - 62.0
Rectal compression	1 (0.3)	24
Symptomatic synechia	1 (0.3)	11.5
Urinary incontinence	20 (5.7)	19.4 [3.7 to 87.8]
De novo SUI	16 / 20 (80.0)	
Recurrent SUI	2 / 20 (10.0)	
Persistent SUI	2 / 20 (10.0)	

Table 3
Surgical postoperative complications: prolapse recurrence.

	n (%)	Presentation time, month, median (range)
Prolapse recurrence	25 (7.2)	55.5 [0 to 122.7]
Other compartment prolapse surgical recurrence	13 / 15 (86.7)	42.0 [0 to 107.7]
After anterior isolated Prolift®	3 / 31 (9.7)	12.4 - 78.2 - 107.7
Rectocele	3 / 31 (9.7)	12.4 - 78.2 - 107.7
Elytrocele	1 / 31 (3.2)	107.7
After posterior isolated Prolift®	12 / 65 (18.5)	48.8 [0 to 122.7]
Other compartment prolapse	10 / 65 (15.4)	36.9 [0 to 83.7]
Rectocele	2 / 65 (3.1)	62.0 - 122.7
Elytrocele	1 / 65 (1.5)	18.4
After total Prolift®	10 / 253 (4.0)	54.1 [11.9 to 89.2]
Cystocele	4 / 253 (1.6)	58.8 [52.7 to 87.8]
Uterine prolapse	6 / 253 (2.4)	45.6 [11.9 to 89.2]
Rectocele	0 / 253	-
Elytrocele	0 / 253	-

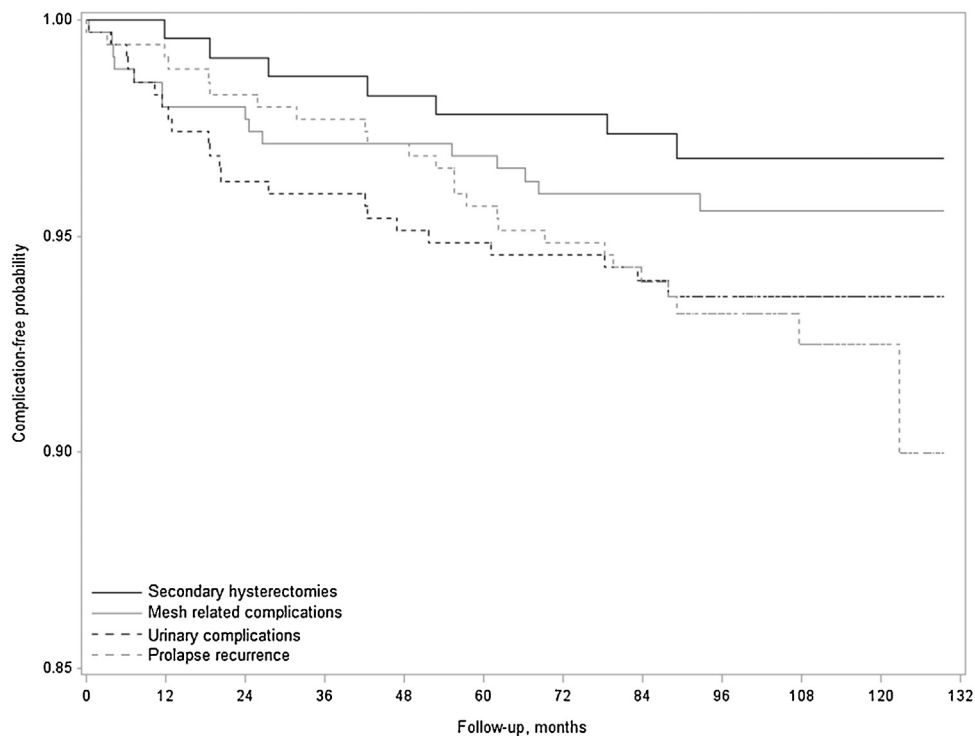


Fig. 2. Complication-free probability across time.

Across time (in months), the percentage of patients without complications such as secondary hysterectomies, mesh-related complications, urinary complications, and prolapse recurrences requiring surgical management.

surgery (prolapse surgery, hysterectomy or incontinence surgery), or surgical indication (data not shown). Only the posterior Prolift type was significantly associated with prolapse recurrence versus total Prolift, where the Hazard Ratio was 4.84 (95%CI = 2.09–11.21); $p = 0.001$). We did not find any association with any complication sub-group.

Comment

Despite its market withdrawal in 2013, it seems that the Prolift system could be associated with good midterm anatomic outcomes and few severe complications [9,12]. Prolift mesh repairs seemed to be quite safe in our experience and with our technical skills; thus, it is obviously important to determine whether its safety and efficiency remained after long-term follow-up, and this data was critically lacking [21]. In this large retrospective cohort of 349 patients, we found a global reoperation rate of 14.5% after

mesh repair, which was similar to Denman et al [22], Heinonen et al [10] and Warembourg et al [23] but higher than most short-term studies. Compared to the data we published about this same cohort after a 3-year follow-up, we found a reassuring and very slight increase in the reintervention rate. Indeed, the global reoperation was 11.6% at that time. The reoperation-requiring mesh exposure rate was 2.6%; most of them occurred early. This result is globally a lot lower than other studies where we found rates from 2.9% to 23% [6,7,14,24,25], but it is comparable to the mesh exposure rates for sacrocolpopexy reported in a 2004 review [26]. Perhaps this issue is the result of T incision avoidance and mesh placement underneath the full thickness of the vaginal wall [27].

The precise etiology of erosion is unknown, but age and sexual activity seem to be involved, and early exposure could be favored by post-operative vaginal hematoma, infection, or bad quality vaginal tissue; however, late exposure could result from chronic

Table 4
Bivariate analysis of global reoperation.

	Event	HR (95%CI)	P-value
Age	–	0.98 (0.95 to 1.01)	0.24
Parity	–	0.89 (0.74 to 1.07)	0.21
Previous surgery	15 / 121 (12.5)	0.91 (0.50 to 1.66)	0.76
Yes	32 / 226 (15.5)		
No			
Previous hysterectomy	8 / 83 (9.7)	0.72 (0.35 to 1.49)	0.38
Yes	39 / 263 (15.9)		
No			
Previous non prothetic prolapse repair	4 / 61 (16.6)	1.24 (0.62 to 2.48)	0.55
Yes	37 / 285 (14.0)		
No			
Previous continence surgery	3 / 46 (6.5)	0.56 (0.20 to 1.55)	0.26
Yes	44 / 300 (15.8)		
No			
Surgeon	37 / 279 (13.9)	0.88 (0.44 to 1.78)	0.73
Senior	1 / 67 (16.8)		
Resident			
Concomitant surgery	11 / 117 (9.90)	0.64 (0.33 to 1.23)	0.18
Yes	36 / 229 (16.7)		
No			
Hysterectomy	6 / 32 (18.8)	1.36 (0.58 to 3.21)	0.48
Yes	41 / 314 (14.0)		
No			
Surgery for SUI	2 / 9 (22.2)	1.84 (0.45 to 7.57)	0.40
Yes	45 / 337 (14.2)		
No			
Cystocele	13 / 57 (23.0)	1.00 (ref.)	0.06
Stage 0-I	6 / 46 (13.0)	0.51 (0.20 to 1.34)	Ref.
Stage II	28 / 243 (12.8)	0.47 (0.25 to 0.89)	0.17
Stage III-IV			0.020
Urine prolapse	16 / 131 (12.9)	1.00 (ref.)	0.67
Stage 0-I	11 / 90 (14.6)	0.93 (0.43 to 1.98)	Ref.
Stage II	7 / 125 (16.1)	1.25 (0.66 to 2.39)	0.84
Stage III-IV			0.50
Rectocele	11 / 93 (14.3)	1.00 (ref.)	0.30
Stage 0-I	18 / 150 (12.3)	1.04 (0.49 to 2.21)	Ref.
Stage II	18 / 103 (17.8)	1.63 (0.77 to 3.42)	0.91
Stage III-IV			0.20
Elytrocele	35 / 268 (14.2)	1.00 (ref.)	0.81
Stage 0-I	4 / 29 (13.8)	1.07 (0.38 to 3.00)	Ref.
Stage II	8 / 49 (16.4)	1.29 (0.60 to 2.77)	0.90
Stage III-IV			0.42
Prolift® type	4 / 31 (21.7)	1.21 (0.42 to 3.47)	0.002
Anterior only	17 / 63 (27.1)	2.88 (1.58 to 5.26)	0.72
Posterior only	26 / 252 (10.6)	1.00 (ref.)	0.001
Anterior and posterior			Ref.

Event is the number of event occurred over the time and the percentage of event at 10 years according to Kaplan-Meier estimation.
HR: Hazard Ratio; CI: confidence interval.

erosion due to mechanical stress and long-term effects of interactions between the mesh and the surrounding tissue. A high rate of mesh exposure should be considered a symptom of a lack of dissection knowledge and appropriate training.

Concomitant hysterectomy was not a risk factor for mesh complications in our series (HR 95%CI=0.69–8.64; $p=0.17$), and it was not even a risk factor specifically for mesh exposure ($p=0.62$). Previous hysterectomy neither. We did not find a statistically significant difference between operation by a resident or by a senior surgeon, so we did not confirm the existence of a learning curve [28], but all residents were supervised by pelvic-floor experienced surgeons.

We counted 7.2% of reoperations for prolapse recurrence, which is higher than other results [12] but less than the other long-term follow-up study [10]. Thus, this may just reflect a longer follow-up, which is supported by a median time for this recurrence of 55.5 months. No patient contacted had a pessary for prolapse recurrence.

86.7% of reinterventions for prolapse recurrence occurred in another compartment and cannot be considered as mesh failures.

According to Denman [22], women who had undergone previous POP surgery were more likely to have reoperation at the same site, but we did not find this difference.

We found a high reoperation rate for prolapse recurrence (18.5%) for patients who had posterior Prolift only (HR comparing to total Prolift 4.84; $p=0.001$), but it was a direct recurrence for only 3.1%. However, the risk of secondary de novo cystocele is also well known after posterior sacrospinous fixation. To date, no studies have shown any benefit of mesh overlay or augmentation of a suture repair for posterior vaginal wall prolapse, and the last Cochrane review (2016) did not support the use of vaginal mesh in the posterior compartment.

Another risk factor of prolapse recurrence in the literature is the young patients age [8], but we did not find this association (HR=0.99; $p=0.53$).

We also found that 5.7% received urinary incontinence surgery. Thus, it was not the most common indication of reoperation in our cohort as it was in the same cohort after 3 years (6.9%) [12] and for Bartley et al [8], who found a higher rate at 15%, which was a little bit more than Altman et al in one randomized trial. This team

found a similar rate to ours after anterior colporrhaphy (6%) [29]. However, only half of our patients had de novo symptoms. Thus, SUI might manifest over time and be related to the same risk factors that caused the prolapse in the first place. Moreover, the anchors of the mesh could alter the normal urethrovesical angle that is part of the continence mechanism, and the extensive dissection we performed during the procedure could cause denervation and scarring of the urethra and its supporting tissue.

The main strength of this study is that it shows long-term outcomes of Prolift meshes, which were lacking in this field [30], compared to other studies, with a maximum follow-up of 4 years [11,12,14]. Nevertheless, 2 studies also showed 7 and 8 years follow-up [10,23].

The cohort size is a major strength as well, as it is the largest published so far, and the use of standardized, validated outcome measures is a strength (Dindo and IUGS/ICA classifications).

Also, prolapse distribution in terms of stage and population was similar in our study and others in the literature, nonetheless this was a single center study.

The weaknesses of this study revolve mainly around its retrospective design and the rate of patients lost in follow-up. Indeed, as it was expected with such a long-term follow-up, many people were not reachable, and 4.3% of our 600 initial patients died (non-related causes). However, patients requiring surgery are usually followed-up for a longer time than those who did not [8]. Thus, we assumed that the reoperation rate was not underestimated. Long-term surveillance, although fraught with limitations, is necessary to demonstrate stable surgeries.

Another weakness of this study is the absence of systematic, long-term, post-operative examination, leading to underestimation of the complications that did not require surgery, such as quality of life problems. We picked surgical reoperations because surgical indications are based on symptoms and life quality deterioration.

We can conclude that even with a long-term follow-up, Prolift meshes show a low reoperation rate for prolapse recurrence but a higher global reoperation rate.

The best solution is to have the right attitude toward our patients, informing them of the risk-benefit situation and counseling them while considering their specificities. In the case of recurrence after surgical treatment for patients showing risk factors for complications, a transvaginal approach has shown positive results compared to laparoscopic surgery [31].

Paper presentation information

This study has been presented at the 9th annual EUGA congress in Amsterdam, Netherlands; at the 40th Collège National de Gynécologie Obstétrique Français (CNGOF) annual days in Montpellier, France; and at the 40th SIFUD-PP (Société Interdisciplinaire Francophone d'Urodynamique et de PelviPérinéologie) annual congress in Montpellier, France.

Author's contributions

Dr. Océane Pécheux: Protocol/project development; Data collection or management; Data analysis; Manuscript writing/editing. Dr. Giraudet Géraldine: Manuscript writing/editing. Mrs. Elodie Drumez: Data analysis. Dr. Di Serio Marcello: Manuscript writing/editing. Dr. Jean-dit-Gautier Estelle: Manuscript writing/editing. Dr. De Landsheere Laurent: data collection and manuscript writing. Pr. Cosson Michel: Protocol/project development; Data collection or management; Data analysis; Manuscript writing/editing.

Conflicts of interest

Pr Cosson is a speaker or expert for Boston Scientific, Allergan, and Fresenius. He is a teacher for surgical sessions for Boston Scientific. He is a co-owner of patents in the field of mesh support for POP surgery, pedagogic innovation and biomechanical simulation. Dr. Giraudet is a speaker and teacher for surgical sessions for Boston Scientific. The other authors do not report any conflicts of interest.

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None.

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