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Prospective long-term results, complications and risk factors in pelvic organ prolapse treatment with vaginal mesh

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ABSTRACT

Objective: To assess the long-term results and complications of pelvic organ prolapse treatment with transvaginal mesh.
Study design: Prospective observational study of 75 women who underwent surgery between 2005 and 2008 by the same surgeon. 44 patients (58,7%) underwent concomitant treatment of stress urinary incontinence.
Anatomical criterion for failure was prolapse grade >I in any compartment. Analysis of functional features consisted of an assessment of urinary, sexual, and defecation symptoms, and pelvic pain. Subjective global evaluation of the treatment was carried out through the Visual Analogue Scale (VAS). Analysis of the early and late complications and their medical or surgical management was performed. Evaluation of risk factors for failure of treatment and extrusion was carried out through logistic regression.
Results: The median follow-up was 5,3 years. The anatomical results showed correction in 91,3% of the patients. Median subjective VAS evaluation: 9/10. Urinary symptoms improved after the surgery. Constipation and dyspareunia rates worsened. Pelvic pain improved. There were two early complications: one rectal perforation, repaired intraoperatively and one pulmonary embolism, managed medically. Late complications: 9 extrusions (3 managed with topical oestrogen, 3 with expectant management, and 3 reoperated, one twice), one cervix elongation and one forgotten gauze (both reoperated), 4 de novo pain managed successfully conservatively. 58,8% of the complications occurred after one year. Risk factors analyzed showed no statistical significance.
Conclusions: Vaginal mesh provides favorable anatomical, functional and subjective outcomes in long-term follow-up. The number of complications is relatively low, but many complications occurred a long-time after surgery.

Introduction

Pelvic organ prolapse (POP) is a frequent health problem in women all over the world, affecting up to one third of them [1]. The estimated lifetime risk of surgery for prolapse or incontinence is 11%, with 1 of 3 patients requiring more than one surgical repair [2]. The traditional approach included the use of the patient's tissues for the reparation, which led to high failure rates. The theoretical reasons for this may have been a bad surgical technique, proceeding's inadequacy; or because of patient's tissues weakness [3].

The use of meshes in abdominal wall hernia repair has significantly increased the success rate. Motivated by this, the use of meshes has been extended to POP. The use of synthetic mesh is considered the gold standard for treatment of vault prolapse abdominally with sacral colpopexy, though the vaginal approach is quicker and cheaper to perform and women have an earlier return to activities of daily living [4].

Since the first publication of the use of a vaginal mesh in 1996 [5], there have been several reports regarding their use. However, there was a lack of homogeneity in the materials utilized and the

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Table 1
Patients baseline features.

Previous grade of prolapse	cystocele	vault prolapse	rectocele
Grade 0	0%	17,6%	33,8%
Grade I	1,4%	12,2%	20,3%
Grade II	37,8%	51,4%	37,8%
Grade III	48,6%	10,8%	4,1%
Grade IV	12,2%	8,1%	4,1%
Median age		67,6 years (45,4–85,1)	
Diabetes		8 (10,5%)	
Menopausal		64 (84,2%)	
Previous abdominal surgery		23 (30,3%)	
Previous vaginal surgery (hysterectomy)		20 (26,3%)	
Tobacco		11 (14,5%)	
Median BMI	26,8 (range 20.3–43)	**Obesity** (BMI $\geq$ 30)	11%

BMI: body mass index.

surgical technique. The development of the commercial kits, available since 2004 as an attempt to standardize the technique, showed initial success rates higher than traditional surgery [6]. In spite of that, there is still scarce literature regarding the long-term, prospective assessment of the results and complications [7–9]. Besides, there are few publications about functional results after the surgery, beyond dyspareunia or postsurgical pain [10].

However, despite the high rate of success, the number of complications related to the surgery is not negligible. In 2008 and 2011, the FDA issued statements due to concern regarding the frequency of complications associated with the use of transvaginal mesh for prolapse repair [11], as also did the European SCENIHR in 2015 [12].

Taking all this into account, the purpose of our study is to show the prospective long-term results, complications and the effects on the most relevant functional features regarding the treatment of POP with tension-free vaginal mesh.

Materials and methods

This is a prospective study of all patients who underwent repair for POP between November 2005 and December 2008 with the tension free transvaginal mesh Prolift®, Ethicon, US ®, in the Department of Urogynecology and Urodynamics, of a major tertiary hospital. Indications for surgery were symptomatic and significant prolapse: POP grade $\geq$ II in any compartment (Baden and Walker system) [13].

The surgical technique consisted of the standardized transvaginal mesh procedure, as described in previous reports [14]. All the patients underwent spinal anesthesia and received preoperative amoxicillin/clavulanic acid as antibiotic prophylaxis. In all patients with pre-existing or occult stress urinary incontinence (SUI), concomitant treatment was performed through suburethral sling (transobturator tape). After the surgery, the patients were taken to their rooms and discharged in 48 h. All the surgeries were carried out by the same experienced urogynecological surgeon (J-C, M.A.)

The follow-up schedule was as follows: first month after the surgery, then third, sixth and twelfth months after surgery, and then annually. In addition, every patient was reviewed at her request.

We carried out a complete urogynecological examination. The anatomical criterion for failure of POP correction was a prolapse grade > I in any compartment.

The analysis of functional features consisted of an assessment of urinary symptoms, including voiding frequency, nocturia, urgency and urge urinary incontinence (UUI), stress urinary incontinence (SUI) and urinary tract infections (UTI). The presence of sexual activity and dyspareunia were also recorded, as well as the appearance of constipation. We also documented the existence of pelvic pain regardless of sexual intercourse. All this data was obtained through direct questions, the answers being "yes" or "no". No validated instruments are adopted. Although severity of symptoms was assessed, the data was categorized as such to facilitate the analysis performed. Subjective global evaluation of the treatment was carried out through the Visual Analogue Scale (VAS).

We analyzed complications, considering early complications those which appeared intraoperatively and in the first month after the surgery, and late complications those which appeared after the first month. They were reported considering the International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery [15] and also according to the Clavien-Dindo classification system. The medical or surgical management and the complications outcome were reported.

In the long-term follow-up, we could not contact 4 patients; in 2 the contact was only via telephone, and both referred to being well. A statistical analysis was carried out under SPSS (version 20.0; SPSS Inc, Chicago, IL) without missing data. Statistical significance was evaluated at the two-sided 0.05 significance level. Comparative analyses were obtained using the Chi Square test for categorical data resorting to Fisher exact test when expected frequencies dictated. For continuous data, T Student test was performed when the size of the groups was greater than 30, resorting to the Mann-Whitney test for smaller groups or those not following a normal distribution.

We studied with univariate logistic regression for the following risk factors: age, BMI, diabetes, tobacco usage, menopause, previous abdominal surgery, previous vaginal surgery and

Table 2
Functional results.

Functional feature	Prior to surgery	After surgery	p
SUI	47,9%	29,6%	0,125
Urgency	55,1%	37,7%	0,019*
Urge incontinence	32,4%	26,8%	0,001*
Voiding frequency < one hour	6,1%	1,5%	1000
Nocturia > one time per night	55,1%	47,8%	0,019*
Frequent UTI (>3/year)	33,8%	26,5%	0,001*
Constipation	26,5%	38,2%	0,004*
Sexual intercourse	40,6%	33,3%	0,000*
Dyspareunia	11,6%	17,4%	0,000*

* Features with statistical significance.

Table 3
Early complications (intraoperatively and in the first month after the surgery).

Early complications	N(%)	IUGA/ICS classification	Clavien-Dindo classification	Management (%)
Rectal perforation	1 (1.3%)	5BT1S2	III	Intraoperative reparation
Pulmonary embolism	1 (1.3%)	7BT2S5	IV	Medical treatment
TOTAL	2 (2.6%)	–	–	Surgical management: 0%

Average loss of haemoglobin: 1.91 g/dl (SD: 1.36). Transfusion rate: 0/75. No visceral, vascular or nerve lesions. No infectious complications related to mesh, fistula or abscess.
N: number of events. %: percentage. IUGA/ICS: International Urogynecologic Association/ International Continence Society. SD: standard deviation.

concomitant treatment of the SUI in the development of treatment failure and extrusion.

Results

A total of 75 women were operated. An isolated anterior Prolift® mesh was inserted in 4 patients (5,3%), an isolated posterior mesh in 1 patient (1,3%) and anterior and posterior in 70 patients (93,3%). 44 patients (58,7%) underwent concomitant treatment of stress urinary incontinence. None of the patients had a concomitant hysterectomy.

The patient's baseline features are described in Table 1.

The median follow-up was 5,3 years (interquartile range 4,4–6,3). The anatomical results showed POP correction in 63/69 (91,3%) of the patients. The failure in the treatment corresponded to the middle compartment –hysterocele- (2 grade II and 3 grade III), anterior compartment (1 grade II) and posterior compartment (1 grade II). No further surgery was required in these cases, as all the patients remained asymptomatic.

Subjective VAS evaluation of results showed a median VAS of 9/10, minimum of 2 in 1 patient, maximum of 10 in 31 patients. There was no statistical difference in VAS outcomes regarding POP correction and complications.

Functional features are described in Table 2. Regarding concomitant SUI and POP surgery, 12 patients had occult incontinence (one remained after the surgery); 32 patients had previous overt urinary incontinence, 11 of which persisted after the surgery (p = 0,132) Also, 4 patients undergoing only POP surgery had SUI *de novo*. None of them needed to be reoperated, as they did not present a severe SUI. 6 patients had de novo UUI, 3 of whom had to take medication. None of the patients operated had urinary retention. Pelvic pain occurred in 9 patients, 4 de novo; although in 7 women with previous pelvic pain, it disappeared.

The complication rate, classification and management are shown in Tables 3 and 4.

Fig. 1 shows a time chart showing the moment which the complications appeared: 58,8% of the complications occurred after one year and 41,2% after 3 years.

The results of the risk factors analyzed for extrusion and treatment failure are shown in Table 5. None of the risk factors analyzed showed statistical significance.

Comment

Since the FDA approved the first mesh product specially designed for the surgical repair of POP in 2001, tension-free vaginal meshes have been marketed as a practical and a durable solution for women seeking POP vaginal surgery. Between 2004 and 2008 the use of vaginal meshes was at its peak. In October 2008, the FDA responded to the emerging complications related to the meshes, followed by an updated safety communication in July 2011. However, there are currently scarce data with regard to long-term results and complications [16,17]. The majority of studies published are retrospective [13,14,18], and those which are prospective have a short or medium follow-up. Moreover, sometimes the evaluation is carried out through telephonic interview [10,19–21]. In this study, a complete periodic evaluation is presented, including interview and physical examination of every patient. The follow-up is prospective and considerably long, with a maximum of 8,8 years. It is strengthened by the single-center setting, which guarantees a unified surgical technique and consistent outcome evaluation. This allowed us to find complications that were asymptomatic, but also those appearing in the long-term follow-up.

With respect to the anatomical results, we found a 91,3% of POP correction. This high percentage correlates to what is reported in the literature, ranging from 79 to 96,5% [10,22–24]. The patients in whom there was a prolapse recurrence, they did not need a reoperation, as they remained asymptomatic, unlike other series [25].

To evaluate the functional features, some authors use personal interviews, or the VAS [21], but many employ different validated questionnaires [10,22,26]. Regarding the global subjective satisfaction of the patient, measured through the VAS, the results are outstanding, with a median of 9, and 44,9% of the patients giving the maximum score. This is very high considering the

Table 4
Late complications (after the first month).

Late complications	N(%)	IUGA/ICS classification	Clavien-Dindo classification	Management (%)
Extrusion	9 (13,2%)	3AT4S2 (3) 3BT4S2 (3) 3AT3S2 (3)	6 grade I 3 grade IIIa	Surveillance: 3 Topical oestrogen: 3 Excision: 3 (4.4%), one twice
Cervix elongation	1 (1.5%)	1BT4S2	III	Reoperation: 1 (1.5%)
Forgotten gauze	1 (1.5%)	6AT4S2	III	Reoperation: 1 (1.5%)
De novo pain	4 (5.9%)	1BT3S2 (2) 1BT4S2 (2)	I	Surveillance: 4
TOTAL	15 (22%)	–	–	Reoperation: 6 (8.9%)

N: number of events. %: percentage. IUGA/ICS: International Urogynecologic Association/ International Continence Society

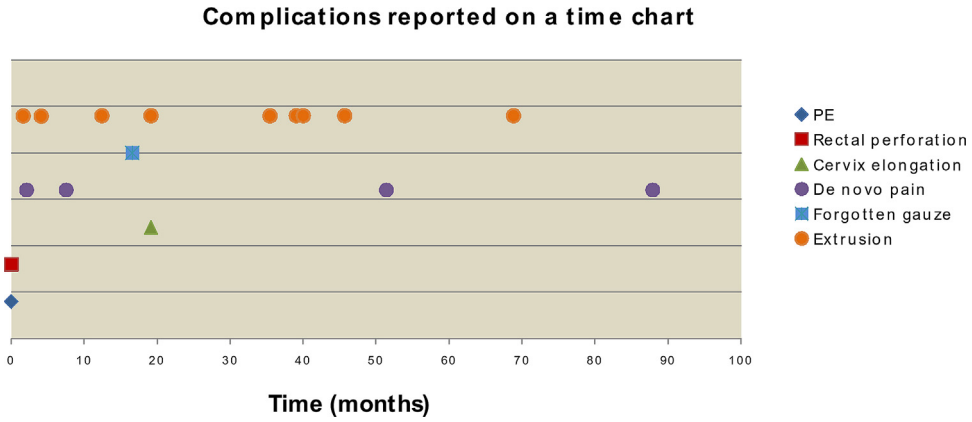

Fig. 1. Complications time chart.The long-term follow-up has highlighted that, remarkably, the number of complications grew during the follow-up, with 58,8% of the complications occurring after one year and 41,2% beyond 3 years.
PE: pulmonary embolism.

complications some of the patients reported. Good subjective results are also found in the published studies [19], Kdous reported an overall satisfaction score in VAS of 71,4% [21].

Concerning the urinary features, all of the items evaluated improved in our study. This improvement was statistically significant in the majority of them. In those articles reporting urinary symptoms, the correction is the most common result [26,27]. Some authors found de novo SUI after the surgery (as well as we did); others reported a worsening of urinary symptoms [22,24], including voiding difficulty [28].

There is little data concerning defecation situation after POP surgery with meshes. Some studies reported less constipation than before [17]. Unlike them, we found a worsening of this symptom in our patients, which was statistically significant, although there were some of them in whom it improved. This may be due to the fact that the majority of patients underwent a posterior mesh, which might obstruct defecation in some cases, although particular care was taken when performing the surgery to avoid it. Little data concerning pelvic pain regardless of sexual intercourse is reported, too [20,25,29]. In our series, a little improvement in this symptom was noticed.

On the other hand, the study of the sexual function after the surgery is very common in the literature. In our series, dyspareunia got worse after the surgical correction of POP, like other studies [25,27]. Meanwhile, other authors have found no changes in sexual function [19,20,30], or even an improvement in sexual function [22].

Table 5
Univariate logistic regression of risk factors in the development of failure of treatment and extrusion.

Factor	Failure of treatment		Extrusion	
	Odds ratio	p	Odds ratio	p
Age	1.022	0.649*	1.019	0.636*
Tobacco	2.437	0.509*	2.057	0.456*
BMI	1.143	0.569*	1.191	0.199*
Diabetes	5.6	0.105*	0	0.143*
Vaginal surgery	0.478	0.485*	0.689	0.654*
Abdominal surgery	1.105	0.913*	1.111	0.890*
Menopause	0.648	0.721*	0.189	0.062*
Concomitant treatment of the SUI	0.236	0.136*	1.056	0.940*

BMI: body mass index. SUI: stress urinary incontinence.
* None of the risk factors analyzed had a statistical significance.

In September 2011, the FDA organized a scientific advisory board and made 34 manufacturers of POP meshes and 7 manufacturers of SUI meshes perform clinical retrospective studies on their products. Currently, over 30.000 cases due to mesh-related complications and law suits on several manufacturers have been brought before the US courts. Reacting to this, several products have been withdrawn from the market by the manufacturers [11,31].

Early complications reported in the literature include visceral injuries (bladder, rectum), bleeding, hematoma, acute urine retention, fever, mesh infection, thrombophlebitis and urinary tract infection [10,21,24]. In this study, the small rectal perforation could be repaired intraoperatively and the mesh was placed, with no further complications. One important medical complication was a case of pulmonary embolism, in a patient without any thromboembolic risk factor, which was successfully managed medically.

Late complications included mesh extrusion, mesh retraction, de novo pain, de novo dyspareunia, vesicovaginal fistula, rectovaginal fistula, abscess and vaginal discomfort [17,22–25,28]. The most common complication was the extrusion of the mesh, constituting up to 40% of them. However, this extrusion was often asymptomatic. In other cases, it has been managed conservatively with topical oestrogen. Nevertheless, reoperation is sometimes required and eventually complete removal of the mesh may be required, depending on the degree of mesh extrusion and symptoms [19,20,24,25,29]. This correlates to what is reported in our study; highlighting that none of the meshes was removed. The discovery of a forgotten gauze, shown on an X-ray, led to its surgical removal.

Risk factors for complications have been studied. Some authors found mesh exposure was more frequent in the anterior compartment; and diabetes and surgeon were independent risk factors for it [32]. Others report an increased risk of complications in younger patients, less prominent prolapse, associated hematomas or concomitant hysterectomies. Greater blood loss and past pelvic surgical operation were other risk factors for mesh exposure [28]. Regarding failure of the surgery, advanced uterine prolapse and lack of surgical experience were associated. None of the features we analyzed showed statistical significance. This is probably due to the scarce cases of failure and extrusion.

The complications have been classified with both the ICS/IUGA and the Clavien-Dindo classifications. (15) Both classifications have been used in some papers, though in many neither classification

has been utilized [20,33]. In our opinion, this may facilitate the comparison between studies, in spite of the limitations these methods of classification may have.

The long-term follow-up has highlighted that, remarkably, the number of complications grew during the follow-up, with 58,8% of the complications occurring after one year and 41,2% beyond 3 years. This is an important matter, as many other studies finish their follow-up in the first one or two years. We have to consider also that the Clavien-Dindo classification does not include a time reference and the classification of the ICS/IUGA in mesh complications does not differentiate between complications occurring after one year. Reasons for vaginal mesh exposure of the mesh material are categorized into tissue causes and biomechanical mesh properties, and also can be related to the surgical technique. Defective vaginal healing is known to be more common following multifilament, microporous tapes. Tissue causes include superficial placement, traumatic dissection, tissue healing (vaginal wall tears, haematoma formation or infection), and thin and atrophic vaginal mucosa, especially in postmenopausal women [34].

This data is relevant as it shows that a long-term follow-up is mandatory in these women and we can probably extrapolate this to all patients undergoing surgery involving meshes. It also provides long-term good-quality information that may be useful if we consider the potential reintroduction of transvaginal mesh in the future.

Although a complete functional situation has been assessed, the absence of use of validated questionnaires should be considered a limitation of our study, mainly because this might have allowed a comparison between different series. We also have to consider the limited sample size.

Conclusions

Pelvic organ prolapse repair through the tension-free vaginal mesh Prolift® seems to provide favorable anatomical outcomes in long-term follow-up. The majority of functional features showed an improvement, although some of them worsened. Nevertheless, the global subjective evaluation of the patients was excellent. This suggests that the overall quality of life of the patients improves, even considering the side effects of the treatment.

The number of complications was comparable to what is reported in the literature. Nonetheless, there were many complications occurring a long-time after surgery. This fact has to be taken into account when considering at what point to finish the follow-up of the patients. Both the ICS/IUGA and Clavien-Dindo classifications may be worth updating to include this particular matter.

Finally, we believe it is mandatory to have a wide experience in the field of pelvic floor surgery to achieve the best results with the lowest complication rate.

Conflict of interest

The authors declare that they have no conflict of interest.

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