

# Is pelvic organ prolapse correction with vaginal mesh suitable with a correct indication and protocolized follow-up?

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## Abstract

The use of vaginal mesh in order to correct Pelvic Organ Prolapse (POP) has been banned by the FDA due to the complications associated with them. The objective is to determine efficacy and safety in the short and long term in a sample of women undergoing transvaginal mesh surgery performed by properly trained surgeons, in a referral center and with a protocolized follow-up. We present a longitudinal, descriptive study of a cohort of 53 patients with POP who underwent transvaginal mesh surgery between 2001 and 2015. The efficacy of the treatment is evaluated quantifying both clinical changes and life quality, as well as the rate for prolapse recurrence and the short- and long-term treatment-related complications. A total of 53 patients with average follow-up of 87 months were included. All of them had their surgery performed by three properly-trained surgeons. Indication for mesh placement was assessed in 49.1% of cases due to previous surgery recurrence. Treatment improved urinary incontinence rates, constipation, voiding difficulty, dyspareunia and quality of life. Long-term complication rate was 9.6% (5.7% exposure, 1.9% urinary obstruction and 1.9% pain). None of the patients presented recurrence in the mesh-treated compartment and 6 patients (11.3%) needed surgery after recurrence in a different compartment at the end of follow-up. Vaginal placement of synthetic mesh for POP treatment is safe in the short-, medium- and long-term when performed in referral centers. The correct indication and long-term follow-up are essential to diagnose and treat possible complications.

## Introduction

Pelvic Organ Prolapse (POP) is a common condition affecting up to a 50% of women during their life.<sup>1</sup> Although it can appear at any age, prolapse-related symptoms most commonly show during the menopausal transition.<sup>2</sup>

Increased life expectancy means that women in developed countries live almost a third of their lives in menopause. This, along with the fact that women lead more active lives, involves an increase in demand for treatment solutions to POP, as it gravely affects women's quality of life and shows an increase in its prevalence.<sup>3</sup> Diagnose and treatment of POP produces both suffering to the patient and a major healthcare costs,<sup>4</sup> so it is crucial to optimize the resources in order to offer an effective therapy with the lowest reinterventions and associated complications rate.

The abdominal route (open or laparoscopic) is considered to be the best choice for treating vaginal vault prolapse, proving low recurrence figures, less dyspareunia and vaginal shortening at the expense of higher morbidity, longer surgical time and higher costs.<sup>5</sup>

Traditional techniques with native tissue for vaginal surgery, hysterectomy and colporrhaphy are still a valid option<sup>6</sup> but there are some circumstances in which they may not be resolute.

Vaginal mesh placement to correct POP has thrown up great controversy in recent years due to the great number of complications communicated in different countries.<sup>7,8</sup> Finally, the FDA banned the use of such devices in 2019.

However, many series<sup>9-14</sup> have communicated positive results after using vaginal meshes, therefore the analysis of the factors involved in their appearance gains special relevance.

The main objective of the present work is to evaluate the results obtained, in terms of safety and efficacy, after treating POP with transvaginal mesh surgery in a sample of women operated by properly trained surgeons, in a referral center and with a protocolized follow-up.

## Materials and Methods

We performed a longitudinal, descriptive study of a cohort of patients with POP who underwent transvaginal braided-polypropylene-mesh (40g/m<sup>2</sup>) surgery between 2001 and 2015. They were all diagnosed, operated and followed-up by the same surgeons (RMJ, GPL, LLA).

The study was approved by a local

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Availability of data and materials: All data generated or analyzed during this study are included in this published article.

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Informed consent: Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

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ethics committee. The guidelines of the STROBE statement were followed.<sup>15</sup>

We recorded demographic data, obstetric and surgical history, prolapse-affected vaginal compartment and grade according to Baden and Walker and POP-Q classifications using standardized terminology ICS-IUGA.<sup>16</sup>

A POP-related symptoms, including

sense of bulging in the vagina, urinary incontinence, voiding difficulty, constipation and dyspareunia before and after the surgery, was conducted by medical history. Postoperative visits were scheduled a month, six months, one, two, five and ten years after the surgery. Patients with less than one-year follow-up were excluded. Patients who had lost follow-up were contacted by telephone and all those who were still alive accepted another visit. At every visit, 250mL of saline was instilled into the bladder using a female bladder catheter. After its removal, urinary incontinence and prolapse exploration was conducted and then the patient underwent an uroflowmetry.

Urinary incontinence was preoperatively classified on four different types: stress, occult or latent stress incontinence, urgency and mixed. The impact of incontinence and POP on quality of life was evaluated by validated questionnaires in Spanish; IQOL,<sup>17</sup> ICQ-SF,<sup>18</sup> PGIS,<sup>19</sup> SUIQ<sup>19</sup> and PISQ-12,<sup>20</sup> that were fulfilled before and each appointment after the surgery, and PGII<sup>21</sup> after it. Questionnaire PISQ-12 was used to evaluate if the patient was sexually active or not and if dyspareunia was present. The postoperative questionnaires results are from the last appointment.

Prolapse surgical correction with mesh was indicated for patients with symptomatic prolapse stage II and higher and affected by previous surgery recurrence or for young patients with anterior compartment POP and without central compartment POP. Patients with apical POP were treated with an abdominal colposacropexy.

Antibiotic prophylaxis was administered during surgery and every effort was made in order to minimize both hematoma and mesh frowning.

We used the Pinnacle Pelvic Floor Repair Kit on anterior and posterior cases, Uphold kit on anterior POP or self-prepared mesh before disposing it, depending on the surgeons' criteria. Hydrodissection was made with adrenaline solution and a vertical incision was performed in every case. Depending on anterior or posterior POP, bladder or rectum was widely dissected from vaginal wall. Every mesh was fixed posteriorly to the sacrospinous ligament. Anteriorly, the cystocele mesh was fixed to the tendinous arch and the rectocele mesh to the puborectalis fascia and perineal body. Two anchoring sutures from the mesh to the cervix were performed in case of any grade of uterine prolapse. Patients with apical POP were treated with an abdominal colposacropexy. The vaginal wall was not trimmed in any patient. A vesical catheter and a vaginal tamponade were maintained

during the first 48 hours.

A Transobturator Adjustable Mesh (TOA) was placed in those patients suffering from either preoperative stress or stress-predominant mixed urinary incontinence.<sup>22</sup>

Anatomical cure was defined both as the absence of prolapse and as having a stage II or lower prolapse in the operated compartment. Clinical cure was defined as the disappearance of the sense of bulging in the vagina associated with the anatomical cure. Surgery was considered to be successful when answers "very much better", "much better" or "a little better" in the PGII questionnaire<sup>21</sup> postoperatively fulfilled by the patient were associated with both anatomical and clinical cure. These rates were evaluated within 6 months, 1, 2, 5 and 10 years.

Recurrence was defined as the presence of a symptomatic POP within six months after surgery. De novo dyspareunia was revealed in patients with no dyspareunia before surgery and with prevalence of dyspareunia one year after the surgery.

Early complications (first 30 days) were classified according to the Clavien-Dindo grading system<sup>23</sup> and late complications according to the ICS-IUGA system.<sup>24</sup>

Descriptive and analytical statistics were performed in SPSS software version 25. For continuous variables, the average was calculated when normal distribution or the median and the interquartile range when non-normal. Quantitative variables were compared by using the chi-square test.

## Results

A total of 53 patients were included with an average follow-up of 87 months (range 12-215). Demographic characteristics and preoperative clinical parameters are described in Table 1.

A mesh was placed in the anterior vaginal compartment in 73.6% (n=39) of the patients, in the posterior compartment in 13.2% (n=7) and in both of them in 13.2% (n=7). A sling for urinary incontinence correction was placed in the same surgical procedure in 45.3% (n=23) of the patients. Of them, an anterior vaginal mesh had been placed in 18 of them (78.2%), a posterior vaginal mesh in 2 of them (8.7%) and both anterior and posterior in 3 of them (13%).

The evolution of the anatomical, clinical and surgery-success rates are shown in Figure 1.

Postoperative clinical changes related to the sense of bulging in the vagina, voiding difficulty, constipation and dyspareunia are summarized in Table 2.

The answers to the questionnaires are shown in Table 3.

The response rate to the questionnaire PGII was 78.8% (n=41). 68.2% of the patients answered feeling "very much better" or "much better" and 21.9% "a little better".

There was one (1.9%) early complication and it was a bladder perforation. Through the follow-up, complications were noted in 5 patients (9.6%); 3 patients (5.7%) presented vaginal mesh exposure. All of them were surgically solved. One patient

**Table 1. Sociodemographic variables and preoperative clinical parameters.**

Age (years)	64
Smoker or ex-smoker	13.2
Number of vaginal deliveries (n)*	2
Instrumental delivery	17.3
Menopausal patients	94.2
Sense of bulging in the vagina	86.7
Voiding difficulty	26
Constipation	17
Dyspareunia**	12
Previous plastic surgery	49.1
Previous hysterectomy	52.8
Previous UI surgery	15.3
Urinary incontinence (UI)	66
Stress UI	11.5
Stress occult UI	11.5
Mixed UI	26.9
Urge UI	17.3

\* The median is calculated. \*\* Patients with dyspareunia (59.5% of the sample).

**Table 2. Clinical evolution of the symptoms aforementioned by the patients depending on the type of mesh used.**

	Anterior MESH			Posterior MESH			Anterior + Posterior MESH		
	Preop	1y	5y	Preop	1y	5y	Preop	1y	5y
N	39	36	21	7	5	3	7	4	2
Sense of bulging in the vagina (%)	87.1	0	14.2	71.4	0	0	85.7	25	0
Voiding difficulty (%)	28.2	15.4	9.5	14.3	20	0	28.6	0	0
Constipation (%)	10.3	11.3	9.5	57.2	20	0	14.3	0	0
Active sexuality	64.1	55	62	57	60	66	42	50	50
Dyspareunia* (%)	9.5	6.6	0	0	0	0	0	0	0

\*For the analysis of the ratio of patients with dyspareunia, only those with an active sexuality are considered. Preop: preoperative value. 1y: one year. 5y: five years.

(1.9%) underwent removal of part of the mesh due to focused pain in the sacral region refractory to medical treatment and another patient (1.9%) due to urinary obstruction (Table 4). The median time to reoperation was 53 months (RI 25-60 months).

None of the patients required surgery for recurrence in the same compartment in which the transvaginal mesh had been placed. At the end of the follow-up, 6 patients (11.3%) required new surgery due to recurrence in a different compartment (Table 4).

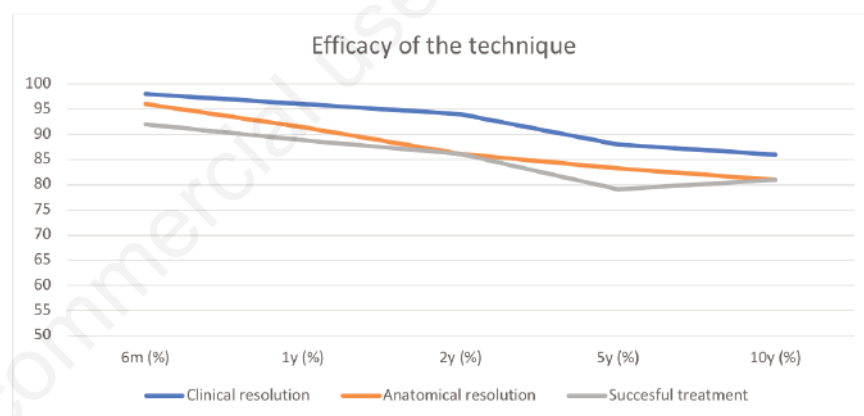
On the flowmetry, the preoperative average maximum flow was 16.4 ml/min. After the surgery the average maximum flow was 17.48mL/min at 6 months, 15.9 mL/min one year after, 16.6 after two years and 15.8 at 5 years ( $p=0,62$ ).

49.1% of patients ( $n=26$ ) had a previous surgery to treat their POP. The mean age in this subgroup is 65.3 years. 11.5% ( $n=3$ ) had complications related to the mesh implant (similar to the entire cohort) and 15.3% ( $n=4$ ) had a recurrence, on average at two years (Table 4).

**Table 3. Answers to the questionnaires.**

Questionnaires	Prior to surgery	After surgery	P
IQOL [13]	60.4	84.24	0.269
ICIQ-SF [14]	15.71	7.87	0.407
SUIQ [15]	14.75	3.08	0.047
PGIS [15]: none+mild	24%	76%	0.01
PGIS [15]: moderate+severe	76%	24%	0.01

IQOL: incontinence quality of life (range 0 to 100); ICIQ-SF: questionnaire about how incontinence affects quality of life; SUIQ: number of incontinence episodes within 7 days; PGIS: patient global impression of severity.

**Figure 1. Evolution of the anatomical cure rate, clinical cure rate and success rate.**

## Discussion

The FDA ban on the use of vaginal mesh in order to correct pelvic organ prolapse has meant a therapeutic change to the protocols of many Pelvic Floor Units around the world. While it is true that the recent published literature about complications related to the use of vaginal mesh was worrisome to all the urogynecologists, many of them have witnessed its publication without finding their patients represented on the published data.

The results obtained in the present study in terms of effectiveness are comparable to the data published in the literature (Table 5).<sup>10,11,25</sup>

Although the results obtained in our study regarding anatomical cure rates are encouraging (it reaches 96% after a year

and then steadily decreases to 81% after ten years), in the authors' view, both those regarding clinical cure rates are (96% after a year and 86% after ten years) and specially those regarding surgery success rates (anatomical cure + clinical cure + patient subjective evaluation, which reaches 86% after a year and 81% after ten years) are of most interest, due to the fact that the disappearance of symptoms is the primary objective of POP treatment.

As can be seen in Table 1, half of the patients operated during this study had already underwent at least one previous unsuccessful POP-correcting vaginal surgery, none of which with vaginal mesh. These are patients treated into routine clinical practice, with previous surgeries and in half of the cases, with incontinence requir-

ing surgical treatment. These characteristics are considered in some published literature as exclusion criteria.<sup>25-29</sup>

From among the evaluated clinical parameters, the disappearance of the sense of bulging in the vagina showed the best result. Voiding difficulty showed a significant improvement in those patients with anterior compartment surgery. Constipation improved fundamentally in patients with posterior compartment surgery, given that constipation is not that frequent in patients with affected anterior and middle compartments. On an overall basis, almost 50% of the cases with previous voiding difficulty improved after POP surgery. Regarding voiding syndrome symptoms: improvement of the urine flow, decrease of the diurnal and nocturnal frequency and decrease of the

need for special body positions to make urination easier or even the prolapse manual reduction (data not published in this study).

Regarding intra-operative complications, our 1.9% reported rate is within the parameters reported in the revised series for the injury of nearby organs.<sup>26</sup>

Regarding dyspareunia, 53% of our patients were sexually active before the surgery, a higher figure than the one presented in the literature<sup>26,28</sup> and similar to the one presented by Gonzalez-Palanca *et al.*<sup>10</sup> Sexual activity remained stable along the follow-up. The reasons for preoperative sexual abstinence given by the patients were widowhood or partner absence, followed by low libido or partner's erection difficulties.

*De novo* dyspareunia after vaginal mesh surgery thoroughly varies depending on the consulted literature (0-14%).<sup>10,30</sup> No case of *de novo* dyspareunia after surgery was reported in our series, but the percentage of women showing pain or discomfort during the sexual intercourse amounted to 21% after six months (compared to the previous 9.5%) and then, decreased to 6.6% in the 12-month visit. The reasons for dyspareunia in women are heterogeneous and difficult to evaluate, including vaginal length, and having a partner.<sup>31</sup> This initial worsening of dyspareunia may be due to the tissular scarring phenomena entailed by the implementation of synthetic materials in menopausal patients with fragile vaginal tissue. On a Cochrane meta-analysis published in 2016,

11 randomized clinical trials which included 764 patients were analyzed, without revealing any statistically significant difference between *de novo* dyspareunia in women whose surgery included vaginal mesh placement and in those whose surgery implied the use of native tissues (RR=0.92, 0.58-1.47).<sup>32</sup>

It has been described in randomized studies a greater immediate post-operative pain in patients whose surgery included vaginal mesh placement than in those whose surgery implied the use of native tissues.<sup>29</sup> In our experience, these patients needed more analgesia during hospitalization compared to the patients who had a hysterectomy or a vaginal colporrhaphy in our department.

**Table 4. Description the patients with early, late complications (Clavien-Dindo, ICS-IUGA)<sup>19,20</sup> and recurrences.**

Patient number	Age	POP previous Surgeries	Type of mesh	Complications	Months until complication	Treatment	ICS-IUGA / c-D
1	67	No	Anterior + TOA	Bladder perforation	Intraoperative	Repair	4AT1S3 / C-D III
2	53	No	Anterior	Voiding difficulty	3	Partial mesh removal	1AcT3S0
3	69	Yes (H+C)	Anterior	Chronic pelvic pain	25	Partial mesh removal	6BeT4S4
4	73	Yes (CA)	Anterior + posterior	Posterior mesh exposure	53	Surgical repair	1BbT4S2
5	56	Yes (CA)	Anterior + TOA	Anterior mesh exposure	60	Surgical repair	3AaT4S1
6	80	No	Anterior + posterior + TOA	Anterior mesh exposure	81	Surgical repair	2AaT4S2
1	80	No	Anterior + Posterior + TOA	Uterus IV	12	Hysterectomy + colposacropexy	
2	64	Yes (H+C)	Anterior + posterior	Vaginal vault III	3	Colposacropexy	
3	42	No	Anterior	Rectocele III	46	Posterior mesh	
4	58	Yes (CA)	Anterior	Uterus III	49	Vaginal hysterectomy + posterior colporrhaphy	
5	53	Yes (H+C)	Anterior	Enterorectocele III	22	Posterior mesh	
6	63	Yes (CA)	Posterior	Cistocele III	24	Anterior mesh	

\*POP degree according to POP-Q classification.<sup>12</sup> C-D: Clavien-Dindo; H+C: hysterectomy and colporrhaphy; CA: anterior colporrhaphy.

**Table 5. Comparison between current series and other series described in literature.**

	n	Age (years)	Previous HT (%)	Previous surgery (%)	Follow-up (months)	SUI synchronic sling	Early comp. (%)	Exposure (%)	Reinterventions (%)
Vinchant <i>et al.</i> <sup>14</sup>	29	62		6.3%	216	35	1.6	25	35
Pécheux <i>et al.</i> <sup>11</sup>	349	63.9	24.4	17.7	102	2.9		2.6	14.3
Sarrió <i>et al.</i>	53	64	52.8	49.1	87	45.3	1.9	5.7	9.6
Duraes <i>et al.</i> <sup>9</sup>	270	65.2	12.4	11.5	66	17.7		0.4	3.4
Laso-Garcia <i>et al.</i> <sup>26</sup>	75	67.6	26.3	0	64	58	2.6	13	8.9
de Landsheere <i>et al.</i> <sup>13</sup>	524	64	21.2	18.7	38	34	0.6	2.5	3.6
Rudnicki <i>et al.</i> <sup>27*</sup>	78	64.7	7.7	0	36	0	11.6	14.7	6.65
González-Palanca <i>et al.</i> <sup>10</sup>	58	66.5	25.86	20.69	34	6.9	9.36	1.7	1.7
Balchandra <i>et al.</i> <sup>12</sup>	159	61	88		28	20	11	4	8.3
Glazener <i>et al.</i> <sup>28*</sup>	435	59.5	29	13	24	0	10	12	9
Altman <i>et al.</i> <sup>29*</sup>	186	64.3	23	16.5	12	0	10	3.2	3.2
Stanford <i>et al.</i> <sup>25</sup>	142	64.7	43.8	0	12	0		6.3	4.22
Rodrigues <i>et al.</i> <sup>30</sup>	97	61.2	21.8	21.8	12	42.6	12.4	7.2	6.2

Previous surgery: POP surgery previous to the analyzed surgery. SUI: stress urinary incontinence. HT: hysterectomy Early Comp: early complications. \*Series in which only data of patients with synthetic mesh implant are included.

During the follow-up, no pain or analgesia-need was observed in the post-operative visits in 98% of the patients, similar to previously chronic pain rates published.<sup>8</sup> One patient showed sacral pain in the 12-month visit. After the failure of the conservative treatment with first-and-second-step analgesics, a complete mesh removal was performed 25 months after its placement, improving pain relief.

These results regarding the incidence of dyspareunia and pain are reassuring, given that the studies that analyze the reasons for mesh removal include mainly women that show disabling pelvic or vaginal pain or dyspareunia as symptoms.<sup>33</sup>

The mesh exposure rate varies from 0.48% to 25%<sup>9,10,14,26,27</sup> and the surgical repair rate from 33% to 100%. Factors related with this complication may be the age of the patients (73 and 80 years) at the moment of the exposure and a history of previous surgery. These factors suggest the role of postmenopausal vaginal atrophy with vascularization loss as the main cause for the vaginal mesh exposure.<sup>10,25,26</sup> The exposure rate is higher when the follow-up is longer, like in our study or in Vinchant *et al.*<sup>14</sup>

Regarding POP recurrence, the absence of recurrence observed in the mesh-treated compartment needs to be highlighted. The six patients that needed reoperation due to POP, needed it due to a new appearing prolapse in a different compartment, mainly because the middle compartment was affected.

Regarding quality of life, over 90% of the patients stated feeling “very much better”, “much better” and “a little better”, according to questionnaire PGII.

There are some limitations of the current study, the retrospective non-randomized design, the fact that it is a single-centre study and the small number of patients. Previous studies published in literature, in all but a few cases, have been retrospective and single-centre.<sup>25,27,28</sup>

Respect the small number of patients treated with a vaginal mesh, the authors find interesting to note that the number of patients who underwent vaginal mesh surgery does not reflect, however, the clinical workload of their unit; but rather it could be considered as the consequence of the precise indication established prior to vaginal mesh surgery. In the daily clinical routine of our centre the number of patients suitable of being treated through traditional vaginal surgery, consisting of hysterectomy and colporrhaphy, is high. Menopausal women with uterine prolapse, associated with cystocele and a certain degree of rectocele, comprise the majority of the patients, and the results that we obtain with this

approach are satisfactory, with a recurrence rate under 10% and an improvement of the quality of life.

The main strength of this study comes from the long and protocolled follow-up that we performed. It has enabled us to diagnose and treat the complications detected, half of which occurred after 53 months.

The clinical experience of the surgeons regarding POP allows to diagnose and to treat the patients via the 3 possible surgical approaches (traditional vaginal, vaginal mesh and colposacropexy, open or laparoscopic). A trained surgeon should have good anatomical knowledge, some practice on cadaver surgery and have performed at least 20 vaginal mesh implants. He should know other approaches to treat POP and should be able to solve surgery complications. Such experience facilitates the indication of the most suitable surgery for each patient.

These results raise the need to develop more prospective and randomized studies in order to evaluate the safety of vaginal mesh in centers with experience enough. In the daily clinical routine, we consider that given our long-term results and the experience of our team, the use of vaginal mesh in order to correct POP should be an option if there is an appropriate indication and always providing the patient with the information about risks and alternatives. Knowing which patients have a higher risk of failure and/or complications (aged, vaginal atrophy), we can avoid vaginal mesh surgery in these cases and keep it for those patients with a better success rate and a lower rate of failure or complications.

## Conclusions

The use of vaginal mesh in order to correct POP has proven to be a safe technique in the short, medium and long term in women who underwent surgery in a specialized center with trained surgeons and selected cases.

In cases of only anterior compartment prolapse with a recurrence or in those cases with a high preoperative risk of recurrence, the use of transvaginal mesh is a safe alternative. The benefits and complications should be considered in each case separately and discussed with the patient in order to optimize the expectations.

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