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# Surgical Treatment of Pelvic Organ Prolapse

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## Abstract

The human being is the only mammal capable of walking and simultaneously maintaining an upright position. This fact, implies somewhat unfavorable repercussions for the pelvic region that must support the weight of the abdominal organs. A prime example of the aforementioned adverse effects of the standing position are pelvic organ prolapses (POP). POP surgery is an increasingly important therapeutic aspect in clinical practice due to the aging of our population, and is increasingly prevalent as a therapeutic option. Surgical techniques can be performed using an abdominal or vaginal approach, depending on the medical history, physical examination, and experience of the surgeon. Laparoscopic sacrocolpopexy is an adequate therapeutic option with a high success rate in 80–100% of cases. However, this technique is not always appropriate, especially for patients who are at high risk for anesthesia, a multi-operated abdomen, or in recurrent prolapse. In these cases, a vaginal approach offers an interesting surgical alternative. In this review, we added our experience with transvaginal single-incision mesh under locoregional anesthesia for correction of female POP. We retrospectively analyzed 78 patients showing a success rate of 92% after more than 12 months of follow up. Transvaginal mesh was developed to maintain the advantage of a vaginal procedure, while reducing the risk of recurrent prolapse compared to native tissue repair and simplifying the surgery compared to sacrocolpopexy.

**Keywords:** Pelvic Organ Prolapse, Reconstructive Surgical Procedures, Gynecologic Surgical Procedures

## 1. Introduction

The human being is the only mammal capable of walking and simultaneously maintaining an upright position. This fact, greatly affected by the law of gravity, implies somewhat unfavorable repercussions for the pelvic region that must support the weight of the abdominal organs. Therefore, throughout evolution, fundamental modifications have emerged in the pelvic skeleton, and in the surrounding muscles and ligaments, to offset the negative effect of the law of gravity. A prime example of the aforementioned adverse effects of the standing position are pelvic organ prolapses (POP).

The prevalence of this pathology is clearly on the rise: it is estimated that the number of women with pelvic organ prolapse will rise from 3.3 million women in 2010 to 4.9 million in 2050. Pelvic floor dysfunction is considered to be underdiagnosed,

affecting 50% of women, although only 10–20% will seek assistance [1]. More than 60% of the patients affected by this condition present more than one pathology as the pelvic floor organs constitute a functional and organic unit [2]. It is estimated that a woman's risk of undergoing surgery related with POP during her life varies from 6.3 to 19%, with 30% requiring one or more surgical interventions due to recurrence [3]. Some authors have reported re-intervention rates for recurrence after primary reconstructive surgery of between 43 and 58% [4].

The anatomical support of the pelvic viscera is provided mainly by the levator ani and the connective tissue junctions of the pelvic organs: vaginal support arises from the connective tissue junctions between the vagina and the pelvic lateral wall, the vaginal wall and levator ani muscles [5].

In 1994, Delancey had already introduced the concept of the division of the support of the pelvic connective tissue in three levels (I-III) that represent apical, mid-vaginal and distal support, respectively. The upper portion of the paracolpium (Level I) consists of a lamina from which the vagina is suspended attaching it to the pelvic wall, and is responsible for suspending the apex of the vagina after hysterectomy. In the middle third of the vagina, the paracolpium joins the vagina laterally to the tendinous arch and the fascia of the levator ani muscles (Level II). This stretches the vagina transversally between the bladder and the rectum. The structural layer that supports the bladder (pubocervical fascia) is made up of the anterior vaginal region and its attachment through the endopelvic fascia to the pelvic wall. Similarly, the posterior vaginal wall and endopelvic fascia (rectovaginal fascia) form the containing layer that prevents protrusion of the rectum toward its anterior surface. The lower third of the vagina (Level III) fuses with the perineal membrane, levator ani muscle, and the perineal body. Defects in the mid-level vaginal base (pubocervical and rectovaginal fascia) result in cystocele and rectocele, while the loss of upper suspensory fibers of the paracolpium and parametrium are responsible for the development of vaginal and uterine prolapse, and these defects of combined form [6].

During examination, the prolapse of the anterior compartment is the most frequently reported site of prolapse and it is diagnosed twice as frequently as the defects of the posterior compartment, and three times more common than apical prolapse [7]. After hysterectomy, 6–12% of women will develop a prolapse of the vaginal vault [8] and in two thirds, multi-compartmental prolapse will be present.

The etiology of POP is believed to be multi-factorial with contributions from both environmental and genetic risk factors. The environmental factors that contribute to POP include vaginal delivery and newborn weight, chronic increases in intra-abdominal pressure, obesity, advanced age and estrogen deficiency [9].

Not all prolapses are clinically symptomatic, and finding mild asymptomatic prolapses during pelvic floor examination is common. If symptoms are present, the most frequent complaints include a sensation of pressure, a lump or protrusion and with evidence upon physical examination of a second degree or greater anterior and / or posterior and / or central vaginal wall prolapse. Ellerkmann et al. found that in 237 women evaluated for POP, 73% reported urinary incontinence, 86% urinary urgency and / or frequency, 34–62% voiding dysfunction and 31% fecal incontinence [10]. Evaluation of a patient with vaginal prolapse requires a comprehensive review of the full spectrum of pelvic floor symptoms and an assessment of how these symptoms affect her quality of life.

## **2. Surgical treatment of pelvic organ prolapse**

POP surgery is an increasingly important therapeutic aspect in clinical practice due to the aging of our population, and is increasingly prevalent as a therapeutic

option, despite surgical and hospitalization times that are three times longer compared to other surgeries related to the pelvic floor such as continence surgery. Given the increasing time and resources that will be required for POP surgery in the future, it is paramount that we perform effective, long-lasting and cost-effective interventions with minimal morbidity.

Historically, most studies evaluating the treatment of POP have focused exclusively on anatomic success without considering other important aspects such as symptoms, vaginal accommodation, and quality of life. In fact, for a patient, individually, the most important result of a surgical procedure is the relief of their symptoms and improvement of their quality of life [11]. However, until recently these areas have been ignored. The objectives of pelvic floor reconstruction are to relieve symptoms, restore anatomy, improve or preserve function, prevent actions that alter other compartments, and improve quality of life [12].

Anterior colporrhaphy was the standard procedure in the management of the prolapsed anterior compartment. That said in the early 2000s, there was a movement toward the use of prosthetics to increase the efficacy of native tissue repair in reconstructive gynecology. This was due to the articles published by Olsen et al. [13] where they reported a reoperation rate of 29% after prolapse or continence surgery and Weber et al. [14] who reported a 70% failure rate of native tissue anterior compartment repair. Recent reassessment of the same demographic 10 years later revealed a significantly lower reoperation rate of 17% [15]. More importantly, Weber et al. [14] and Sand et al. [16] reported in randomized controlled clinical trials that anterior colporrhaphy was successful in managing cystocele in only 30%. A recent re-analysis of the latter data, using the hymen as the threshold for objective success, reported considerably better results, with only 10% anatomic recurrence beyond the hymen, 5% symptomatic recurrence, and a lower reoperation rate of 1% at 23 months of follow-up [17]. During the decade between these initial and later publications, surgeons introduced a large number of biologic and mesh grafts to improve the outcomes of prolapse surgery. In later studies such as that of Julian et al. [18] it was shown that patients with several vaginal repairs had better results with a new repair with prosthetic material, in this case a Marlex® mesh (Bard, Covington, GA), compared to previous colporrhaphy, although follow-up reported an erosion rate of up to 25%.

The 2016 Cochrane Review also reported on 16 trials that evaluated nearly 2,000 women with the aim of comparing anterior colporrhaphy versus permanent polypropylene mesh POP repair. The meta-analysis showed that recurrence of anterior wall prolapse (RR 0.34, 95% CI 0.25 to 0.46) and reoperation for prolapse (RR 0.44, 95% CI 0.24 to 0.46) were significantly less common after mesh repair compared to colporrhaphy. There were no differences between the groups in terms of quality of life outcomes or dyspareunia rates. However, the transvaginal polypropylene mesh group had higher rates of reoperation due to mesh exposure, stress urinary incontinence or prolapse (RR 1.62, 95% CI 1.15 to 2.28), and prolapse in the apical or posterior compartment (RR 1.85, 95% CI 1.01 to 3.37) compared to anterior colporrhaphy. Surgical time (MD 17.9 min, 95% CI 10.0 to 25.8), transfusion rate (RR 2.37, 95% CI 1.32 to 4.24), cystotomy (RR 4.65, 95% CI 1.22 to 17.77) and de novo stress urinary incontinence (RR 1.55, 95% CI 1.02 to 2.35) were higher after use of transvaginal polypropylene mesh compared to colporrhaphy. The mesh erosion rate was 11.5% and 7% underwent surgical correction for repair [19].

One fact that we must take into account is that recently, most of the products made with polypropylene meshes evaluated in this meta-analysis have been withdrawn by the manufacturers due to the ongoing litigation regarding the use of this type of material vaginally. Because of this, new transvaginal polypropylene prosthetic products have emerged that have been introduced to decrease the rate

of complications, specifically mesh erosion. Altman et al. [20] based on a multi-center prospective case series, which evaluated 207 women with apical prolapse undergoing the Uphold® pelvic floor system (Boston Scientific, USA), reported a subjective success rate of 90% per year and a reoperation rate for mesh exposure of 1.3%. Similarly, De Tayrac et al. [21] found at 3 years, in 79 women with grade 3–4 cystocele, an anatomical success rate of 95%, a satisfaction rate of 98% and a mesh exposure rate of 1.3% using a mesh of lightweight (28 g / m<sup>2</sup>) polypropylene (Surgimesh® Prolapse Xlight, Aspide Medical, France) [21].

Studies where the device used was Restorelle® (Coloplast, Minneapolis, USA), report rates of absence of postoperative complications of 98.2%. The most frequent complications included urinary retention (8.7%), urinary tract infections (5.5%), and hematoma (2.7%). Other complications related to neighboring organs (bladder, rectum, and ureters) were very rare (<1%). A total of 2.8% of the patients had grade III complications according to the Clavien-Dindo classification (mesh extrusion). 80.3% did not present complications during the 3 months of study follow-up. Despite these promising data, the follow-up time of this study is short to ensure the absence of complications within a longer follow-up period [22]. Despite the current negative sentiment around transvaginal mesh, these new lightweight mesh products require further reassessment.

In the 2016 Cochrane meta-analysis of grafts vs. Native tissue repairs for vaginal prolapse, only one case of reoperation for dyspareunia or pain was reported in the nearly 1000 cases of transvaginal mesh evaluated [19]. However, pain and dyspareunia were the main causes of adverse events that triggered the 2011 FDA (Food and Drug Administration) warnings on the safety of transvaginal mesh [23]. These findings raise the possibility that pain and dyspareunia after transvaginal mesh surgery may be underreported, and possibly only identified in trials with longer term evaluation.

Alternatively, autologous material was considered as a possible option to synthetic prosthetic grafts with a lower risk of host rejection or infection. Gandhi et al. reported preliminary results of a randomized control trial comparing anterior colporrhaphy alone vs. fascia lata graft for cystoceles [24]. In 1 year they could not demonstrate that the addition of the fascia lata graft improved the success rate compared to anterior colporrhaphy alone, being 71% compared to 82% (p 0.07), however, the rate of recurrent anterior prolapse in examination was lower after biological graft repair compared to anterior colporrhaphy (RR 0.74, 95% CI 0.55 to 0.99 n = 646, I<sup>2</sup> = 29%, low-quality evidence), being the operative time for colporrhaphy shorter than the biological graft procedure (MD -10.35, 95% CI -14.45 to -6.24).

Reoperation after POP surgery for recurrence is an important measure of the effectiveness of the procedure. It is important to note that reoperation rates represent the “tip of the iceberg” in terms of surgical failures, as there are women with recurrent symptomatic prolapse who do not wish to undergo another operation. However, repeat surgery for recurrent POP is always an undesirable result that should, in most cases, be considered as a failed surgical procedure. Reoperation rates after POP surgery vary widely in the literature, largely due to different definitions and timelines. In a meta-analysis of 258 studies evaluating the reoperation rate after apical prolapse repairs, Diwadkar et al. reported a reoperation rate of 3.9% (95% CI: 3.5–4.4%) for traditional vaginal vault suspensions (sacrospinal ligament suspension and uterosacral vault suspensions) after a mean of 32 months, 2.3% (95% CI 1.9–2.7%) for sacrocolpopexy with follow-up mean 26 months and 1.3% (95% CI 1.0–1.7%) after transvaginal mesh procedures with a mean follow-up of 17 months. In particular, the total reoperation rate, including reoperations for recurrent POP and complications, was higher in the transvaginal mesh group (8.5%) [25].

The reoperation rate after POP surgery was defined in the joint report by the ICS (International Continence Society) and the IUGA (International Urogynecological Association), making a clear distinction between additional surgeries after primary surgical correction of POP, as the character of these can be very heterogeneous. The classification of these surgeries was established as follows:

- Primary prolapse / different compartment surgery - prolapse in a new compartment after previous surgery in a different compartment.
- Repeat surgery - is a repeat operation for prolapse that arises from the compartment that was previously operated on.
- Surgery for complications (e.g. exposure or extrusion of the mesh, pain, or hemodynamic compromise of the patient, hemorrhage).
- Surgery for conditions not related to prolapse (e.g. subsequent surgery for stress urinary incontinence or fecal incontinence).

Recently, Ow et al. retrospectively compared 237 women who underwent 185 native tissue repairs and 161 transvaginal mesh repairs for recurrent prolapse. The transvaginal mesh group had significantly lower follow-up rates of symptomatic prolapse, prolapse upon examination, and reoperation for prolapse, than the native tissue repairs group. However, the mesh exposure rate (anterior 15%, posterior mesh 21%) and associated reoperation (anterior 9%, posterior 15%) were significantly higher [26]. Trials such as this one show that in women with recurrent prolapse, transvaginal mesh has significant advantages and disadvantages compared to native tissue repairs and this profile is similar to that described for primary repairs, except that the exposure rates of the mesh appear to be higher in recurrent POP surgery.

Another surgical alternative on the rise in the last decade is laparoscopic or robotic sacrocolpopexy. This was born with the purpose of maintaining the existing good results of abdominal sacrocolpopexy but with the advantages of minimally invasive surgery. The case series demonstrate adequate acceptance in the short and medium term, with success rates of 91% (range 60–100%), subjective success rates of 79–98% [27, 28] and a mean reoperation rate of 5.6%. In a meta-analysis, it was concluded that, in general, a large group of vaginal surgery with and without mesh is associated with a higher risk of prolapse recurrence upon examination (RR 1.9 95% CI 1.3–2.7), of reoperation for prolapse recurrence (RR 2.3 95% CI 1.2–4.3), postoperative stress urinary incontinence (RR 1.9 95% CI 1.2–2.9) and dyspareunia (RR 2.5 95% CI 1.2–5.5) compared with sacrocolpopexy [29]. However, sacrocolpopexy was associated with a higher rate of paralytic ileus or small bowel obstruction (2.7% vs. 0.2%,  $p < 0.01$ ), of complications related to intraperitoneal mesh or suture (4.2% vs. 0.4%,  $p < 0.01$ ) and thromboembolic disease (0.6% vs. 0.1%,  $p = .03$ ) [30].

The robotic sacrocolpopexy is the currently latest version of this technique. The robotic approach is associated with objective cure rates of 84%–100%, subjective cure rates of 92–95%, and a mesh erosion rate of 2% (range 0–8%). In general, we can find postoperative complications in this meta-analysis in up to 11% (range 0–43%), with serious complications in 2%, with a conversion rate of <1% to open surgery (range 0–5%) [31].

Traditionally, researchers have defined surgical success using anatomical results (POP-Q stage 0–1 - **Table 1**) and defined surgical failure as POPQ stage 2 or greater. More recently it is suggested that these anatomical definitions are too strict as more

<b>Pelvic organ prolapse quantification system (POP-Q)</b>	
<b>Stage</b>	<b>Description</b>
0	No prolapse, anterior and posterior points are all $-3$ cm, and C or D is between $-TVL$ and $-(TVL-2)$ cm
1	The criteria for stage 0 are not met, and the most distal prolapse is more than 1 cm above the level of the hymen (less than $-1$ cm)
2	The most distal prolapse is between 1 cm above and 1 cm below the hymen (at least one point is $-1$ , $0$ , or $+1$ )
3	The most distal prolapse is more than 1 cm below the hymen but no further than 2 cm less than TVL
4	Represents complete procidentia or vault eversion; the most distal prolapse protrudes to at least $(TVL-2)$ cm

**Table 1.**  
*POP-Q staging criteria.*

than 75% of women presenting for annual gynecological exams with no symptoms of pelvic organ prolapse would not be found in the definition of “optimal anatomical result” and almost 40% would not meet the definition of “satisfactory anatomical result” [32]. The absence of symptoms of vaginal protrusion postoperatively has a significant relationship with the patient’s evaluation of general improvement and improvement in quality of life after surgery, while anatomical success alone does not, and thus vaginal protrusion symptoms are of great importance when evaluating the surgical outcome of POP [11]. Another possible factor to take into account in the different studies is the concept of success used together with the POP classification used. Some authors have used the Baden-Walker prolapse classification system instead of the POP-Q, other studies have used a combination of anatomical criteria and the presence or absence of symptoms to define the success of the treatment. Such variability makes it difficult to compare the results between the different studies.

### **3. Case study**

#### **3.1 Aim and scope**

In this study we will show the results obtained at our center with one of the most recent devices for the transvaginal correction of female POP, the Restorelle® single-incision mesh (Coloplast, USA). This product was later withdrawn from the market along with other transvaginal prosthetic devices for the correction of POP (April 2019), following its ban by the FDA.

Restorelle® Direct Fix Mesh products incorporate Smartmesh® technology (physiologically compatible ultralight mesh). It provides long-term strength while maintaining the vaginal elasticity of natural tissue. Its placement allows for an anterior sacrospinous ligament approach, using a disposable device (Digitex®) designed to place sutures without direct visualization. The proximal arms of the mesh are sutured to the anterior sacrospinous ligament and the distal arms of the mesh are sutured to the arch of the pelvic tendinous fascia.

#### **3.2 Study design and material and methods**

Retrospective study of patients who underwent surgical correction of POP in the same center between January 2016 and December 2017 with the Restorelle®

device. We analyzed demographic variables, prolapse characteristics, associated symptoms, gynecological history, recurrence, and degree of satisfaction taken from the existing medical history. The degree of POP was evaluated according to the Baden-Walker classification. The surgical indication was symptomatic patients with grade  $\geq 2$  POP (primary or recurrent). All interventions were performed by a single surgeon after an antibiotic prophylaxis protocol.

### 3.3 Results of the study

We retrospectively analyzed 78 patients operated on at our center with a mean age of 64.2 years (48–78). The comorbidities evaluated were diabetes mellitus (DM) (21%), arterial hypertension (48%), with a body mass index (BMI) of 27.5 kg/m<sup>2</sup> and a mean parity of 2.2 births (1–5). 36% of our patients had a history of gynecological surgical, the most prevalent being hysterectomy in up to 50% of the operated patients. The most frequently treated prolapse was anterior (72%), followed by posterior (12%) and mixed anterior–posterior (12%), with only one case of apical and posterior prolapse. Of these, 4 were recurrent prolapses. The most common grade of prolapse was III and IV with a frequency of 54% and 42%, respectively (**Table 2**).

Regarding the functional and clinical results, 50% of the sexually active patients had preoperative dyspareunia, which persisted after the intervention in two

Demographics	Variable value (n = 78)
Age (years)	64.2 (48–78)
BMI (kg/m <sup>2</sup> )	27.5 (21.9–33.3)
<25	13 (16.7%)
25–29.9	46 (59%)
>30	27 (24.4%)
DM	17 (21.8%)
Arterial hypertension	38 (48.7%)
Clinical history	
Parity	2.2 (1–5)
Previous gynecological operation	28 (36%)
Previous hysterectomy	14 (18%)
Previous POP surgery	4 (5.1%)
Pelvic organ prolapse	
Cystocele	57 (73.1%)
Rectocele	9 (11.5%)
Apex	1 (1.3%)
Mixed	11 (14.1%)
Grade	
Stage 2	2 (2.6%)
Stage 3	43 (55.1%)
Stage 4	33 (42.3%)

*Values are presented as median [range] or number (%); BMI: body mass index; POP: pelvic organ prolapse.*

**Table 2.**  
*Demographic variables and clinical characteristics before surgery.*

<b>Results</b>	<b>Preoperative</b>	<b>Postoperative</b>
Dyspareunia	21 (26.9%)	2 (2.6%)
Urinary incontinence:	38 (48%)	24 (30.7%)
Urgency	29 (37.2%)	27 (34.6%)
Stress	24 (30.8%)	12 (15.4%)
Mixed	15 (19.2%)	8 (10.3%)
Unmasked UI		9 (11.5%)
Complications		
Extrusion	5 (6,4%)	
Pain	3 (3,8%)	
Functional recurrence	3 (3,8%)	
Anatomical recurrence	7 (9%)	

**Table 3.**  
*Results and complications during follow-up.*

patients. Preoperative UI (urinary incontinence) was present in 48%, with urgency, stress UI and mixed UI in 37%, 31% and 19% respectively. 18% of these patients resolved their UI and 12% had postoperative UI (**Table 3**). We obtained a success rate of 92%, understood as absence of extrusion (6%), pain (3%) or functional recurrence (3%) 6 months after surgery. The anatomic recurrence rate was 9%. The total Clavien-Dindo IIIa complication rate was the most prevalent with 6.4% (extrusion), followed by grade II (3.8%). There were none in group IV or V. Cases of extrusion were resolved on an outpatient basis with local anesthesia. The mean follow-up time was 13.5 months. In general, the patients were satisfied (57.7%) or very satisfied (36%), and only 6.4% of the patients were dissatisfied and none were very dissatisfied.

#### **4. Discussion**

Surgical techniques can be performed using an abdominal or vaginal approach, depending on the medical history, physical examination, and experience of the surgeon. Laparoscopic sacrocolpopexy is an adequate therapeutic option with a high success rate in 80–100% of cases [33, 34]. However, this technique is not always appropriate, especially for patients who are at high risk for anesthesia, a multi-operated abdomen, or in recurrent prolapse. In these cases, a vaginal approach offers an interesting surgical alternative. Transvaginal mesh was developed to maintain the advantage of a vaginal procedure, while reducing the risk of recurrent prolapse compared to native tissue repair.

In the short and medium term, our results are similar to the articles published in relation to the success rate of studies with the same device and implantation route (92% in our series vs. 80.3%) [22] and different prosthetic devices but with the same implantation route (91.3%) [35], although its comparison is difficult due to the existence of different follow-up times. In our series, the minimum follow-up time was 6 months, while in studies such as the one published by Ferry et al. [22] they only had 3 months of follow-up. We could say that our success rate is slightly higher, despite a longer follow-up. Our good results may be due to the fact that all surgeries were performed by a single surgeon with extensive experience in vaginal

POP correction surgery with mesh interposition. If we compare other techniques with a recent boom, such as laparoscopic or robotic sacrocolpopexy [27, 28], there are also no great differences with respect to the success rate, 92% in our series versus 80–100% in those mentioned.

Our anatomical correction rate at 6 months of follow-up was 91%, similar to that found in other studies with this same device, 87.9% [22] or other light weight devices with the same implantation route, which oscillates between 79 and 96.5% [35–37], although their comparison is equally difficult due to different follow-up times. This same mesh surgery with the same anatomical correction rate criterion was 98.7% at 36 months for De Tayrac et al. [21] and 93.7% for Denance' et al. [38]. Most of the published studies are retrospective [39], and those that are prospective have a follow-up period that is too short. If we compare other techniques such as robotic sacrocolpopexy [27], we find similar rates of absence of anatomic recurrence (95%).

Regarding the complications observed, the mesh extrusion rate in our series was 6.4% compared to 1.3–11.5% published in other studies with lightweight vaginal mesh (28 g / m<sup>2</sup>) [19, 21]. In a study published with the Restorelle® device, an extrusion rate of 2.8% was observed, lower than that obtained at our center. Again, this difference can be justified because the postsurgical follow-up at our center was more than double that of the referenced study [22]. Furthermore, in general, we can affirm that it is difficult to compare our data with the literature, as there is great diversity of previously available prosthetic products.

The functional results obtained are similar to those published to date. We can find postoperative dyspareunia in 1.76% of patients in some existing studies after the use of transvaginal mesh [36, 40], a rate very similar to that of our study with only two existing cases. In the case of laparoscopic sacrocolpopexy, there seems to be a lower risk of dyspareunia compared to the transvaginal implantation device (RR 0.39, 95% CI 0.18) [41, 42]. Incontinence rates were lower after correction of the prolapse, mainly, stress urinary incontinence improved [40, 43] and 12% of new cases appeared. On the other hand, the appearance of de novo stress urinary incontinence is common in the treatment of prolapse with the use of prosthetic material (RR 1.55, 95% CI 1.02 to 2.35 - anterior colporrhaphy versus use of transvaginal mesh), a fact that patients undergoing this surgery should always be advised of. However, our rate of de novo urinary incontinence with the use of transvaginal mesh is similar to that published with the laparoscopic colposacropepy technique (12%) [41].

Summarizing, we can state that transvaginal single incision-mesh have several advantages compared to classical approaches like colposacropepy or other mesh devices. It avoids the peritoneal cavity, truly important in patients with previous abdominal surgeries, reducing the risk of paralytic ileus and making possible a shorten recovery. As we have shown in our cases study, it can be done under locoregional anesthesia, allowing to perform this surgery almost without hospital stay. And finally, the esthetic results are obviously better, as we can avoid any abdominal scar, a fact that is especially transcendent in young women.

Our study presents several limitations. The first of these is the retrospective and non-randomized nature of our study. Furthermore, all the interventions were carried out by the same surgeon with great experience, which makes it difficult to reproduce these results in other centers and makes it difficult to compare them with other studies. On the other hand, the results of the treatments of non-oncological pathologies usually respond to very high expectations on behalf of the patients, so we can consider a limitation of our study the absence of quality of life questionnaires that assess the impact of success obtained after surgery and possible complications during follow-up.

## 5. Conclusion

In our experience, the Restorelle® device and its transvaginal placement is a safe procedure, with low morbidity and a high satisfaction rate in properly selected patients and in the hands of expert surgeons. Complications are rare and can be resolved by outpatient surgery.

Considering long-term complications is essential to properly weigh the risk-benefit ratio of each procedure, which is why more studies with a longer follow-up period than those currently available in the literature are necessary to judge this type of device with more evidence.

### Conflict of interest

The authors declare no conflict of interest.

### Appendices and nomenclature

BMI	Body mass index
DM	Diabetes mellitus
FDA	Food and Drug Administration
ICS	International Continence Society
IUGA	International Urogynecological Association
POP	pelvic organ prolapses
UI	urinary incontinence

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