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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.