

**G.E. PALADE UNIVERSITY OF MEDICINE, PHARMACY, SCIENCE AND
TECHNOLOGY OF TÂRGU MUREȘ**

DOCTORAL SCHOOL OF MEDICINE AND PHARMACY

**DOCTORAL THESIS
SUMMARY**

**The contribution of self-fixating mesh to the surgical
treatment of pelvic organ prolapse**

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DIN TÂRGU MUREȘ

TÂRGU MUREȘ 2022

Introduction

Pelvic organ prolapse (POP) is a pathology defined by herniation of the organs of the small pelvis through the vagina. This condition is found in millions of women and is accompanied by comorbidities such as urinary, anal, or sexual dysfunction. According to the European Society of Menopause and Andropause, about 50% of women will be affected by a form of prolapse during their lifetime, but only 10%–20% of them will seek treatment. The incidence of this pathology increases with age and also with the number of natural births, but also several other factors lead to the relaxation of the pelvic floor, including genetic factors, obesity, smoking, constipation, etc.

Surgery is the last option of treatment, being more common in the age group between 50 and 60 years. Although there are many surgical techniques designed to repair the defect, an optimal procedure is still being sought to treat the comorbidities associated with this pathology.

The aims of the doctoral thesis

Through this study, we aimed to achieve the following objectives:

- 1) Highlighting the feasibility of using Parietex ProGrip™ Self-Fixating Mesh in the surgical treatment of POP by conventional approach;
- 2) Highlighting the feasibility of using Parietex ProGrip™ Self-Fixating Mesh in the surgical treatment of POP by laparoscopic approach;
- 3) Highlighting the complications, early and at distance, that appeared after the surgical interventions;
- 4) Quantification of patients' quality of life after surgery;
- 5) Resolving postprocedural complications and recurrences.

The general part of the doctoral thesis includes two chapters. The first chapter describes the anatomy of the pelvis in women. Chapter two describes general aspects of pelvic organ prolapse, such as epidemiology, aetiology, risk factors, and treatment methods. The motivation of the research is presented in the second part of the thesis, "Personal contribution". To achieve the purpose of the research, three clinical trials were conducted.

Study 1: Conventional sacrocolpopexy using self-fixating mesh

The main objective of this chapter is to study the feasibility of utilising the Parietex ProGrip™ Self-Fixating Mesh in conventional sacrocolpopexy. The main benefit of using this type of mesh is the fact that it does not require auxiliary fixation means, such as sutures, resorbable or non-resorbable tacks, etc. The study was a prospective one in which 20 patients with POP were enrolled. We followed the intraoperative aspects, the advantages of the conventional approach, the advantages/disadvantages of using Parietex ProGrip™ Self-Fixating Mesh, the perioperative results, the recurrence rate, and the quality of life of patients. Of the 20 patients, seven had vaginal vault prolapse, six had a POP grade 3, and 14 had POP grade 2. The patients included in the study were menopausal and had a mean age of 68.05 ± 7 years. Most were multiparous, only three of them had a single birth, and the body mass index was $31.26 \pm 3.02 \text{ kg/m}^2$, expressed as mean $\pm$ standard deviation. The operating time was 154 ± 37.04 minutes, and the hospitalisation period was 7 ± 1.12 days. No patient required urgent blood transfusion, preoperative haemoglobin was 12.69 ± 1.23 , and postoperative haemoglobin was 12.71 ± 1.45 ($p = 0.33$). The objective cure rate was 95%, and the subjective one was 94.12%. The failure of the surgery was represented by a recurrence of POP grade ≥ 2 . We did not detect intraoperative complications or complications related to the presence of the mesh. Postoperative complications were identified in five patients. Two patients developed urinary tract infections, a Clavien–Dindo type I complication, which remitted under antibiotic treatment; two patients had postoperative events, a Clavien–Dindo type IIIb complication, and required abdominal wall repair surgery; one patient had a recurrence at 6 months postoperatively, a Clavien–Dindo type IIIB complication, and required vaginal colectomy and posterior colporrhaphy.

Study 2: Laparoscopic sacrocolpopexy using the Parietex ProGrip™ Self-Fixating Mesh

The main objective of this study was to describe the key points of the use of Parietex ProGrip™ Self-Fixating Mesh in sacrocolpopexy by laparoscopic approach. The secondary objective was to present the initial results of using this mesh in the laparoscopic approach. For this study we collected data on age, parity, operating time, hospitalisation period, perioperative complications, and prior treatments of POP correction. The operating time was calculated from the skin incision to its suture. The period of hospitalisation was calculated starting from the day of admission. Perioperative complications were defined as those complications that occur during surgery or at most 8 weeks postoperatively, while early postoperative complications are considered to occur within 6 months after surgery. Therapeutic failure was defined as a recurrence of POP grade II or higher. We did not detect any intraoperative, early, or late postoperative complications. The mean

age of the study group was 65.33 ± 85 years. The mean hospital stay was 3 days, and the mean operative time was 211 ± 12.58 minutes. All patients were multiparous, and the mean body mass index was 28.1 ± 4.12 kg / m².

Study 3: Abdominal and laparoscopic sacrocolpopexy: a comparative analysis of the two approaches.

In this study, we proposed a comparative analysis of abdominal sacrocolpopexy versus laparoscopic sacrocolpopexy in terms of the use of Parietex ProGrip™ Self-Fixating Mesh.

General discussions

This study was deeply affected by the SARS-CoV-2 virus pandemic, but the concern for this topic and implicitly for helping patients with POPs was realised by winning a research project entitled "Urodynamics and clinical-biological parameters associated with surgical treatment of pelvic organ prolapse using ProGrip™ self-adhesive meshes", registered with number 294/1 / 14.01.2020. In this study, we aimed to create a micturition profile of patients who may have postoperative complications, reflecting the need for a urodynamic test and identifying possible complications of micturition following sacrocolpopexy with self-fixating meshes from the ProGrip™ series.

General conclusions

- ✓ This mesh is well tolerated by patients, and the lack of foreign body reaction or rejection of the mesh encourages its implementation in the surgical treatment of POP.
- ✓ The lack of use of auxiliary fixation means (sutures, tacks, adhesives) removes the risk of pathologies associated with them. The use of the Parietex ProGrip™ Self-Fixating Mesh is easy, and the lack of fasteners shortens the operating time;
- ✓ The disadvantage of using this self-fixating mesh is that it is difficult to manoeuvre in laparoscopic sacrocolpopexy. The presence of the microgrips, whose role is in fixation, causes the mesh to adhere very easily to surrounding tissues;
- ✓ The use of a non-adhesive sterile foil is useful for the manoeuvrability of this self-fixating mesh;
- ✓ The presence of colorectal diverticulosis is a contraindication in sacrocolpopexy using self-fixating mesh because the lactic acid micro grips can erode the walls of the colon at the level of the diverticulum. On the other hand, the inflammatory complications of diverticulosis increase the risk of infection and thus the rejection of mesh;
- ✓ The surgical results are satisfactory, considering that we had only one recurrence.
- ✓ Functional results are promising, with most patients reporting an improvement in quality of life.

The originality of the thesis

Through the approached topic, characterised by the deep degree of multidisciplinarity (general surgery, urology, gynaecology), the presented paper opens up new perspectives of multidisciplinary collaboration, aiming to improve the multidisciplinary treatment of patients with POP.

This study extended the indications for the Parietex ProGrip™ Self-Fixating Mesh, originally designed for the surgical treatment of inguinal hernias, to the surgical treatment of POP.

The initiation of urogynaecologists and colorectal surgeons into these combined techniques opens up prospects for multidisciplinary collaboration and even the opening of centres dedicated to this pathology in Târgu Mureş.