Perioperative complications and short-term outcomes of sacrocolpopexy using self-adhesive mesh

Ann Ital Chir, 2022 93, 3: 349-354
pii: S0003469X21036320
Online ahead of print 2021 - Nov. 10
free reading: www.annitalchir.com

Marian Botoncea*, Septimiu Voidăzan*, Martha Orsolya***, Vlad Olimpiu Butiurcă*, Simona Gurzu°, Călin Molnar*, Claudiu Varlam Molnar°°

G.E. Palade University of Medicine, Pharmacy, Science and Technology, Targu Mures, Romania
**First Department of Surgery*
***Department of Epidemiology*
****Department of Urology*
°Department Pathology
°°Department Obstetrics and Gynecology

Perioperative complications and short-term outcomes of sacrocolpopexy using self-adhesive mesh

BACKGROUND AND OBJECTIVES: *The aim of this study was to investigate the perioperative complications and short-term outcomes of patients who underwent sacrocolpopexy using a self-adhesive mesh.*
MATERIALS AND METHODS: *This is a prospective, monocentric study conducted between October 2019 and December 2020. We included 20 consecutive patients on whom sacrocolpopexy using the Parietex ProGrip™ Self-Fixating Mesh (Medtronic, Minneapolis, MN, USA) was performed. The patients' demographics, operative data, perioperative complications, and functional and anatomical outcomes were assessed.*
RESULTS: *A total of 20 patients were included in this study. The objective cure rate was 95%, and the subjective cure rate was 94.12%. The failure of the surgery was defined as the recurrence of pelvic organ prolapse (POP) ≥ grade II. The preoperative POP quantification classifications were as follows: grade I: 0%; grade II: 70%; grade III: 30%; and grade IV: 0%. There were no mesh-related complications or other intraoperative complications. The postoperative complications included two urinary tract infections, two incisional hernias, and a prolapse recurrence. The mean operative time was 154 ± 37.04 minutes, and the mean hospital stay time was 7 ± 1.12 days.*
CONCLUSIONS: *The present study found that the use of the Parietex ProGrip™ Self-Fixating Mesh in abdominal sacrocolpopexy was not associated with greater rates of complications.*

KEY WORDS: Pelvic organ prolapse, Sacrocolpopexy, Self-fixating mesh

Introduction

Pelvic organ prolapse (POP) is a common gynecological condition that affects up to 50% of the female population, with a negative impact on their quality of life [1]. Almost 12.6% of them end up requiring repair surgery within their lifetimes [2].

Mesh abdominal sacrocolpopexy (ASC) is considered to be the "gold standard" for apical/vaginal vault POP, with consistent results [3]. This procedure was introduced in 1958 by Huguier and Scalin, expanded upon in 1962 by Lane, and modified over time; it consists of fixing the vaginal stump to the anterior surface of the sacrum [4,5].

Although this procedure produces good and lasting results, data from the medical literature suggest that the recurrence rate increases with time, and the risk of mesh extrusion is about 10.5% [6]. Furthermore, this procedure brings some complications due to the presence of the mesh or the means of fastening [6,7].

Pervenuto in Redazione Aprile 2021. Accettato per la pubblicazione Maggio 2021
Correspondence to: Septimiu Voidazan, C.E. Palade University of Medicine, Pharmacy, Science and Technology, Targu Mures, 540139, Romania (e-mail: septimiu.voidazan@umfst.ro)

To reduce the complications related to the fastening means, we used a self-fixating mesh for sacrocolpopexy; however, few scientific data supporting this are available. The Parietex ProGrip™ Self-Fixating Mesh (Medtronic, Minneapolis, MN, USA) (Fig. 1) is a biocomponent mesh designed for hernia repair. This dual-layer mesh is made of a layer of monofilament hydrophilic polyester over which a polylactic acid layer is attached in the form of microgrips. The presence of these microgrips helps with fixation [7].
This study aimed to evaluate the safety and efficiency of sacrocolpopexy using the Parietex ProGrip™ Self-Fixating Mesh.

Materials and Methods

Study Setting

The present study involved consecutive patients with pelvic organ prolapse who underwent surgical treatment in Surgical Clinic No. 1, Emergency Clinical County Hospital of Târgu Mureș, between October 2019 and December 2020. A total of 20 consecutive patients underwent sacrocolpopexy using the Parietex ProGrip™ Self-Fixating Mesh. The surgeries were performed by the same multidisciplinary team-consisting of 2 general surgeons, one with colorectal experience and a gynecologist-following the same surgical steps. The research team also included a urologist.
The patients were requested to fill out 2 questionnaires-the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7)-prior to the surgery and 3 months following it. We used these questionnaires to evaluate the severity and frequency of POP symptoms (PFDI-20) and also evaluate the quality of life (PFIQ-7) [8].
A perioperative complication was described as a complication that occurred during surgery or within the 8 weeks following surgery, while short-term complications were considered those occurring within six months. The operative time was calculated starting from skin incision to the closure of the skin. The duration of the hospital stay was calculated starting from the day of admission to the discharge day. The blood loss was estimated by measuring the levels of hemoglobin pre- and postoperatively.

Ethical Approval

This was a prospective, single-center study conducted after obtaining the approval of the Ethics Committee of the Emergency Clinical County Hospital of Târgu Mureș (nr.32647/14.12.2018), and that of the G.E. Palade University of Medicine, Pharmacy, Science and Technology of Târgu Mureș (nr. 592/12.12.2019). Informed consent was obtained from all the patients involved in this study.

Inclusion Criteria

We included patients with symptomatic POP and patients with POP of grade 2 or higher, based on the Pelvic Organ Prolapse Quantification system (POP-Q) [9], who were surgically treated in our department.

Exclusion Criteria

Patients who were not fit for general anesthesia and those who refused surgery were excluded from this study.

Preoperative Evaluation

Before the surgical procedure, all the patients included in this study underwent gynecological examination. The patients were examined in both sitting and lying positions to assess the influence of pressure. The grade of the POP was clinically evaluated using POP-Q. All the patients underwent a urological examination before the surgery to evaluate occult stress urinary incontinence. Patients with complicated stress urinary incontinence benefited from a pressure-flow urodynamic test.
All the patients underwent preoperative blood and urine tests prior to the surgery. Urethral catheterization was performed, and betadine solution was used to prepare the vaginal cavity.
Anticoagulant treatment was started the evening before the surgery, and 1.5 g of cefuroxime was administrated perioperatively, starting 15 min prior to the surgery.

Operative Technique

The patients were placed in a modified lithotomy position with low stirrups. The main surgeon was positioned on the left side of the patient; the gynecologist, on the right; and the 3rd surgeon, between the patient's legs.
The procedure began with a midline incision or, occasionally, a Pfannenstiel incision. We continued with the exploration of the peritoneal cavity to check for unex-

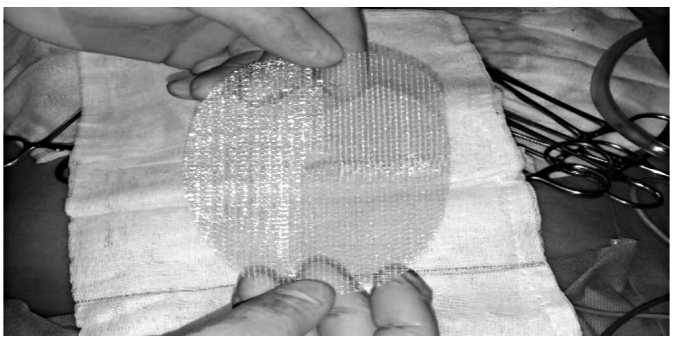

Fig. 1: Parietex ProGripTM Self-Fixating Mesh (Medtronic, Minneapolis, MN, USA).

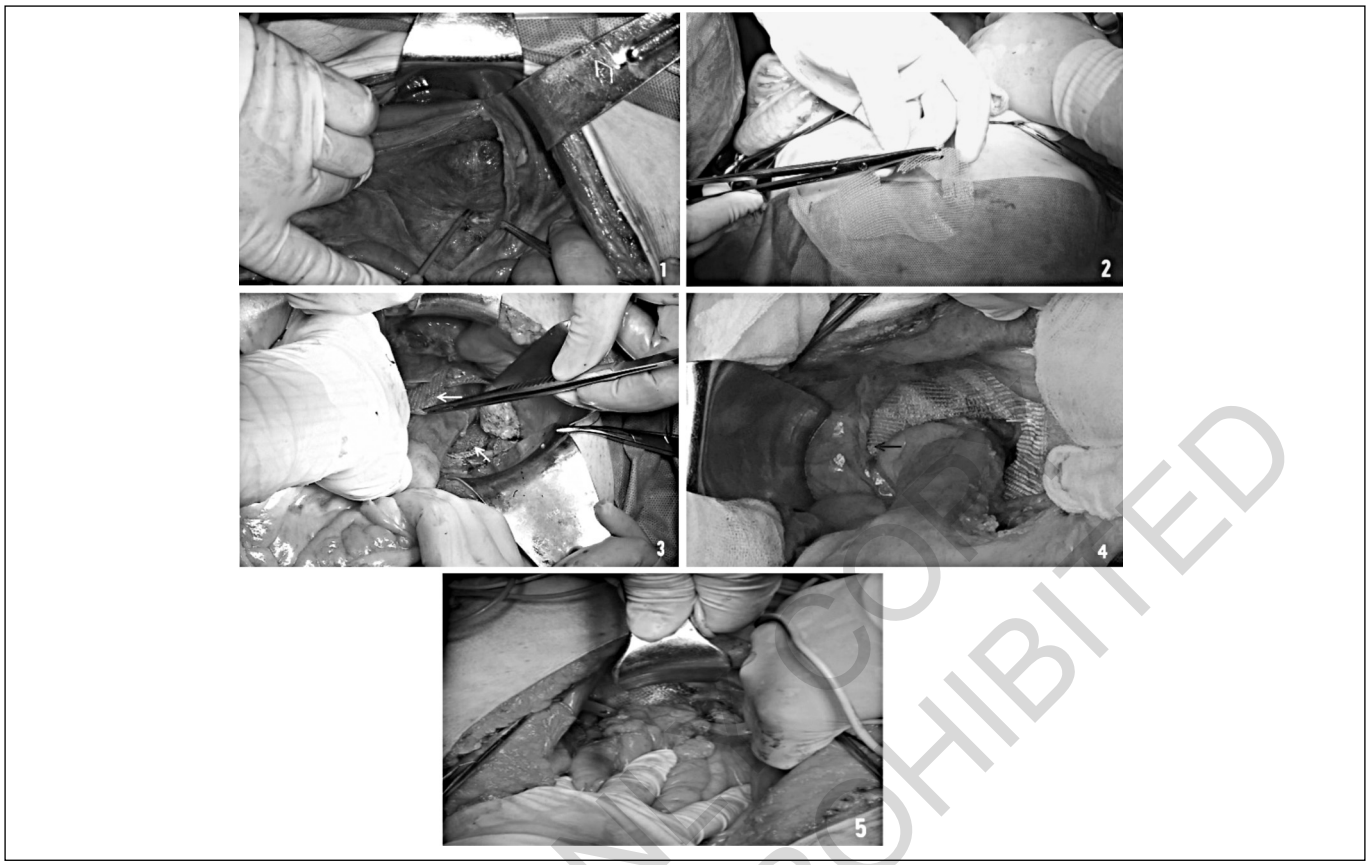

Fig. 2: (1) Exposing the sacral bone and promontory (red arrow). (2) Adapting the diameter of the central orifice of the mesh according to the diameter of the patient's rectum and mesorectum. (3) The arms (white arrows) of the mesh embraced the rectum and mesorectum, becoming attached to the vaginal stump. (4) Mesh fixed to the promontory (green arrow) and vaginal stump (blue arrow). (5) Final aspect after suturing the peritoneum and drainage.

pected abnormalities, and after that, total hysterectomy was performed. If the patient had had a previous hysterectomy, then the vaginal stump was exposed by pushing it up with a probe from the vagina, and the covering peritoneum was dissected. To fixate the mesh to the vaginal stump, a larger area was dissected between the pubocervical and rectovaginal fascia. An incision was made on the mid-side of the peritoneum adjacent to the recto-sigmoid colon. We exposed the sacral bone and promontory. We continued the dissection to the posterior cul-de-sac, avoiding damage to the ureters and rectum. A Parietex ProGrip™ Self-Fixating Mesh was prepared by adjusting the diameter of the hole to fit the diameter of the rectum and mesorectum. To prevent extrinsic stenosis, the diameter was usually 1–2 cm larger. The mesh was then fixated to the vaginal stump and promontory by digital pressure, without using other fastening means. The mobile part of the mesh (the arms) embraced the rectum and mesorectum, becoming attached to the vaginal stump, while the fixed part attached to the sacral promontory. The excess of the cul-de-sac was excised, double drainage of the sacrococcygeal area was performed, and the mesh was peritonealized using resorbable sutures. The abdomen was closed using separate fascial sutures (Fig. 2).

2.7. Postoperative Care

Six hours after surgery, the patients began a liquid diet. Antibiotic treatment continued for five days, while anticoagulant treatment continued throughout hospitalization. The wound dressing was changed every day, and the drainage tubes were removed on the third postoperative day. Patient mobilization started early, on the second postoperative day.

Follow-Up

The follow-up was carried out following the timeline below (Fig. 3).
We continued the multidisciplinary monitoring of the patients, with the follow-ups planned at 18, 24, and 36 months following the surgery.

Statistical Analysis

Data were prospectively collected and included patients' demographics (age, body mass index, POP classification according to POP-Q, multiparity, de novo stress urinary

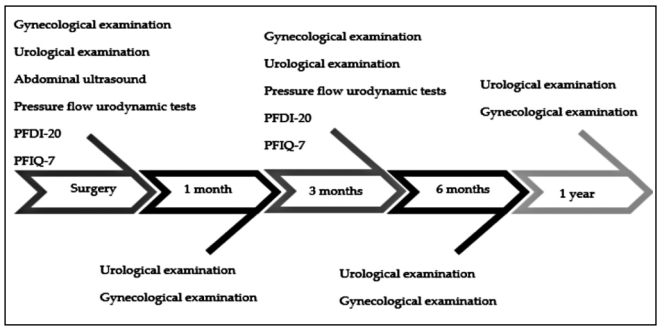

Fig. 3: Chronology of the planned follow-up.

incontinence (SUI), and de novo dyspareunia) and operative data (operative time, estimated blood loss, intraoperative and postoperative complications, and hospital stay time). The functional outcomes were quantified based on the PFDI-20 and PFIQ-7 questionnaires, which were completed pre- and postoperatively.

The Graph Pad State Software version 3.6 (San Diego, CA, USA) was used for statistical analysis. The data are expressed as nominal or quantitative variables.

Frequencies aere used to characterize the nominal variables. The quantitative variables were compared using t-tests. The Kolmogorov–Smirnov test was used to test the normality of distribution of the quantitative variables, and the results are characterized by means ± standard deviations or medians and percentiles (25-75%), when appropriate. A *p*-value lower than 0.05 was considered statistically significant.

Results

A total of 20 patients with POP who fulfilled the inclusion criteria were included in this study and, subsequently, surgically treated. The mean follow-up time of the patients was 11.7 ± 1.34 months. Of the 20 patients, 7 had vaginal vault prolapse, 7 had POP grade 3, 13 had POP grade 2, and 1 had POP grade 1. The patients' characteristics are shown in Table I.

Table II shows the perioperative characteristics and surgical parameters in the study group. Of the concomitant pelvic surgeries, 13 involved retropubic cystopexy (65%), 4 involved rectopexy (20%), 2 involved sigmoidopexy (10%), and 13 involved a hysterectomy (65%).

Intraoperative and Postoperative Complications

One patient with POP grade II had a prolapse recurrence 6 months following the surgery. The patient developed a grade 2 rectocele that was treated by transvaginal posterior colpectomy with colporrhaphy.

There were no intraoperative complications. None of the patients required urgent blood transfusion. Additional complications are shown in Table III.

Table I - *Preoperative characteristics of the patients.*

	N. = 20 Patients
Age (year, mean ± SD)	68.05 ± 7
Body mass index (kg/m2, mean ± SD)	31.26 ± 3.02
Parity (n)	
Yes	17 (85%)
No	3 (15%)
Menopause (n)	
Yes	20 (100%)
No	0
Prolapse stage (n)	
POP-Q I	0 (0%)
POP-Q II	14 (70%)
POP-Q III	6 (30 %)
POP-Q IV	0
History of urogynecological procedures (n)	
Hysterectomy	8 (40%)
Transvaginal mesh procedure	1 (5%)

Table II - *Perioperative characteristics and surgical parameters*

	N. = 20 Patients	
Operative time (minutes, mean ± SD)	154 ± 37.04	
Hospital stay (days, mean ± SD)	7 ± 1.12	
Preoperative Hgb (g/dL, mean ± SD)	12.69 ± 1.23	p = 0.33
Postoperative Hgb (g/dL, mean ± SD)	12.71 ± 1.45	
Associated surgical procedures		
Abdominal hysterectomy	12 (60%)	
Rectopexy	4 (20%)	
Anterior retropubic cystopexy	13 (65%)	
Sigmoidopexy	2 (10%)	
Colposuspension	2 (10%)	
Adhesiolysis	18 (90%)	
Hernia repairs	3 (15%)	

Functional Outcomes

A total of 17 patients responded to the postoperative questionnaire. None of the patients developed de novo SUI or de novo constipation. Two patients developed de novo dyspareunia, which was relieved by the use of local lubricants and vaginal estrogen cream. Except for one patient, all reported significant improvements in terms of preoperative symptomatology (Table IV).

Except for one patient who had recurrent pelvic organ prolapse, none had a prolapse higher than grade I.

Discussion

The main objective of this study was to investigate the perioperative complications and short-term outcomes of patients who underwent sacrocolpopexy using a self-adhesive mesh. The second objective of this study was to evaluate the efficiency and safety of using the Parietex ProGrip™ Self-Fixating Mesh in abdominal sacrocolpopexy. There were no data in the medical literature

TABLE III - *Postoperative complications.*

	N. = 20 Patients
Urinary tract infection	2 (10%)
Incisional hernia	2 (10%)
Prolapse recurrence	1 (5%)

TABLE IV - *Preoperative and postoperative mean values for the PFDI-20 and PFIQ-7 questionnaires.*

	Preoperative Value (Mean ± SD)	Postoperative Value (Mean ± SD)
PFDI-20	233.9 ± 33.92	134.7 ± 37.60
PFIQ-7	228.7 ± 42.67	117.8 ± 42.36
p value	0.0001	0.0001

regarding the use of this mesh in this surgical procedure; we are the very first group to use this mesh in abdominal sacrocolpopexy, to the best of our knowledge. In our study, we did not observe mesh-related complications or other intraoperative complications. This may be due to the short follow-up period. The average time of mesh erosion was between 2 and 33 months [10]. A longer follow-up showed 10.5% erosion at 7 years following surgery [11].

The prolapse failure rate in our study was 5%; by contrast, a recent study on abdominal sacrocolpopexy reported a failure rate of up to 23% [12].

The average operating time of 154 ± 37.04 min was higher than that declared by Rogers et al. (108.2 min) [11] and that reported by Inan et al. [13]. This longer operative time can be explained by the associated abdominal pathology, such as adhesions, and also by the concomitant operations. Furthermore, the operative time varies across different studies and reflects the surgical volume and the necessity of concomitant surgeries [4].

Our mean hospital stay time was 7±1.12 months, which is long when compared to that in other international studies using the same abdominal approach. This longer hospital stay may be because patients were kept longer for better postoperative monitoring, and two of them required prolonged antibiotic treatment to treat urinary tract infections.

All the patients were menopausal, and most were multiparous (85%).

The mean follow-up time of the patients was 11.7±1.34 months; one patient who experienced recurrence was followed up only at 6 months following the surgery, when correction surgery was indicated. We are continuing the multidisciplinary monitoring of patients at 18, 24, and 36 months following surgery.

The subjective outcomes of this study, obtained by the completion of two questionnaires preoperatively and at three months following the surgery, show significant improvements. The subjective cure rate was 94.12% across 17 patients. In a recent study published by Mattsson et al., the quality of life of patients improved after 2 years following surgery; 90% of them stated that their conditions improved, and 72% reported significant improvement [14].

No statistically significant differences were detected in the hemoglobin values before and after surgery. This is due to the fact that we did not have massive bleeding and may be due to postoperative hemodilution.

The laparoscopic approach of this surgical technique using the Parietex ProGrip™ Self-Fixating Mesh seems to be difficult due to the maneuverability of this mesh. The initial results for the laparoscopic approach, as well as tips and tricks, will be presented in a separate study.

Study Limitations and Strengths

The limitations of this study included the low number of patients enrolled (n = 20) and the short period of follow-up. The strengths of this study are the fact that the preoperative evaluation of the patients was performed by a multidisciplinary team (a surgeon, gynecologist, and urologist), the surgeries were performed by the same operating team, and the patient follow-up was performed by the same multidisciplinary team.

Conclusions

The present study found that the use of the Parietex ProGrip™ Self-Fixating Mesh in abdominal sacrocolpopexy was not associated with greater rates of complications. This mesh is well tolerated by patients, with no foreign body reactions or mesh exposure. Surgical outcomes after this procedure were satisfacatory despite the fact that we had one prolapse recurrence.

Funding

This research was supported by the G.E. Palade University of Medicine, Pharmacy, Science and Technology of Târgu Mureș, research grant number 294/1/14.01.2020. This study was not sponsored by any surgical device company.

Riassunto

Background e Obbiettivi: Lo scopo di questo studio era quello di indagare sulle complicanze perioperatorie e gli esiti a breve termine di pazienti che sono stati sottoposti a sacrocolpopessi utilizzando una rete autoadesiva.

Materiali e Metodi: Si tratta di uno studio prospettico e monocentrico condotto tra Ottobre 2019 e Dicembre 2020. Abbiamo analizzato 20 pazienti consecutivi su cui è stata eseguita la sacrocolpopessi utilizzando il Parietex ProGrip™ Self-Fixating Mesh (Medtronic, Minneapolis, MN, USA). Sono stati valutati i dati demografici dei pazienti, i dati operativi, le complicanze perioperatorie e gli esiti funzionali e anatomici.
Risultati: Un totale di 20 pazienti è stato analizzato in questo studio. Il tasso di cura oggettivo era del 95%, e il tasso di cura soggettivo era del 94,12%. Il fallimento dell'intervento chirurgico è stato definito come la ricorrenza del prolasso dell'organo pelvico (POP) ≥ grado II. Le classificazioni preoperatorie di quantificazione POP erano le seguenti: grado I: 0%; grado II: 70%; grado III: 30%; e grado IV: 0%. Non ci sono state complicazioni legate alla rete o altre complicazioni intraoperatorie. Le complicanze postoperatorie includevano due infezioni del tratto urinario, due ernie incisionali e una recidiva prolassica. Il tempo medio operativo era di 154±37,04 minuti, e il tempo medio di permanenza in ospedale era di 7±1,12 giorni.
Conclusioni: il presente studio sostiene che l'uso della rete auto-fissante Parietex ProGrip® nella sacrocolpopessi addominale non era associato a maggiori tassi di complicanze.

References

1 Hijazi S, Echtle D, Aboumarzouk OM, Heinrich E: *Abdominal sacrocolpopexy with Pelvicol xenograft and concomitant Burch colposuspension.* Int J Women's Health 2017; 9, 625-30, doi:10.2147/IJWH.S134239.

2. Ko KJ, Lee KS: *Robotic Sacrocolpopexy for Treatment of Apical Compartment Prolapse.* Int Neurourol J 2020; 24, 97–110, doi: 10.5213/inj.2040056.028.

3. Biler A, Ertas IE, Tosun G, Hortu I, Turkay U, Gultekin OE, Igci G: *Perioperative complications and short-term outcomes of abdominal sacrocolpopexy, laparoscopic sacrocolpopexy, and laparoscopic pectopexy for apical prolapse.* Int Braz J Urol, 2018; 44, 996–1004, doi:10.1590/S1677-5538.IBJU.2017.0692.

4. Zhao Y, Martin BS: *Robotic-assisted laparoscopic sacrocolpopexy: Initial Canadian experience.* Can Urol Assoc J, 2020; 14, E257–E263, doi:10.5489/cuaj.6121.

5. Biler A, Ertaş İE, Tosun G, Hortu İ, Demi RA, Taner CE, Özeren M, Şendağ F: *Perioperative complications and short-term outcomes of ab-dominal sacrocolpopexy, laparoscopic sacrocolpopexy, sacrospinous ligament fixation, and iliococcygeus fixation proce-dures.* Turk J Med Sci, 2018; 48, 602-10.

6. Dwyer L, Kumakech W, Ward K, Reid F, Smith A: *Laparoscopic sacrocolpopexy (LSCP) using an ultra-lightweight poly-propylene mesh.* Eur J Obstet Gynecol Reprod Biol X, 2019; 2, 100008.

7. Botoncea M, Molnar C, Mărginean C, Martha O, Gurzu S, Butiurca VO, Andrei BS, Molnar CV: *Parietex ProGrip Self-Fixating Mesh in Surgical Treatment of Pelvic.* Organ Prolapse Chirurgia 2020; 115, 650-55, doi:10.21614/chirurgia.115.5.650.

8. Zuchelo LTS, Bezerra IMP, Da Silva ATM, Gomes JM, Soares JM, Jr Baracat EC, de Abreu LC, Sorpreso IC: *Questionnaires to evaluate pelvic floor dysfunction in the postpartum period: A systematic review.* IJWH, 2018; 10, 409-24.

9. Madhu C, Swift S, Moloney-Geany S, Drake MJ: *How to use the Pelvic Organ Prolapse Quantification (POP-Q) system?* Neurourol Urodyn, 2018; 37, S39–43.

10. Rani S, Handa N, Goel P, Mehra R: *Conservative surgical management of mesh erosion following abdominal sacrocopopexy.* J Mid-Life Health, 2020; 11, 34.

11. Rogers RG, Nolen TL, Weidner AC, Richter HE, Jelovsek JE, Shepherd JP, Harvie HS, Brubaker L, Menefee SA, Myers D, et al.: *Open sacrocolpopexy and vaginal apical repair: Retro-spective comparison of success and serious complications.* Int Urogynecol J, 2018; 29, 1101-110.

12. Naumann G: *Quo vadis urogynecology 2020. Innovative treatment concepts for urinary incontinence and pelvic organ prolapse.* Geburtshilfe Frauenheilkd, 2021; 81, 183-90, doi:10.1055/a-1302-7803.

13. Inan AH, Beyan E, Budak A, Kanmaz AG: *Evaluation of patients undergoing abdominal sacrocolpopexy due to symptomat-ic pelvic organ prolapse in terms of gastrointestinal complications.* Pak J Med Sci, 2018; 34, 940-44.

14. Mattsson NK, Karjalainen PK, Tolppanen A-M, Heikkinen AM, Sintonen H, Härkki P, Nieminen K, Jalkanen J: *Pelvic organ prolapse surgery and quality of life. A nationwide cohort study.* Am J Obstet Gynecol, 2020; 222, 588e1, doi:10.1016/j.ajog.2019.11.1285.