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An original method of surgical correction of enterocele using a titanium implant with transobturator-sacrospinal fixation

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ABSTRACT

AIM: This study aimed to optimize the outcomes of surgical treatment of enterocele using the original model of "titanium silk" mesh implants with their transobturator-sacrospinal fixation.

MATERIALS AND METHODS: A comprehensive clinical examination and surgical treatment of 22 patients aged 53–68 years with enterocele who had undergone surgical interventions for various forms of POP, were conducted. All patients underwent surgery using the surgical technique developed for enterocele correction using an original "titanium silk" mesh implant model with transobturator-sacrospinal fastening. Outpatient monitoring of patients in the early and delayed postoperative periods was carried out after 1, 6, 12, and 24 months.

RESULTS: During dynamic follow-up, patients were satisfied with the results of the surgical treatment, POP symptoms were stable, and no signs of relapse and mesh-associated complications were observed.

CONCLUSION: The study confirmed the effectiveness and safety of a new surgical technique for enterocele correction using an original model of a mesh implant "titanium silk" with transobturator-sacrospinal fixation in patients with enterocele who had undergone surgery in the past for various forms of POP. However, further research in this direction is needed.

Keywords: pelvic organ prolapse; enterocele; mesh implant "Titanium silk"; titanium "anchor" ligature fixators in soft tissues.

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Оригинальный способ хирургической коррекции энтероцеле при помощи титанового имплантата с трансобтураторно-сакроспинальной фиксацией

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АННОТАЦИЯ

Введение. Цель работы — оптимизация результатов хирургического лечения энтероцеле при помощи оригинальной модели сетчатых имплантатов «титановый шёлк» с их трансобтураторно-сакроспинальной фиксацией.

Материалы и методы. Проведено комплексное клиническое обследование и хирургическое лечение 22 пациенток в возрасте от 53 до 68 лет с энтероцеле, перенёсших в прошлом оперативные вмешательства по поводу различных форм пролапса тазовых органов (ПТО). У всех пациенток реализована разработанная хирургическая методика коррекции энтероцеле при помощи оригинальной модели сетчатого имплантата «титановый шёлк» с трансобтураторно-сакроспинальным креплением. Амбулаторное наблюдение за пациентками в раннем и отсроченном послеоперационном периоде проводили через 1, 6, 12 и 24 мес.

Результаты. В процессе динамического мониторинга отмечена удовлетворённость пациенток результатами хирургического лечения, стойкое нивелирование симптомов ПТО, отсутствие признаков рецидивов заболевания и mesh-ассоциированных осложнений.

Заключение. Проведённое исследование показало эффективность и безопасность разработанной новой хирургической методики коррекции энтероцеле при помощи оригинальной модели сетчатого имплантата «титановый шёлк» с трансобтураторно-сакроспинальным креплением у пациенток с энтероцеле, перенёсших в прошлом оперативное вмешательство по поводу различных форм ПТО, что свидетельствует о необходимости дальнейших исследований в этом направлении.

Ключевые слова: пролапс органов малого таза; энтероцеле; сетчатый имплантат «титановый шёлк»; фиксаторы лигатур в мягких тканях — «якоря» из титана.

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利用钛植入物和经尿道-骶骨固定手术矫正肠套叠的新方法

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摘要

论证。本文的目的是利用“钛丝”网状植入物的原始模型及其经尿道骶骨固定来优化肠套叠手术治疗的效果。

材料与方法。我们对22例年龄在53至68岁之间、过去曾因各种形式的盆腔器官脱垂（pelvicorganprolapse, POP）而接受过手术治疗的肠套叠患者进行了全面的临床检查和手术治疗。所有患者都接受了已开发的肠套叠矫正手术技术，该技术采用了钛丝网植入物的原始模型，并进行了经尿道骶骨固定。术后1、6、12和24个月后，对患者进行了早期和延迟期门诊随访。

结果。在动态监测过程中，患者对手术治疗效果、盆腔器官脱垂症状的稳定平复、无疾病复发迹象和mesh相关并发症表示满意。

结论。这项研究表明，在过去因各种形式的盆腔器官脱垂而接受过手术治疗的肠套叠患者中，使用钛丝网植入物和经尿道骶骨附着物的原始模型进行肠套叠矫正的新手术技术是有效和安全的，这表明有必要在这一方向开展进一步的研究。

关键词：盆腔脏器脱垂；肠套叠；“钛丝”网状植入物；软组织中的结扎固定器--钛制“锚”。

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INTRODUCTION

Pelvic organ prolapse (POP) is an extremely common condition with enterocele accounting for 17% to 37% of cases. An enterocele is also commonly referred to as a hernia of the parietal peritoneum of the true pelvis containing loops of small bowel and/or omentum [1–2]. This disorder is caused by thinning or tearing of the rectovaginal and/or pubocervical fascia, resulting in close contact between the peritoneum and the vaginal mucosa. The overstretched peritoneum of the rectouterine pouch often contributes to the prolapse of the posterior vaginal fornix, sometimes to the extent that the fornix prolapses with the contents of the hernia sac beyond the vulvar ring. Predisposing factors for enterocele are deep rectouterine space, pelvic surgery with damage to the pubocervical and/or rectovaginal fascia, and alternation of normal pelvic topography after hysterectomy, uterine ventrofixation, and other prolapse treatments [1–4]. Reports of functional failure of some surgical procedures are often associated with incomplete surgical restoration of normal pelvic organ arrangement, inadequate treatment of fascial defects, and inadequate extent of surgery [1, 3].

Unfortunately, various surgical techniques, both abdominal and vaginal, using native tissue and/or synthetic implants have only a minimal effect on the surgical outcomes. The recurrence rate of POP remains high, ranging 33.3% to 40.0%. The incidence of mesh-related complications is in the range of 1% to 17% [5–9].

The study aim was to optimize outcomes of surgical treatment of enterocele using an original model of titanium silk mesh implants with transobturator and sacrospinal fixation.

MATERIALS AND METHODS

The study was conducted from 2021 to 2023 in the gynecology departments of the Sechenov Center for Motherhood and Childhood and the National Medical Research Center "Treatment and Rehabilitation Center" of the Ministry of Health of the Russian Federation, which are clinical bases of Obstetrics and Gynecology Department No. 1 of the N.V. Sklifosovsky Institute of Clinical Medicine of the Sechenov First Moscow State Medical University (Sechenov University).

A comprehensive clinical evaluation and surgical treatment were performed in 22 female patients aged 53 to 68 years with recurrent POP manifesting 5–12 years after initial surgery. Eight patients (subgroup A) had previously undergone supravaginal amputation of the uterus with excision of the cervical mucosa and muscularis layer and cervicovaginopexy using titanium mesh implants; seven patients (subgroup B) had received treatment of anterior prolapse and cystocele using polypropylene implants, and the remaining 7 patients (subgroup C) had undergone hysterosuspension using aponeurotic flaps.

All patients were postmenopausal, with postmenopausal status ranging 2 to 19 years.

The study group was formed by thematic sampling. The *inclusion criteria* were as follows:

- Age 53 to 68 years,
- Enterocele after a previous surgery for different types of pelvic prolapse,
- Signed voluntary informed consent for study participation,
- Consent to placement of titanium implants,
- Consent to a surgery as specified.

Non-inclusion criteria:

- Inflammatory diseases of the pelvic organs and/or abdominal cavity,
- Severe extragenital diseases, including systemic ones, with frequent exacerbations, polyvalent allergy, acute infectious diseases and neuropsychiatric disorders,
- Decubital cervical ulcers,
- Congenital or acquired deformities of the pelvic bones and/or hip joints that contraindicate transvaginal surgery.

Exclusion criteria:

- Refusal to participate in the study,
- Gynecological cancers.

Patients were evaluated according to the standards of care in pelvic inflammatory diseases, including analysis of complaints, collection of medical history, physical examination, gynecological and rectal examinations, instrumental (transvaginal echography, transperineal echography, colposcopy) and other examinations based on clinical symptoms and necessary preoperative preparation in each patient.

The complaints and the time of their manifestation were thoroughly reviewed, considering heredity, extragenital diseases, menstrual and reproductive functions. Previous gynecological diseases, surgical procedures, and history of the current disease were evaluated [4, 10].

A gynecological examination included evaluation of external and internal genitalia at rest and during straining, a bimanual examination followed by a rectal examination to differentiate enterocele from rectocele. The international Pelvic Organ Prolapse Quantification System (POP-Q) was used for prolapse grading. A pelvic ultrasound was performed using Voluson P8 (General Electric, USA), equipped with multi-frequency transvaginal and convex transducer.

A detailed analysis showed a similarity of complaints in all subjects. First of all, patients felt discomfort due to the presence of a foreign body inside or outside the vagina (100%), pain in the lower abdomen and lower back (86.4%), discomfort, inconvenience and even pain during sexual intercourse (72.7%), and as a result, the impossibility of a normal sex life. Chronic constipation was reported in 36.4% of patients. Three patients (13.6%) believed that the "foreign body" protruding beyond the vulvar ring during straining and physical activity was uterine prolapse.

Vaginal discomfort first appeared 3–5 years after the first surgery for POP in 7 patients, 6–8 years in 8 patients, 9–10 years in 5 patients, and 11–12 years in 2 patients.

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However, the majority of women (63.6%) did not seek medical advice until 3–6 years later, trying to avoid repeat surgery and hoping for non-surgical treatment.

Family history data showed a maternal history of POP in one in every four women and a grandmaternal history in one in every seven women, apparently indicating the hereditary nature of POP.

As for extragenital diseases, 63.6% of patients had cardiovascular diseases, 36.4% had varicose veins, 13.6% had chronic bronchitis, 45.5% had chronic gastritis and chronic cholecystitis, 22.7% had hernias, 27.2% had hypermobility and dislocation of joints, 40.9% had arthrosis, 54.5% had osteochondrosis of various parts of the spine, which indicates possible congenital structural disorders of the connective tissue.

Menstrual function and menopausal age of the subjects were comparable and showed no special characteristics. The mean age of menarche was 13.2 ± 1.3 years, and the mean age of menopause was 52.3 ± 2.8 years.

The majority (86.4%) of patients had 1 to 2 previous vaginal deliveries, and 13.6% had 3 full-term vaginal deliveries. In 77.3% of women the trauma of the soft pelvic canal made the delivery difficult. This is one of the pathogenetic factors for POP.

A history of uterine fibroids combined with grade II C-prolapse was reported in 36.4% of the women, 9% had a benign ovarian tumor, 13.6% had an ovarian cyst, 31.8% had grade II descent of the anterior vaginal wall and cystocele, and 31.8% had grade II prolapse of the anterior vaginal wall and uterus.

At the age of 44–56 years, all subjects received surgical treatment for primary POP and gynecological comorbidities as follows: laparoscopic subtotal hysterectomy with excision of the mucomuscular layer of the cervix and lateral cervicovaginopexy using titanium mesh implants (36. 4%); treatment of anterior prolapse and cystocele using polypropylene implants (31.8%); hysterosuspension using aponeurotic flaps (31.8%). Five patients aged 28 to 40 years underwent organ-preserving surgery for benign tumors and endometrioid ovarian cysts.

According to physical, gynecological, and rectal examinations, all patients had pelvic floor dysfunction as evidenced by a gaping genital fissure at rest or during straining. A hernia sac prolapsed from the posterior vaginal fornix with the apical part reaching the level of the vaginal entrance in the majority of women (86.4%), and in 13.6% the hernia sac partially prolapsed beyond the introitus. An enterocele occurs when the peritoneum of the rectouterine pouch becomes overstretched and thin, loses elasticity, or the rectovaginal fascia is damaged.

Transvaginal and transperineal echography showed the picture of pelvic floor dysfunction (muscle diastasis was detected in the area of the tendon center; the height of the central tendon of the perineum was less than 10 mm).

In three subgroups (A, B, and C), the cervix was located above or at the level of the pubic symphysis. No bladder or rectum contour deformities or displacements were observed. Functional tests (Valsalva maneuver, cough test) did not show hypermobility of the urethra. At the same time, a protrusion was seen in the vagina from the area above the level of the dentate line of the anal canal. Loops of small bowel and/or omentum were located in this protrusion.

Uterine fibroids were diagnosed in 2 of 7 patients in subgroup B and in 3 of 7 women in subgroup C with 1 to 3 interstitial/subserous nodes 1.0–1.5 cm in diameter.

Surgery was indicated for recurrent POP such as enterocele and pelvic floor dysfunction.

Russian and foreign researchers believed that surgery is the most treatment option for POP [1, 3, 4]. However, despite many techniques, there is no universal treatment for all types of pelvic descent. The incidence of recurrent cases remains high, so gynecologists, as well as urologists and proctologists who also deal with such issues, continue to develop new original treatment options for POP that can be used (sometimes in combination) to achieve not only good but also stable results [11–14]. Many generations of medical professionals have been searching for new techniques for surgical treatment of POP and evaluating their results, and these data together with innovative medical technologies provide a new original four-step technique of enterocele treatment by a transvaginal surgery using titanium silk mesh implants in patients after previous surgery for various forms of POP.

The main surgical techniques for abdominal repair of enterocele with obliteration of the rectouterine pouch include Moshkovich technique, Galban technique, and plication of the uterosacral ligaments. The basic technique using the vaginal approach involves identification of defects in the upper or transverse parts of the rectovaginal fascia, the overstretched peritoneum of the rectouterine pouch, which is a hernial sac through which abdominal organs, usually loops of small bowel and/or omentum, prolapse into the vagina. Subsequent steps include dissection and excision of the hernial sac, suturing of the hernial orifice, and repair of fascial defects [1, 15].

In our study, patients in three subgroups, A, B, and C, were operated on via the transvaginal approach with repair of the enterocele (under spinal anesthesia) using a titanium silk pentagonal mesh implant.

Surgical technique

Step 1. A Foley catheter was inserted into the bladder under aseptic conditions. After preliminary hydropreparation, the vaginal wall above the enterocele was fixed with clamps (Figure 1, *a, b*) and the vaginal mucosa was dissected longitudinally to the peritoneum without damaging the latter. The hernia sac was then dissected down to its orifice (Figure 2, *a, b*). Surgical landmarks included the level of the cervix (subgroups B, C) or the cervical stump (subgroup A) anteriorly, the level of the coccyx posteriorly, and the level of the sciatic spines at the left and right sides. During dissection, the

hernia sac was carefully separated from the anterior wall of the rectum. After emptying the hernia sac, a non-absorbable purse-string suture was placed at the sac orifice.

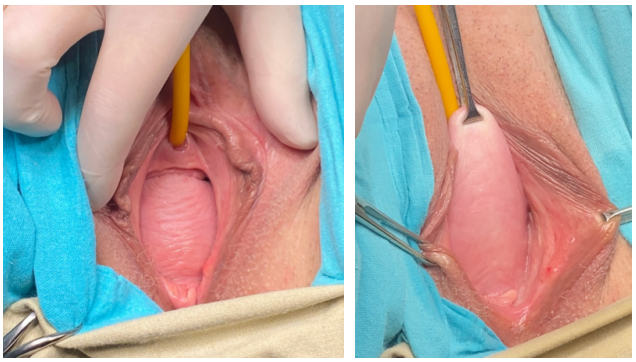
Step 2. Channels to the sacrospinous ligaments on both sides were created using sharp and blunt techniques. Ligature fixators (monolithic titanium anchors with non-absorbable sutures) were inserted into the sacrospinal ligaments in the soft tissues using metal conductors (Figure 3).

A medial longitudinal incision was made along the anterior wall of the vagina. The edges of the mucosa were separated from the underlying tissue using blunt and sharp techniques and then channeled to the upper edges of the obturator membranes. The distal ends of two ribbon-like implants were guided transobturatorly through the created channels and brought out into the inguinal and femoral folds on both sides. The proximal ends of the tapes were passed through the soft tissues of the lateral walls of the cervix to the posterior surface of the cervix and secured with non-absorbable sutures to the posterior lip of the ectocervix 1 cm above the external os. A ribbon-shaped titanium implant (Figure 4, *a, b, c*) can be used for this surgical manipulation.

The anterior vaginal wall was reconstructed using single absorbable sutures.

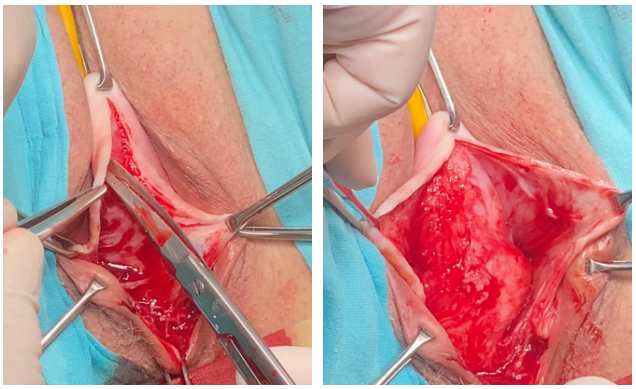
Step 3. Based on the individual morphometric parameters of each patient, a pentagonal flap in the shape of the tip of a spear was cut from the titanium silk fabric, with tip facing the entrance of the vagina (point O; Figure 5). The base of the spear as a platform with two almost right angles (points X, Y) was sutured to the posterior lip of the cervix at the level of the titanium band. The lateral parts of the spear in the area of obtuse angles (points Z, Q) were sutured with non-absorbable ligatures secured in anchors fixed in the sacrospinal ligaments. Additional sutures were placed to the lateral surfaces and the tip of the "spear" (point O) with non-absorbable ligatures, providing multifocal fixation to the underlying tissues (Figure 6).

Step 4. Colpoperineorrhaphy with levator plasty was performed using the classical technique. An antiseptic tampon was inserted into the vagina. The duration of surgery ranged from 45 to 65 minutes with an average of 56.0±7.4 minutes. Blood loss ranged from 60 to 160 mL (87.0±15.6 mL).



a *b*

Fig. 1. *a*, *b* — Enterocele before surgery.



a *b*

Fig. 2. Dissection of the hernial sac: *a, b,* operation stages.

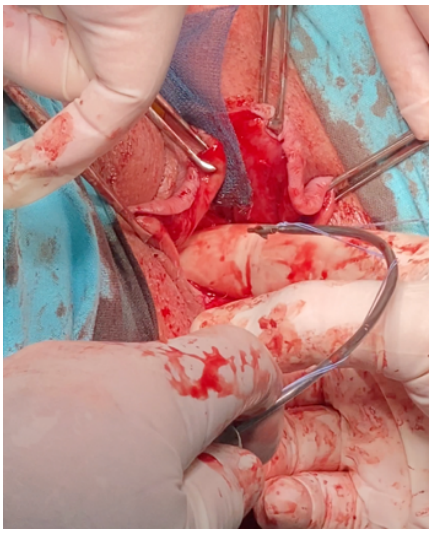


Fig. 3. Installation of ligature fixators in soft tissues: titanium "anchors" in the sacrospinal ligaments.

RESULTS

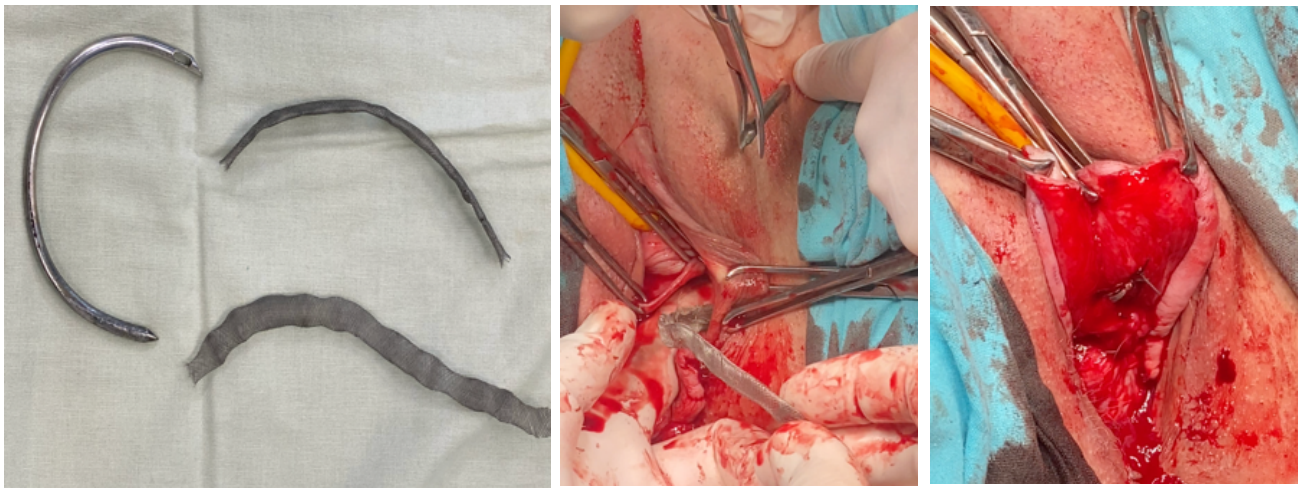
In the post-operative period, patients received antibacterial, anticoagulant, analgesic and bowel stimulation therapy as indicated. The perineal sutures were healed by primary intention. The length of hospital stay was 5–7 days (6.0±1.2 days).

Patients were followed up at 1, 6, 12, and 24 months.

Patient satisfaction with the results was recorded during the follow-up period. Gynecological and rectal examinations at rest and during stress tests (Valsalva maneuver, cough test) showed that transvaginal and transperineal echography over time did not detect any significant displacement of the pelvic organs and the titanium implant, and there were no mesh-related complications.

CONCLUSION

Our study demonstrated efficacy and safety of the proposed surgical technique for enterocele repair using the



a *b* *c*

Fig. 4. Transobturator placement of tape-shaped titanium implants: *a,* tape-shaped titanium implants and impactor (needle); *b,* transobturator placement of tape-shaped titanium implants; *c,* consolidation of the proximal ends of tape-shaped mesh implants with the posterior cervical wall.

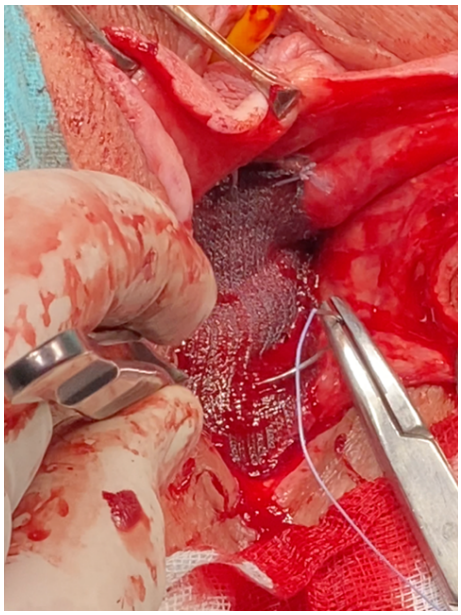


Fig. 5. Installation of a mesh implant "titanium silk" in the shape of a "spearhead."

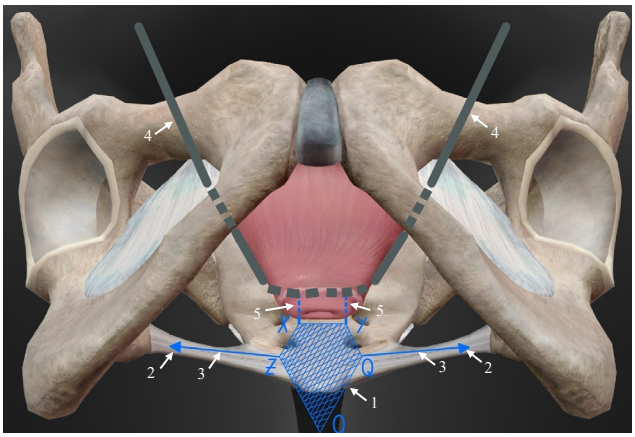


Fig. 6. Installation of a titanium mesh implant in patients with enterocele and a preserved uterus: 1, "spear-shaped" mesh titanium implant; 2, ligature fixators in soft tissues —"anchors" made of titanium; 3, nonabsorbable ligatures fixed in "anchors"; 4, ribbon-shaped titanium implants transobturatorially carried out and fixed to the posterior cervical wall; 5, nonabsorbable ligatures consolidated with a titanium silk mesh implant (points X and Y), ribbon-shaped implants, and posterior cervical wall.

original model of the titanium silk mesh implant with transoburator and sacrospinal fixation in patients with enterocele who had previously undergone surgery for various forms of POP. Further research is needed in this area.

ADDITIONAL INFO

Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. A.I. Ishchenko — the concept and design of the study (20%); A.A. Kazantsev — the concept and design of the study (5%); A.A. Ishchenko — editing (10%); I.D. Khokhlova — writing the text of the article (15%); T.A. Dzhibladze — editing (10%); O.Yu. Gorbenko — collection and design of photo and video materials (5%); Yu.V. Chushkov — collection and design of photo and video materials (5%); I.V. Gadaeva — collection and design of photo and video materials (5%); A.D. Komarova — writing the text of the article (15%); A.G. Ozdemir — collection of literature (5%); A.P. Moskvicheva — collection of literature (5%).

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Ethics approval. The study was approved by the Local Ethics Committee of the I.M. Sechenov First Moscow State Medical University (Extract from Protocol No. 03-22 dated 02/03/2022).

Consent for publication. All the patients who participated in the study signed an informed consent to participate in the study and publish medical data.

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