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Reconstruction of the rectovaginal septum with a W-mesh for rectocele

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ABSTRACT *AIM: to assess of late results of original method of rectocele repair with non-absorbable polypropylene W-form mesh.*

PATIENTS AND METHODS: the pilot study included 37 patients which underwent surgery for rectocele repair using original technique of W-mesh. The late results were assessed in 21 (56.6%) of them ≥ 6 month after surgery. Before the surgery and 6 months after, patients underwent a clinical assessment of symptoms. Specialized questionnaires for assessment of constipation (Colonic evacuation disorder scale, PFDI-20, Cleveland Clinic Constipation Score) were used. Defecography and anorectal manometry were performed before and in 6-months after surgery for evaluation of pelvic floor disorders.

RESULTS: no obstructive defecation symptoms were revealed in 85.7% of patients 6 month after surgery. In ≥ 6 months after surgery all questionnaires showed decrease in scores by more than 2 times. Comparison of the results before and 6 months after the surgery showed significant differences for all questionnaires ($p < 0.0001$). According to defecography performed before and after the surgery a significant reduction ($p < 0.05$) of rectocele depth, time of rectal voiding (decreased by 1.5 times) and residual volume of contrast agent (decreased by 2.5 times) were revealed. There are no severe complications requiring re-operation were observed.

CONCLUSION: transvaginal mesh repair of symptomatic rectocele demonstrated good clinical results 6 months after surgery. Good results were revealed in 85,7% of patients confirmed by specialized questionnaires and defecography.

KEYWORDS: *rectocele, mesh implant, pelvic organ prolapse, plastic surgery of the rectovaginal septum, pelvic floor prolapse syndrome*

CONFLICT OF INTEREST: *The authors declare no conflict of interest.*

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INTRODUCTION

Rectocele is a protrusion of the rectal wall towards the vagina (anterior rectocele) or towards the anococceal ligament (posterior rectocele), the latter is much less common [1]. The rectocele incidence among women, according to various authors, ranges from 7.0% to 55.0%. However, clinical manifestations of the disease observed only in 25% of them [2–4]. Clinical manifestations of rectocele designated by a common name — obstructive defecation syndrome, which includes a number of symptoms: constipation, a feeling of incomplete emptying of the rectum, the need to use manual pressing on the back wall of the vagina or perineum to empty the rectum. Rectocele can also manifest itself as a feeling of a foreign body in the vagina and dyspareunia.

When rectocele with clinical manifestations is detected, conservative therapy is prescribed as the first stage, which includes measures aimed at improving bowel emptying, as well as strengthening the pelvic floor muscles [1,5]. In the absence of the effect of conservative therapy, the question of surgical treatment raised. There are various surgical methods for

rectocele, one of which is the installation of a mesh implant in the area of the rectovaginal septum. At the beginning of the XXI century, foreign variants of implantation systems, such as Prolift™ (Johnson & Johnson Company ©, USA) and Elevate™ (American Medical System, USA), became widespread. According to the results of many studies, these methods have demonstrated good clinical results of treatment, but their use in some cases is associated with the possibility of developing serious early and long-term postoperative complications. The causes of complications are most often associated with the surgical procedure itself, in which the 'wings' of the mesh implant are carried out and fixed to the structures of the pelvic floor using special conductors without direct visual control. These techniques use mesh implants made of non-absorbable material — polypropylene, which can also contribute to the development of complications. So, the study by Kasyan, G. et al. (2014) provides data on complications that occurred after the installation of the Prolift™ mesh implant within 3 months after the surgery. Because of this study, it was found that a total of 152 (22.5%) of 677 operated patients had complications [6]. Intraoperative and early postoperative complications were reported in 88 (13.0%) patients: in 15 (2.2%) cases intraoperative bleeding with a volume of more than 500 cm^3 developed; pelvic hematoma was observed in 37 (5.5%) patients; perineal hematomas — in 17 (2.5%) patients; injuries of the urinary system organs occurred in 14 (2.1%) patients; rectal lesion was noted in 5 (0.7%) cases. Complications associated with the installed mesh implant occurred in 64 (9.4%) cases. Among the frequent complications were erosion of the vaginal mucosa (32/677 [4.8%]), as well as dyspareunia with pain in the pelvic region in (16/677 [2.4%]) cases.

In the study by Vaiyapuri G.R. et al. (2011) are described long-term complications observed 1 year after the installation of the Prolift™ mesh. In this study, 209 patients were tracked 1 year after the surgery, of whom 24 (12.0%) patients had vaginal erosion, 12 (5.7%) patients had dyspareunia, and in 2 (1.0%) cases, patients noted the appearance of chronic pelvic pain [7]. In 2011, the U.S. Food and Drug Administration (FDA) published a warning about the dangers of using mesh due to possible complications; and therefore the use of these mesh implants has become limited in a number of countries [8].

In order to reduce the risk of complications during the installation of mesh, methods have begun to be developed, in which the implant to be installed, depending on the required size, is cut out intraoperatively; in addition, its installation takes place under the control of vision with fixation to sedentary structures of the pelvic floor. Also, in order to prevent complications, have been developed techniques that use biological collagen implants that have better biological compatibility with the patient's tissues than synthetic implants. At the FSBI RNMRC of Coloproctology in the period of between 2012 and 2015, a study was conducted on the use of synthetic (Ultrapro™ , Johnson & Johnson Company© , USA) and biological implants (Permacol™ , Sofradim© , France) to strengthen the rectovaginal septum during rectocele correction [9]. In both groups, plastic surgery of the rectovaginal septum by transvaginal access was used, consisting in the installation of a rhomboid implant cut out intraoperatively. After cutting out, the implant is placed on the anterior surface of the rectum with its subsequent fixation to the levator muscles, as well as with separate sutures to the place of attachment of the levator muscles to the descending branch of the pubic bone. When evaluating the treatment results 1 year after the surgery, according to defecography, it was found that in the group with the use of biological implants, the difference in the size of the protrusion of the anterior wall of the rectum before and after the surgery was insignificant ($p > 0.05$), in contrast to the group with synthetic implants ($p < 0.05$).

To date, the issue of developing a technique that allows to effectively eliminating rectocele with minimal risk of complications remains relevant. Thus, the method of treatment of rectocele — the rectovaginal septum plastywith a W-shaped mesh (patent No. 2675352 of 2018) was developed at the FSBI RNMRC of Coloproctology.

Since 2019, a prospective observational study has been launched to assess the effectiveness of this technique.

PATIENTS AND METHODS

For the period from 2018 to 2021, 37 patients were included in the study. In 6 months or more after the surgery, the results of the treatment were evaluated in 21 (56.8%) patients. In the remaining 16 (43.2%) patients, the time after the surgery did not reach 6 months.

The criteria for inclusion in the study are:

- Presence of rectocele of the 2nd-3rd degrees in patients (data from clinical examination and X-ray defecography).
- Clinical signs of obstructive bowel movement syndrome:
  - feeling of incomplete emptying of the rectum;
  - difficult defecation;
  - the need to use a manual assistance to empty the rectum.
- The presence of one or more radiological signs of rectal emptying disorder:
  - the direction vector of fecal masses is partially or completely directed towards the rectocele;
  - prolongation of the time of emptying the rectum;
  - increase in the residual volume of the rectal contents;
  - the absence of internal rectal invagination, in which the invaginate is displaced distal to the level of the rectocele and 'unlaces' it.

The average age of the patients was 54 ± 7.6 (32–65) years. The body mass index on average was25.86 ± 3.47 (21.4–35.5). Among the concomitant somatic pathology, hypertension prevailed, which observed in 8 (38.0%) patients. One (4.8%) patient had a history of hysterectomy. Assessing the nature of physical activities during life, 10 (47.6%) patients indicated the heavy nature of physical labor. 85.7% (18/21) of the patients had natural delivery. The history of the disease was 5 (0.7–19) years. According to the defecography, 19 patients had grade 3 rectocele (more than 4 cm), 2 patients had grade 2 rectocele (from 2 to 4 cm).

Before the surgery, the patients underwent a clinical check-up; instrumental diagnostics was performed, which included: high-resolution manometry, which allows to determine the type of functional defecation disorder, ultrasound with a rectal sensor, as well as defecography. In 6 and 12 months after the surgery, the following tests were performed: complex sphincterometry, which allows to identify indirect signs of defecation disorders during a straining test, ultrasound with a rectal sensor, defecography.

Before and after the surgery, questionnaires were used: the system of score evaluation of violations of colon evacuation function, developed at the FSBI RNMRC of Coloproctology of the Health Ministry of Russia; the register of pelvic floor disorders — Pelvic Floor Distress Inventory (PFDI-20); the Cleveland constipation Scale (Wexner Scale).

The system of score evaluation of violations of the colon evacuation function comprises 9 questions and allows to fully assessing the presence and nature of violations of the colon evacuation function.

This scale has a maximum of 22 points, which characterizes the worst function of emptying the rectum.

The PFDI-20 questionnaire comprises 20 questions and has a maximum of 300 points corresponding to the worst symptoms of pelvic organ prolapse.

The advantage of the questionnaire is that with the help of its application, it is possible to assess the symptoms of pelvic organ prolapse, since it includes questions on not only the violation of emptying of the rectum, but also questions on anal continence and violation of urination.

The Cleveland Constipation Scale includes 8 questions on the violation of emptying of the rectum and constipation. The scale has a maximum of 30 points, which characterizes unsatisfactory indicators. The advantage of this scale is that it includes questions that allow as per subjective complaints to conduct a clinically differential diagnosis between slow-transit and proctogenic constipation.

In addition, by interviewing the patients, a subjective assessment of the time of emptying of the rectum (in minutes) before and after the plastic surgery of the rectovaginal septum with a mesh implant was carried out. According to the time of rectal emptying, all the patients divided into 2 groups.

The first group included the patients with a rectal emptying time of up to 5 minutes; the second group included the patients with a rectal emptying time of more than 5 minutes.

Surgery Technique

Bowel cleansing for the surgery includes taking a laxative based on polyethylene glycol in a volume of 3–4 liters on the eve of the surgery.

The surgery was performed by transvaginal access. After a longitudinal incision of the vaginal mucosa (Fig. 1), the rectovaginal septum is split (Fig. 2), the rectum is mobilized from the right and left in an acute and blunt way to the level of the sacro-spinous ligaments.

In Figure 3, the intestine is shifted to the right and the area of the sacro-spinous ligaments is visualized, which are contoured in the form of whitish-colored strands, tightly elastic on palpation. With a vikril 2–0 thread, separate stitches are applied to the ligaments on each side, the ends of the threads, to which the wings of the mesh are subsequently fixed, are taken on holders.

After that, 3–4 corrugating sutures are applied to the anterior wall of the rectum with a 3–0 Vicryl thread. The measurement of the length of the rectum area on which the implant will be placed and the distance between the sutures applied to the sacro-spinous ligaments is performed. A W-shaped mesh implant is cut out and modeled according to the previously defined dimensions (Fig. 4). The study uses a lightweight partially absorbable Ultrapro™ mesh (Johnson & Johnson Company©, USA).

Then, through the 'wings' of the mesh, the sutures previously imposed on the sacro-spinous ligaments are carried out and the mesh is freely, without tension, straightened and lowered onto the rectal anterior wall. The proximal end of the mesh fits freely on the rectal surface; it is not fixed with special stitches (Fig. 5).

The distal edge of the mesh is fixed in the area of the lower corner of the wound to the muscular structures of the "perineal body", and then the vaginal mucosa is sutured with separate nodular sutures (Fig. 6).

The technique has several key features that distinguish it from the technique of installing the Prolift™ and Elevate™ mesh systems: firstly, the possibility of intraoperative cutting and modeling of a mesh implant of the required size, depending on the length of the rectocele; secondly, an important feature is the fixation of the "wings" of the implant to the non-displaced, strong structures of the pelvic floor under direct visual control,

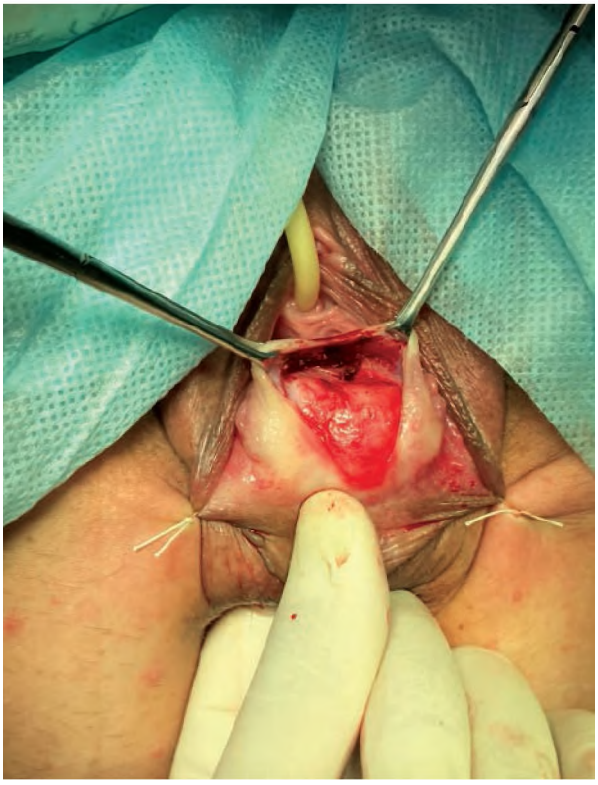

Figure 1. *Vaginal mucosa section. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

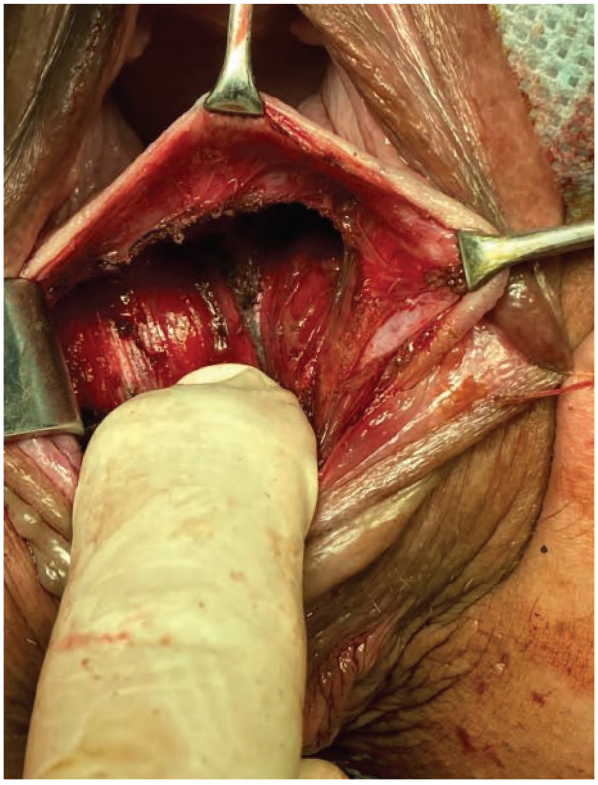

Figure 2. *Rectal anterior wall mobilization. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

without the use of special conductors. This prevents the development of such serious intraoperative complications as perforation, bleeding. Also, the direct intraoperative cutting out of the mesh implant in size allows to avoid tension between the 'wings' of the mesh, which makes it possible to freely fix the implant, which allows to prevent the development of long-term complications in the form of dyspareunia, pain syndrome. Thirdly, the implant is fixed to the strong structures of the pelvic floor — sacro-spinous ligaments, which is the prevention of implant displacement in the long-term postoperative period. An important advantage is the use of a lightweight partially absorbable Ultrapro™ mesh, which can also be a prevention of complications in the near and long-term postoperative period.

In the postoperative period, daily sanitation of the suture line in the vagina is carried out with antiseptic solutions, the patients observe bed rest for 2–3 days. In order to prevent infectious complications, antimicrobial therapy is prescribed to the patients for 5 days — metronidazole at a dosage of 500 mg 3 times a day. The urinary catheter removed on the 3d day; in order to regulate the stool, volume-forming laxatives based on psyllium are prescribed. After the surgery, the patients are limited to sitting down for 2 weeks. The postoperative hospital stay was 8 (5–14) days. Subsequently, during a follow up after 2–3 weeks, the sutures in the vagina removed.

RESULTS

When assessing the severity of the obstructive bowel movement syndrome symptoms before and after the surgery, it was revealed that 16/21 (76.2%) patients used manual vaginal assistance before the surgery, and after the surgery only 1 (4.8%) patient presented the need for periodic manual assistance. Before the surgery, all (21) patients had difficulty emptying the rectum. After the surgery, only 3 (14.3%) patients had periodic difficulty with the defecation act.

Before and after the surgery, the patients estimated approximately and subjectively the time required for emptying the rectum. The data on the comparative evaluation of this parameter are given in Table 1.

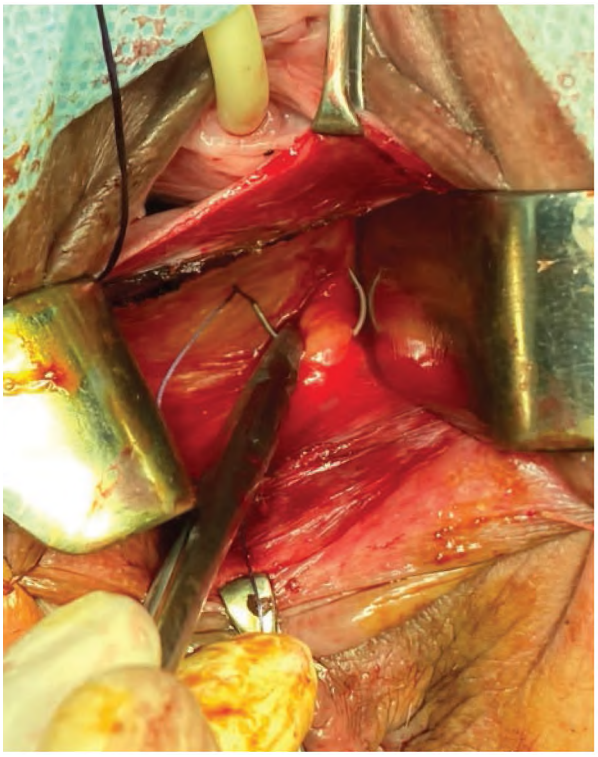

Figure 3. *Rectum right displacement. The sacrospinous ligaments saturation is performed. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

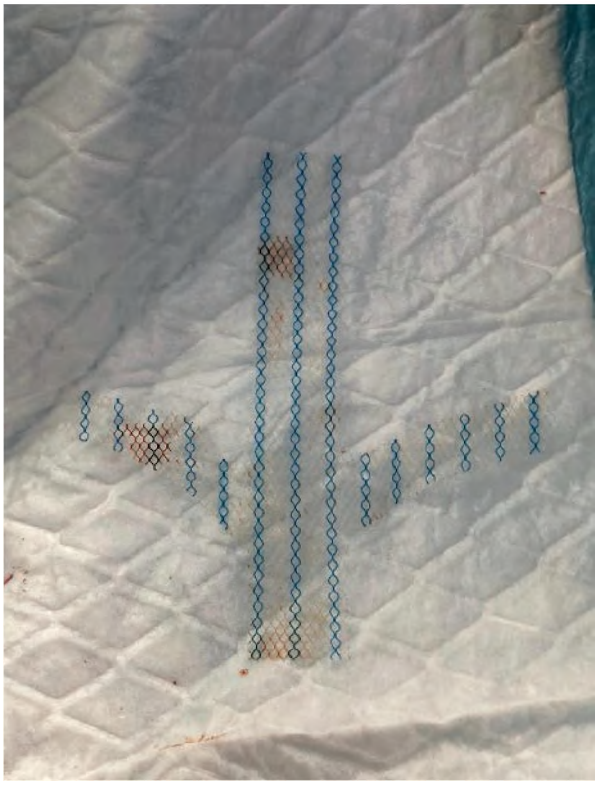

Figure 4. *Mesh implant's shape and size example. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

When evaluating the data, it can be seen that in 14 (66.7%) patient before the surgery, the duration of rectal emptying exceeded 5 minutes, but after the surgery only in 2 (9.5%) patients the time required for emptying the rectum was more than 5 minutes; the differences are statistically significant ($p < 0.05$). Before the surgery the periodic need for enemas or microclysms was noted by 8 (38.1%) patients; after the surgery 2 (9.5%) patients periodically continued to use microclysms.

In the postoperative period, early and late complications were evaluated. It should be noted that there were no serious complications that required surgery.

Among the early complications, 4 (19.0%) hematomas were detected in the area of the postoperative wound. In all cases, the hematoma was emptied by revision of the wound between the sutures in the vagina, followed by sanitation of the area of its location. In one case, due to the abundant discharge of hemorrhagic discharge, it was necessary to install silicone drainage between the seams.

Among the late postoperative complications, it is possible to note the extrusion of the distal edge of the mesh in 1 (4.8%) case, which was detected during a control examination in 6 months after the surgery. This section of the mesh with a length of up to 1 cm was excised during the examination; subsequently the wound was epithelized. In 1 (4.8%) patient 1 month after the surgery, pain of a pulling nature appeared in the groin area, which persisted during evaluation in 6, 12 and 24 months after the surgery; however, this complication did not require any special therapeutic measures.

Before and after the surgery, special questionnaires were used, which allow a comprehensive, dynamic assessment of the symptoms of rectocele and other manifestations of pelvic floor prolapse syndrome.

According to the results of the survey, it was found that on all three scales, in 6 months or more after the surgery, there was a decrease in scores by more than 2 times, while a comparison of the score level before and 6 months or more after the surgery showed pronounced statistically significant differences ($p < 0.0001$).

Before and after the surgery, defecography was performed, in which the following main indicators were evaluated: the direction vector of the fecal masses, the depth of the rectocele, the time of evacuation of the rectal contents, the residual volume.

When assessing the direction vector of fecal masses according to the defecography data

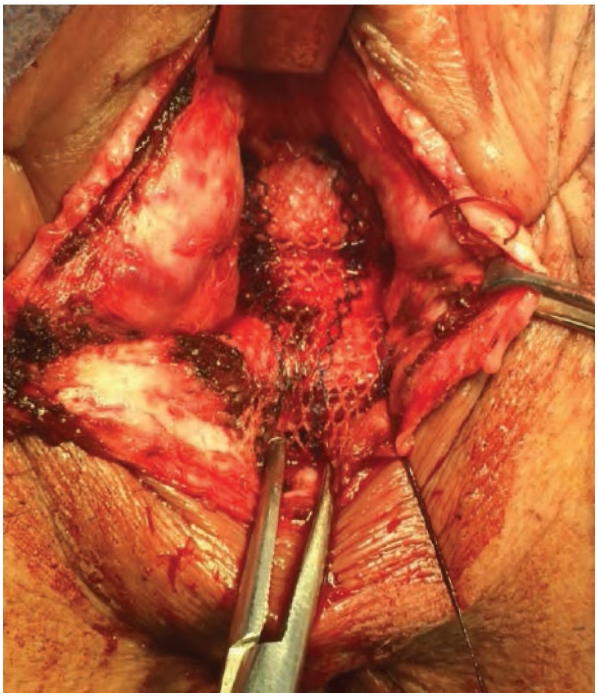

Figure 5. *The mesh implant is located in the rectum anterior wall. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

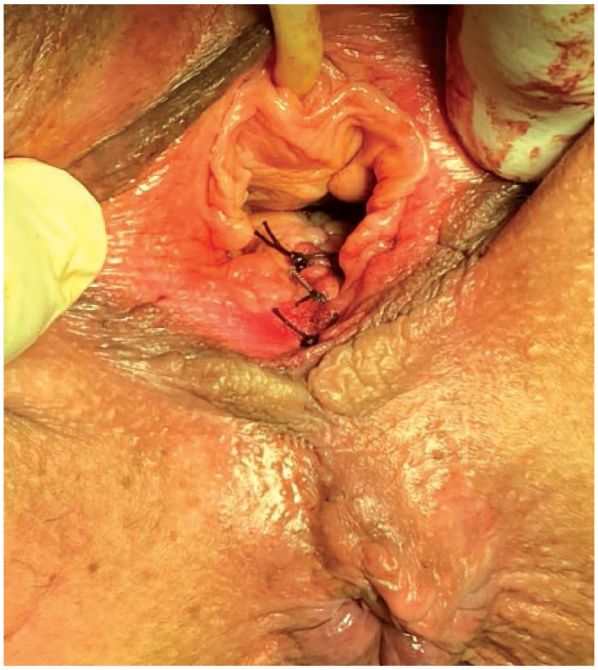

Figure 6. *Vaginal wound is sutured with separate sutures in the longitudinal direction. Patient T., 42 years old, diagnosis: 3rd grade rectocele*

Table 1. *Comparative evaluation of rectal emptying time before surgery and ≥ 6 months after surgery (N = 21)*

	Before surgery N (%)	6 months or more after surgery N (%)	p*
Time required for emptying the rectum (min.)	≤ 5 minutes: 7 (33.3%) > 5 minutes: 14 (66.7%)	≤ 5 minutes: 19 (90.5%) > 5 minutes:2 (9.5%)	< 0.05

*Note: * Fisher criterion*

Table 2. *Results obtained from patient questionnaires using rectal emptying dysfunction and constipation scores before surgery and ≥ 6 months after surgery (N = 21)*

Scale	Before surgery	6 months or more after surgery	p*
The system of point evaluation of violations of the evacuation function of the colon (NMRC of coloproctology named after A.N. Ryzhykh)	10 (6–16)	5 (1–8)	< 0.0001
PFDI-20**, Me (min-max)	101.1 (64.6–179.2)	48.9 (7.3–150)	< 0.0001
1) POPDI-6***	37.5 (8.3–66.7)	12.5 (0–54.2)	< 0.0001
2) CRAD-8****	34.4 (15.6–62.5)	15.6 (3.1–37.5)	< 0.0001
3) UDI-6*****	25 (8.3–79.2)	20.8 (0–83.3)	< 0.0001
Cleveland Constipation Scale (Wexner)	12 (5–19)	5 (1–9)	< 0.0001

*Note: * Wilcoxon criterion; ** Registry of pelvic floor disorders; *** Registry of disorders caused by pelvic organ prolapse; **** Registry of disorders of the lower gastrointestinal tract; *****Registry of urination disorders*

before the surgery, the vector was directed towards the rectocele in 11 (52.4%) patients, towards the anal canal as well as towards the anal canal and rectocele in 10 (47.6%) patients. After the surgery the fecal mass direction vector only towards the rectocele was not observed in any patient, while in all 21 (100%) patients the vector was directed into the anal canal or into the anal canal and rectocele; these differences are statistically significant ($p < 0.05$). When assessing such indicators of defecography before and after the surgery as rectocele depth, rectal contents evacuation time, and residual volume, a significant decrease in rectocele depth, rectal contents evacuation time (decreased by 1.5 times) and residual volume (decreased by 2.5 times) was revealed. It should be noted that all the results are statistically significant ($p < 0.02$ and $p < 0.0001$, respectively).

Prior to the surgery, all the patients underwent high-resolution manometry. As a result of this examination, 2 (9.5%) patients had functional defecation disorders in the form of dissenergy of the pelvic floor muscle function of the I type (puborectal loop spasm), and therefore they were prescribed physiotherapy in the form of BOS therapy. After a course of BOS therapy (9 sessions) during repeated examination, a manometric pattern of type III was revealed, indicating the dissynergic nature of defecation. Due to the persistence of the obstructive defecation symptoms, the patients underwent the surgery in the volume of plastic surgery of the rectovaginal septum with a W-shaped implant according to the above method. In 6 months or more after the surgery, all the patients underwent complex sphincterometry, according to the results of which during a straining test, no indirect signs of functional defecation disorders were detected in any observation, indicating an increase in pressure in the anal canal or the absence of its decrease by more than 20% of the value of the basal resting pressure.

Table 3. *Results of X-ray defecography in patients before surgery and ≥ 6 months after surgery (N = 21)*

Defecography data	Before surgery	6 months or more after surgery	*p*
The vector of orientation of fecal masses	In rectocele: 11 (52.4%)	In rectocele: 0 (0%)	< 0.05*
	In the rectocele and anal canal: 3 (14.3%) + In the anal canal: 7 (33.3%)	In the rectocele and anal canal: 4 (19%) + In the anal canal: 17 (81%)	
Rectocele depth (cm)	5.2 (3.8–8.8)	0 (0–4)	< 0.02**
Evacuation time, seconds. (the norm is up to 19 seconds.)	30 (10–45)	20 (10–45)	< 0.0001**
Residual volume, % (the norm is up to 20%)	25 (20–50)	10 (10–30)	< 0.0001**

*Note: * Fisher criterion; ** Wilcoxon criterion*

DISCUSSION

Despite the fact that today a large number of surgeries have been proposed to correct the rectocele, the issue of choosing a surgery technique remains relevant. The most common method of rectocele correction is plastic surgery with local tissues (anterior levatoroplasty).

However, the high incidence of symptoms recurrence in the long term limits the use of this technique. Stapler transanal rectal resection allows to eliminate the excess of the rectal mucous membrane with simultaneous strengthening of the rectovaginal septum. However, this surgery is effective in case of unstrained and unexpressed rectal protrusion, as well as in combination of rectocele with small internal rectal invagination and internal hemorrhoids. Currently, rectocolposacropexy is an actively used method. So, according to Abdelnaby, M. et al. (2020), who performed a comparative analysis of the results of treatment of anterior rectocele using 2 methods — laparoscopic rectosacropexy and posterior colporaphy, it was found that the both methods showed satisfactory results (anatomical correction of the rectocele, improvement of the rectal evacuation function, improvement of the quality of life according to questionnaires). However, the rectosacropesia technique had statistically significant advantages in assessing the anatomical effect of the surgery, defecography data, as well as the results of a questionnaire using the Cleveland Scale Constipation (Wexner) ($p < 0.0001$) [10]. Nevertheless, the invasiveness of this technique limits its wide application for the isolated rectocele correction. Systems for the installation of mesh implants such as Prolift™ and Elevate™ have high efficiency in the long-term postoperative period.

However, currently their use in a number of countries is limited due to the high frequency of early and long-term postoperative complications associated with the implant installation technique and the material from which the mesh is made. The methodology developed at the FSBI RNMRC of Coloproctology of the Health Ministry of Russia takes into account the shortcomings of the technique of installing foreign versions of mesh implants (Prolift™ and Elevate™) and allowed to avoid serious complications during the surgery and in the postoperative period. For the evaluation period of the treatment results, which was 6 months or more after the surgery, this technique showed good effectiveness evaluated using specialized questionnaires, and demonstrated the absence of serious complications in the postoperative period. The technique can take its place among surgeries for the anterior rectocele correction.

CONCLUSION

The results of using the method of rectovaginal septum plasty with a W-shaped mesh implant in

patients with rectocele of the 2nd-3rddegrees demonstrated good clinical efficacy when evaluated in 6 months or more after the surgery, confirmed by the results of the survey using specialized questionnaires, as well as the results of defecography. The use of the technique is not accompanied by the development of serious complications that require surgery, both in the early and in the long-term postoperative period. Nevertheless, for a more detailed assessment of the effectiveness of this technique, it is necessary to evaluate the treatment results in the long-term follow-up period (12 months or more after the surgery) on more clinical material.

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Concept and design of the study: *Ivan V. Kostarev, Anton S. Lukianov, Alexander Yu. Titov*
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