ST. PETERSBURG STATE UNIVERSITY

Printed as a manuscript

BELOUSOV
ALEKSANDR MIKHAILOVICH

"Prospects for the clinical application of anti-adhesive mesh endoprostheses in surgery of the anterior abdominal wall"

Scientific specialty 3.1.9. Surgery

Dissertation

for a Doctor Degree in Medical Science

Translation from Russian

Research advisor:
Doctor of Medical Sciences,
Professor Matveev N. L.

Saint Petersburg

2024

CONTENT

INTRODUCTION

The relevance of the research

Patients with primary ventral and postoperative abdominal wall hernias account for 20 to 30.7% of all patients with hernias. This group is in second place after patients with inguinal hernias. About 2 million operations are performed annually worldwide for ventral hernias [151]. They account for up to 25% of the total number of interventions performed in general surgery departments [229].

The problem of hernias of the anterior abdominal wall is socially significant. Hernias mainly affect patients of working age, the presence of hard work aggravates the course of the disease. The healthcare system also carries a heavy burden. The healthcare system spends significant resources on helping patients with abdominal hernias. For example, in the United States, the cost of inpatient treatment of postoperative hernia in 2011 amounted to $60989, which corresponds to $7.3 billion per year for the healthcare system as a whole [181].

Minimally traumatic, safe surgical treatment of hernias of any localization is of fundamental importance for solving this problem.

In recent years, a number of guidelines have been published indicating that the most widely used procedures for the treatment of abdominal wall hernias are laparoscopic intraperitoneal plastic surgery (LapIPOM) and open retromuscular mesh plastic surgery (Sublay). It has also been shown that there is a significant difference in the results of plastic surgery of primary ventral (umbilical, epigastric) and postoperative hernias, which makes it necessary to conduct separate studies for these nosologies [251, 317].

LapIPOM hernioplasty belongs to the category of low-traumatic and standardized techniques. It makes it possible to identify and eliminate not only the main hernial defect, but also other small fascial defects, the presence of which was not known before the operation [281]. In addition, when compared with traditional open hernioplasty, the operation gives an excellent cosmetic result.

As a rule, it does not take much time to perform the operation, since with intraabdominal installation of the prosthesis there is no need for extensive

mobilization of abdominal wall tissues. The absence of the need for complex dissection significantly reduces the learning curve. With IPOM, it accounts for about 20 surgical interventions, while with competing endovideosurgical retromuscular plastic surgery (eTEP), at least 50 [139].

When compared with traditional hernia treatment methods, laparoscopic hernioplasty IPOM can reduce postoperative pain, the number of wound and infectious complications, with a comparable recurrence rate [128, 116]. There are a number of publications indicating that the method reduces the risks of postoperative complications in elderly and senile patients [124].

Despite a number of undeniable advantages, the main "claim" to the IPOM technique remains the intra-abdominal arrangement of the mesh, which can provoke the formation of adhesions. At the end of the XX century, at the stage of the introduction of the technique, due to the imperfection of mesh endoprostheses, the frequency of visceroparietal adhesions was in some cases more than 50%, while in most cases there were no indications of clinically significant complications associated with adhesions [169]. As technologies for the production of composite mesh endoprostheses improved, the number of adhesions recorded after surgery decreased significantly [171].

A feature of modern implants used in IPOM is the presence of a visceral coating that mechanically prevents the adhesion of abdominal organs in the early postoperative period, followed by delayed mesothelization of the mesh. Such composite endoprostheses are difficult to manufacture and have a high cost, which significantly hinders the widespread use of the method.

All of the above determines the relevance of developing conceptually new approaches to intraperitoneal hernioplasty, as well as innovative endoprostheses with anti-adhesive properties that would have high efficiency but lower cost.

The purpose of the research

Improving the results and increasing the availability of modern hernioplasty technologies by developing an innovative anti-adhesive endoprosthesis for intraperitoneal implantation and its application technology.

Research tasks

1. To develop an innovative anti-adhesive endoprosthesis for intra-abdominal plastic surgery based on the pathophysiologically sound concept of early mesothelization.

2. To evaluate the safety profile of polyester mesh endoprostheses with fluoropolymer coating during intra-abdominal placement.

3. To study the biomechanical properties and biocompatibility of modern composite endoprostheses for intraperitoneal plastic surgery in a chronic experiment.

4. To investigate the features of the reparative process and the process of adhesion formation during intra-abdominal placement of mesh endoprostheses with anti-adhesive properties.

5. In the experiment, to compare the features of the formation of adhesions, as well as the tissue reaction to polyester mesh endoprostheses with a fluoropolymer coating and polyester mesh with an anti-adhesive collagen layer.

6. In the course of a chronic experiment, to identify the dependence of the formation of adhesions on the place of installation of an endoprosthesis with anti-adhesive properties in the abdominal cavity.

7. Based on a retrospective analysis, determine the optimal mesh endoprosthesis and fixation method for intra-abdominal plastic surgery.

8. To evaluate the results of clinical use of an anti-adhesive polyester mesh endoprosthesis with fluoropolymer coating in patients with hernias of the anterior abdominal wall.

9. To analyze the clinical and economic effectiveness of the use of anti-adhesive polyester mesh endoprostheses with fluoropolymer coating for intra-abdominal plastic surgery in patients with hernias of the anterior abdominal wall.

Scientific novelty of the research

Within the framework of the presented study, a pathophysiologically sound concept of early mesothelization of intraperitoneal hernioprosthesis was formulated. Based on this concept, the use of an innovative polyester endoprosthesis with a

photopolymer coating for intra-abdominal hernioplasty was proposed. As part of the presented study, anti-adhesive composite mesh endoprostheses were studied, their biomechanical properties and biocompatibility in intraperitoneal plastic surgery were studied, and the safety and effectiveness of IPOM surgery were confirmed. The analysis of the formation of the neoperitoneum depending on the design of the mesh endoprosthesis was performed. During this work, it was found that a polyester mesh endoprosthesis with a fluoropolymer coating has anti-adhesive properties, does not interfere with early mesothelization, while it does not cause pronounced inflammatory reaction and the formation of an excessive connective tissue capsule. The features of the adhesive process were revealed depending on the placement zone of the mesh implant. It was found that the presence of a non-absorbable anti-adhesive layer in composite endoprostheses is associated with severe perifocal inflammation and a high risk of developing peritrosthetic infection. A retrospective analysis of large-volume clinical material was carried out, which made it possible to identify the optimal model and characteristics among the available anti-adhesive implants. The results of adhesive fixation of a mesh endoprosthesis in iromplasty were studied for the first time. A prospective clinical study has demonstrated the safety, clinical and clinical cost-effectiveness of using polyester endoprostheses with fluoropolymer coating for IPOM plastic surgery in patients with anterior abdominal wall hernias.

Practical significance of the study

In the course of the work carried out, the presence of anti-adhesive properties of a polyester endoprosthesis with a fluoropolymer coating was established, which allows it to be used for intraperitoneal plastic surgery in patients with ventral hernias. As part of the study, an innovative leaky endoprosthesis for IPOM plastics made of polyester with a fluoropolymer coating with anti-adhesive properties was improved and studied and introduced into clinical practice for use in patients with ventral hernias. Based on a retrospective analysis, the effect of the anti-adhesive layer on the results of treatment of patients after intraperitoneal hernioplasty was evaluated. The effect of the method of fixation of the mesh endoprosthesis on the results of hernioplasty has been studied.

Approbation of the dissertation results and implementation in practice

The materials of the dissertation were reported and discussed on the territory of the Russian Federation: Conference of Surgeons of the Moscow region "Achievements and prospects for the development of surgery in the Moscow region", Vidnoye, November 10, 2022; XIV Congress of Surgeons of Russia, Moscow, November 25-27, 2022; 49th session of the Central Research Institute of Gastroenterology, Moscow, March 2-4, 2023; VI All-RussianThe 2nd Congress of Herniologists, St. Petersburg, June 09-10, 2023; The first multidisciplinary herniological congress "Beyond the formality", Moscow, September 22-23, 2023; Meeting of the N.I. Pirogov Society of Surgeons, Moscow St. Petersburg, February 14, 2024; International Scientific and Practical Conference "New Technologies in the new world", Moscow, March 21-22, 2024; Interregional conference "Continuity is the key to success in surgery", Saransk, 06/27/2024.

Publications

11 articles have been published on the topic of the dissertation in publications from the list recommended by the Higher Attestation Commission.

Personal contribution of the author

The author personally conducted the following elements of the dissertation research: planning, organization and conduct of all stages of the chronic experiment, data collection and processing. The introduction of a polyester mesh endoprosthesis with a fluoropolymer coating into clinical practice and the implementation of intra-abdominal plastic with its application. Creating a database and performing statistical processing of the results obtained.

The structure and scope of the dissertation

The dissertation consists of an introduction, a literature review, a description of the material and research methods, research results and their analysis, conclusions, conclusions, practical recommendations, a list of references, and an appendix. The dissertation is presented on 310 pages of typewritten text, illustrated with 67 tables and 118 figures. The bibliographic index includes 383 works, of which 114 are domestic and 269 are foreign publications.

Main scientific results

1. Formation and study of the concept of early mesothelization of mesh endoprostheses in intra-abdominal placement. Chapter 3, section 3.2.1.6.; Chapter 6. Page 225, 233; [19] (personal contribution of the author of at least 80%)

2. The study of the process of adhesion formation in a chronic experiment. Chapter 3. section 3.2.1.3; Chapter 3. Page 103; Chapter 6. Page 238; [11, 18] (personal contribution of the author of at least 80%)

3. The dependence of the formation of adhesions on the place of installation of the endoprosthesis. Chapter 3. Page 113; Chapter 6. 225 [8] (author's personal contribution of at least 80%)

4. The effect of the fixation method affects the retraction of the endoprosthesis and the formation of adhesions. Chapter 3. Page 113; Chapter 6. 236 [8,9] (personal contribution of the author of at least 80%)

5. To study the effect of a type of composite endoprosthesis with an anti-adhesive layer on the clinical results of IPOM plastic surgery. Chapter 4, section 4.1.; Chapter 6. 246 [71, 72] (personal contribution of the author of at least 80%)

6. Ultrasound technique based on the assessment of the sliding of the parietal and visceral peritoneum in the area of implant localization allows to assess the adhesive process. Chapter 2. 89; Chapter 6. 250 [7, 10] (author's personal contribution of at least 80%)

7. Evaluation of the clinical efficacy of anti-adhesive polyester endoprostheses with fluoropolymer coating. Chapter 5, 191; Chapter 6, Page 251 [20] (personal contribution of the author of at least 80%)

8. Study of the impact of the cost of consumables on the introduction of high-tech innovative techniques into everyday surgical practice. Chapter 1. Page 43 [74] (author's personal contribution of at least 80%)

Provisions to be defended

1. Polyester endoprostheses with a fluoropolymer coating have structural and physical properties that ensure the optimal and physiological course of the interaction of synthetic material and surrounding tissue.

2. Mesh endoprostheses with a fluoropolymer coating have an appropriate safety profile and have a biological inertia, which allows them to be used for intra-abdominal plastic surgery.

3. Modern composite endoprostheses used for intra-abdominal plastic surgery have a fundamental difference in the type of anti-adhesive coating, which, in turn, has a major impact on the repair process.

4. During intra-abdominal stirring of anti-adhesive endoprostheses, the main influence on the reparative process is provided by the preservation of the base peritoneum and the structure of the implant.

5. Polyester mesh endoprostheses with a fluoropolymer coating and polyester mesh with an anti-adhesive collagen layer equally lead to the formation of a moderate adhesive process.

6. The location of the composite mesh endoprosthesis in the upper floors of the abdominal cavity is associated with a more pronounced adhesive process due to possible contact with parenchymal organs.

7. The most favorable results of intra-abdominal plastic surgery in patients with ventral hernias are observed when using composite endoprostheses with a absorbable anti-adhesive coating. The type of fixators does not have a significant impact on the result of the operation.

8. The results of operations using an anti-adhesive polyester mesh endoprosthesis with a fluoropolymer coating for intra-abdominal plastics are comparable to those using similar implants.

9. The cost of surgery using composite anti-adhesive endoprostheses is mainly influenced by the price of consumables. The use of fluoropolymer-coated meshes for this type of intervention makes it possible to improve clinical and economic efficiency.

Chapter 1. HISTORICAL BACKGROUND AND CURRENT STATE OF THE PROBLEM OF TREATMENT OF ANTERIOR ABDOMINAL WALL HERNIAS (LITERATURE REVIEW)

1.1. Evolution of principles of surgical treatment of ventral hernias. Intraperitoneal plastic surgery as a result of technological development of surgery

1.1.1. The relevance of the problem of ventral hernias

Medical significance

Patients with ventral abdominal wall hernias account for 20 to 30.7% of the total number of patients with hernias [46;23;95;34;244;27]. This group is in second place after the group with inguinal hernias.

About 2 million operations are performed annually worldwide for ventral hernias [151]. They account for up to 25% of the total number of interventions performed in general surgery departments [229]. In Germany, the number of operations for ventral hernias reaches 50 thousand per year [153], and in the USA – up to 400 thousand per year [312]. In the UK, about 10 thousand surgical interventions are performed annually only for postoperative hernias [115].

In recent decades, the frequency of postoperative ventral hernias has increased by more than 9 times. Such explosive growth is associated with an increase in the number of surgical interventions on abdominal organs, including in cancer patients and elderly and senile patients [41314; 244:345;28]. If we transfer the indicators of the number of operations to the general population, then every 3-5 inhabitants of the planet has a risk of postoperative hernia [107;202].

Socio-economic significance

The socio-economic significance of the problem of ventral hernias arises from an understanding of the structure of the cohort of patients. The majority of patients belong to the most able-bodied age group. In addition to temporary disability associated with the manifestations of the disease itself, patients need a certain period of time for preoperative examination, hospital stay and rehabilitation in the postoperative period [62]. Often, a period exceeding 30 days is required only for

surgery and recovery in the postoperative period [96]. This has a significant impact on professional activity [22; 176334;13].

The frequency of complications and relapses

An equally important problem in the treatment of ventral hernias is the frequency of complications in the early and long-term postoperative period. So in the work of T.Bisgaard et al. In the examination of more than 3,000 patients operated on for ventral hernias, complications requiring repeated hospitalization were detected in 5.3% of cases [150]. Complications related to the postoperative wound, such as hematoma, seroma and suppuration, were observed in 46% of cases. Severe pain syndrome was observed in 7% of cases. Up to 4.1% of complications occur in the first month of the postoperative period, and the postoperative mortality is 0.1%.

The ratio of nosologies of complications of the postoperative period after the introduction of prosthetic hernioplasty methods underwent some correction. This is due to the fact that a number of prostheses, especially at the initial stage of the implementation of the technique, had insufficient biological compatibility. As a result, the frequency of complications such as chronic seroma and suppuration of the surgical wound tended to increase [40;24;32;249;43].

The number of recurrences in the treatment of ventral hernias, even with the use of a mesh implant, reaches 34.5%, and overweight patients are more susceptible to them [164; 373; 106]. The indicator depends not only on the method of performing the operation and the unfavorable course of the early postoperative period. The frequency of hernia recurrence tends to increase depending on the time since the operation was performed. Thus, according to a randomized study conducted by J. Burger et al., it was found that the recurrence rate of hernia after local tissue repair after 3 years was 43%, and after 10 years it increased to 63% [160].

The elimination of complications and relapses significantly increases the final cost of treatment. The use of traditional operations ultimately turns out to be less profitable. So according to D. Davila et al. inpatient treatment of patients after classical access surgery is 14,520 US dollars, while after laparoscopic surgery it is 12,649 US dollars [181].

1.1.2. Stages of development of herniology and modern principles of treatment of ventral hernias

The first mention of hernia as a nosology can be found in ancient Egyptian papyri dated to about 1500 BC. Later mentions of hernias are found in the writings of Hippocrates, dated to the IV century BC. Roman scientist Aulus Cornelius Celsus (Latin Aulus Cornelius Celsus) in the I century AD. in his work "About medicine" defined hernia as the protrusion of the viscera through acquired or congenital "gates" and for the first time used the term "hernios". He also proposed one of the first methods of differential diagnosis of strangulated hernia and dropsy of the testicular membranes – scrotal diaphanoscopy. Despite the fact that hernia treatment was carried out earlier, there is a reliable indication of surgical intervention in the writings of Claudius Galenus (Latin Galenus), dated to the II century AD. He suggested using the reduction of hernial protrusion and stitching of the edges of the hernial defect as a treatment [82; 202]. Later, threads made of gold, silver, bronze, tin, and copper were used to close the hernial gates, tinctures of iodine, seawater, and concentrated alcohol were injected into the area of the hernial gates, and prolonged bed rest was recommended. Despite the long history of its existence, until the 19th century, hernia surgeries essentially had no pathophysiological justification, were crippling and often ended in death [23].

Herniology received a rebirth at the turn of the XIX and XX centuries after the introduction of pain relief methods into practice. The scientific basis for the surgical treatment of inguinal hernia by the method of tension plasty was laid by the Italian surgeon E. Bassini, who performed the first hernioplasty in 1884 and described the results of his work in 1887 [374]. The classical technique proposed by Bassini has been repeatedly modified in the future. Such famous surgeons as A. Moschkowitz, C. McVay, W. Halsted offered their modifications of the operation. For a long time, the method proposed in 1890 by P. Postempski, in which the inguinal canal was eliminated and the spermatic cord was moved into the subcutaneous tissue, was no less popular than the Bassini method [311].

Russian surgeons have also published a number of scientific papers on the local plastic closure of hernial defects in the inguinal and femoral zones. In 1900, A.N. Prokunin published his dissertation work "On the anatomy and root treatment of femoral hernia", in 1911 A.P. Krymov published the manual "The Doctrine of hernias" [88; 64]. An active discussion of the problem of hernia treatment in Russia is associated with the congress of surgeons in 1908, at which N.F. Bogoyavlensky, I.P. Aleksinsky, N.I. Napalkov and O.A. Yutsevich made reports on the problem [37; 52].

With the introduction of aseptic and antiseptic methods, the problem of infectious complications and postoperative mortality has been solved to a greater extent. The high recurrence rate of the disease came out on top. After applying classical techniques, their frequency reached 12 – 42.5% and only in specialized centers fell below 10% [118; 91].

Since the middle of the XX century, due to good long-term results, the operation proposed by E. Shouldice, in which the recurrence rate in the author's version was less than 1%, has been recognized as the "gold standard" in the treatment of inguinal hernias [341]. However, further studies have shown that the widespread use of the method does not allow such results to be achieved. Relapses are much more common and range from 6 to 15,5% [122; 370; 65].

The next stage in the development of herniology began in the mid-50s of the last century and was associated with the name F. Usher. In 1959, he proposed a technique for non-tensioning hernioplasty of inguinal and ventral hernias using polypropylene plates as an alloplastic material [316]. Attempts to use various alloplastic materials have been made before, but their results were unsatisfactory due to poor biological compatibility of prostheses [70].

In 1965, J. Rives, using a polypropylene Marlex endoprosthesis, for the first time placed it in the preperitoneal space from the inguinal access, which reduced the recurrence rate to 1.3% [323]. Somewhat later, in 1973, R. Stoppa reported on the use of the preperitoneal space for the installation of a prosthesis in the treatment of inguinal hernias [351]. The main idea was the location of the mesh between the

peritoneum and the transverse fascia, which partially allowed it to be fixed due to intra-abdominal pressure, that is, to use a mechanism that leads to the formation of a hernia. Despite the good results, preperitoneal plastic surgery has not been widely used for a long time.

The "gold standard" of a non-protracted method of inguinal hernia treatment has long been the technique proposed by I. Lichtenstein in 1986 [267]. The author strengthened the posterior wall of the inguinal canal with an implant, placing it between the muscles and the aponeurosis of the external oblique abdominal muscle. The technique made it possible to achieve a relapse-free course of the long-term postoperative period in more than 1000 patients. The widespread introduction of the technique slightly increased the recurrence rate, but it did not exceed 1.5% [330].

The introduction of endoscopic technologies in the treatment of hernias began in the 80s of the last century. In 1982, R. Ger reported on the successful treatment of patients using a prototype of a modern herniostepler [211]. In the treatment of inguinal hernias, the author used an open peritoneal access and restored the internal inguinal ring with stainless steel clips, while a laparoscope was used in one of the patients during the operation.

In 1992, M. Arregui et al. For the first time, a transabdominal preperitoneal plastic surgery (TAPP) of an inguinal hernia using a large implant was reported [126]. At the same time, J. Dulucq [194], J. McKernan and H. Laws [280], E. Phillips et al. [304] used endovideosurgical preperitoneal access (TEP).

The methods of treatment of ventral hernias have developed in parallel with the methods of treatment of hernias of inguinal localization. The main difficulty for a long time was the lack of clear classifications that did not allow patients to be divided into homogeneous groups. As with inguinal hernias, at the first stages, tension methods were used to eliminate the hernial defect by reducing aponeurotic and muscular tissues. In some cases, this led to a significant increase in intra-abdominal pressure, which resulted in both a large number of relapses and significantly increased postoperative mortality due to the development of respiratory failure.

Even at the beginning of the 20th century, attempts were made to use a fragment of one's own fascia to hide a herniated defect (McArtur, 1901; M. Kirschner, 1923; Le Mesurier, 1924), rectus abdominis muscle (Mattson, 1946), and a skin graft (Gossec, 1949) [215]. Most of these methods were not widely used.

The active development of methods for the treatment of ventral hernias, as well as inguinal hernias, is associated with the work of F. Usher, J. Rives and R. Stoppa [323; 351; 316]. The use of inert alloplastic materials and the use of preperitoneal cellular spaces for their placement made it possible to partially solve the problem of intraperitoneal hypertension that occurs during the plastic surgery of large postoperative hernias.

However, the use of mesh prostheses in some cases did not allow to achieve good results, since during prosthetics it was impossible to isolate them from the abdominal organs. The solution to the problem of tissue tension was the use of separation plastic methods, the first of which was proposed by O. Ramires in 1990. In the classical version, this type of plastic surgery made it possible to achieve medialization of the rectus muscles at a distance of 3 to 10 cm on each side and close the defect of aponeurosis to 20 cm [314; 340]. The method also had disadvantages, for example, due to the destruction of part of the neurovascular bundles, the number of complications such as necrosis of the skin flap increased [29; 42]. Another disadvantage was the appearance of the so-called "frog belly" in patients, which occurs due to relaxation of the lateral abdominal muscles [30].

In 2008, A. Carbonell et al. proposed a retromuscular variant of separation plastic surgery, which created a space for the implant between the internal oblique and transverse muscle [163]. The method made it possible to obtain a significant supply of tissues and place the implant in a physiologically advantageous space, but led to denervation of the rectus muscles due to damage to the neurovascular bundles passing through the dissection zone [161].

In 2012, Y. Novitsky proposed a modification of the separation plastic called TAR (transversus abdominis muscle release) [300]. Dissection was performed between the transverse muscle and the transverse fascia, which allowed, in addition

to obtaining a favorable space for the location of the prosthesis, to create a significant supply of tissues and preserve neurovascular bundles. If the fixation of the endoprosthesis was carried out at the first stages, then later it was possible to completely abandon the fixation without loss of quality of long-term results. When compared with the O. Ramires operation, the rear separation plastic in modification Y. Novitsky led to fewer relapses and postoperative complications [255; 182]. At the moment, this technique, including in the endoscopic (eTEP-TAR) version, is the operation of choice in the treatment of complex hernias with domain loss [303; 300].

The next stage in the development of retromuscular and preperitoneal hernioplasty is associated with the development of endosurgical extraperitoneal access (eTEP) [139]. The technique made it possible to reduce surgical trauma and, as a result, the number of intraoperative and postoperative complications, but significantly increased the time of the operation itself [159].

The technique of intraperitoneal plastic surgery with a Marlex endoprosthesis was first proposed by J.D. McCarthy in 1981 [278]. The author identified only 2 relapses in a group of 25 patients. Later, in 1993, K. LeBlanc published the results of laparoscopic hernia treatment using a similar technique [261]. The proposed operation became the basis of the modern IPOM methodology. Its advantages, even with traditional access, were the relative ease of implementation, short operation time and good long-term results with a recurrence rate from 3.7 to 6,4% [223; 230; 133].

The improvement of methods for the treatment of ventral hernias is happening faster every year. However, despite the accumulated experience, the search for new effective methods of abdominal wall restoration continues [12; 34; 139].

1.1.3. Intraperitoneal plastic surgery as the most optimal option for surgical treatment of small and medium-sized ventral hernias

The results of hernia surgery largely depend on the position of the endoprosthesis in the tissues of the abdominal wall. The implant can be located in the following positions [293]:

1. Onlay – on the border between subcutaneous tissue and muscle-aponeurotic structures of the abdominal wall;

2. Inlay – at the level of the hernial defect with fixation to its edges;

3. Retromuscular (Sublay) – with median hernias behind the fibers of the rectus abdominis muscle in front of its posterior leaf;

4. Retromuscular – with lateral hernias between the muscles of the side walls of the abdomen;

5. Preperitoneal – between the muscular-aponeurotic structures of the abdominal wall and the peritoneum;

6. Intraperitoneal (IPOM) – under all layers of the abdominal wall, including the peritoneum (in the abdominal cavity).

Due to the relative ease of implementation, the Onlay technique was most widely used at the first stages of the development of prosthetic hernioplasty [296]. Over time, it became clear that the technique is not optimal, as it is accompanied by a fairly high frequency of wound complications and gives relapses in 5.0 – 25% of cases [186; 143; 358; 227; 350]. The Inlay technique is not recommended for use, since, in addition to the disadvantages of Onlay plastics, it causes a significantly higher number of relapses [266].

Compared to previous techniques, retromuscular plastic surgery leads to a much lower incidence of relapses and complications. The recurrence rate in Sublay plastic surgery ranges from 10.7 to 16% [186; 227]. The reason for this is precisely the location of the implant, in which there is uniform pressure on all its departments and additional support due to the abdominal wall muscles [226]. All this contributes to a much better integration of the prosthesis [201].

If preperitoneal plastic surgery in the laparoscopic version is the most pathogenetically justified and technically feasible treatment method for inguinal hernias, then indications for it are limited for median ventral hernias. Due to the difficulties in separating the peritoneal flap, the operation becomes difficult to reproduce, and in thin patients it simply cannot be performed [136; 380].

In this case, the use of intraperitoneal hernioplasty seems to be the most optimal. It has all the advantages of the previous operation, has a shorter execution time, but requires the use of endoprostheses with an anti-adhesive coating [272; 301; 345]. For a long time, IPOM hernioplasty was used in the laparoscopic "interposition" version, when the hernial gate was not sutured [371]. In some cases, this caused the formation of seromas and the occurrence of so-called pseudo-relapses, as well as increased the number of relapses. The introduction of the IPOM Plus technique, in which a hernial defect is pre-sutured, made it possible to reduce the number of these negative points [297; 227; 355].

IPOM hernioplasty belongs to the category of low-traumatic and standardized techniques. It makes it possible to identify and eliminate not only the main hernial defect, but also other small fascial defects, the presence of which was not known before the operation [71]. When compared with traditional open hernioplasty, IPOM surgery gives an excellent cosmetic result [285].

As a rule, a large amount of time is not spent on the operation, since with intraabdominal placement of the prosthesis there is no need for extensive mobilization of abdominal wall tissues. It is enough to prepare a "platform" for installing a mesh for the section of mobilization of the round ligament of the liver and umbilical ligament, as well as to excise the hernial sac. On average, it takes 44 to 155 minutes [313]. As a rule, the technique surpasses Sublay hernioplasty in this indicator [132; 196]. However, a number of publications note that the time of traditional operations and IPOM hernioplasty is practically the same [116]. Similar results are more often observed in works where a separate assessment of the results of treatment of primary and postoperative hernias is not carried out.

The absence of the need for complex dissection significantly reduces the learning curve. With IPOM, it amounts to about 20 surgical interventions, while with eTEP it is at least 50 [222; 72].

Extensive interventions on the abdominal wall are one of the predictors of the development of postoperative complications from a postoperative wound [142;231]. The minimum number of manipulations with IPOM leads to a decrease in their

number [140; 285; 144]. When evaluating the treatment results of 9907 patients with postoperative hernias from 2009 to 2016 registered in the Herniamed registry, the incidence of postoperative complications was significantly lower with IPOM hernioplasty than with Sublay (3.4% vs. 10.5%; p <0.001) [251]. In the same study, the frequency of repeated operations associated with complications in Sublay was more than 3 times higher (4.7% vs. 1.5% in IPOM; p <0.001).

When compared with traditional plastic surgery techniques, laparoscopic hernioplasty IPOM can reduce both postoperative pain [286], the number of wound and infectious complications [331; 116], and the frequency of relapses [144]. There are a number of publications indicating that the method reduces the risks of postoperative complications in elderly and senile patients [100; 220; 44].

According to a number of authors, the recurrence rate in IPOM plastic surgery from traditional and laparoscopic access is the lowest among all methods of treatment of ventral hernias and ranges from 1.4 to 6,4% [223; 160; 205; 207; 230; 326; 133; 187]. Their opponents, on the contrary, point out that the recurrence rate is approximately on the same level as Sublay hernioplasty [381; 116; 251]. It should be noted that a high recurrence rate is noted at the stages of mastering the technique. For example, in one of the studies, the recurrence rate from 1993 to 1995 was 20%, and from 1996 to 1998 – 10% [129]. The use of the IPOM Plus technique allows to reduce the number of recurrences, in which it is possible to use the technique even with large defects up to 168 cm^2 [361].

The average period of hospitalization of patients after IPOM hernioplasty ranges from 1.3 to 2.9 days [263; 205]. When compared with Sublay hernioplasty, the patient's rehabilitation period is significantly shorter [286; 331].

Despite the fact that the cost of consumables for performing IPOM is quite high, reducing the length of hospital stay, fewer complications and rapid rehabilitation gives the technique an advantage when compared with traditional methods of treatment [140; 154]. The cost-effectiveness of the operation is confirmed by a study by R. Fernández Lobato et al., the results of which showed a

reduction in costs by 1,260 euros compared with traditional intervention (2,865 versus 4,125 euros) [203].

The higher final cost of treatment for traditional operations largely depends on the cost of treating complications and relapses. An analysis of the Premier Alliance patient database for the period from 2009 to 2014 showed that the total cost of inpatient treatment of patients with recurrent hernia was higher in the group of traditional interventions compared with the group in which laparoscopy was performed (US$14,520 versus US$ 12,649; p = 0.045) [180].

1.1.4. Disadvantages of intraperitoneal plastic surgery that require the search for modern technological solutions

Complications

Evaluation of the results of treatment of patients with postoperative hernias registered in the Herniamed registry showed a significantly higher incidence of intraoperative complications in IPOM than in Sublay (2.3% vs. 1.3%; p <0.001) [251]. The authors point out that bleeding and intestinal damage were more common. Other authors also point to the high frequency of such complications [381; 128]. In a number of studies, intraoperative complications reach 13.3% of cases [160].

Enterotomy

One of the arguments hindering the implementation of the technique for a long time has been such an indicator as the frequency of iatrogenic enterotomies [319]. According to A. Sharma, during the performance of 2,346 laparoscopic hernioplasty from 1994 to 2011, 33 cases of iatrogenic enterotomy with 2 deaths were noted [339]. The average figure is 1.78% [71]. In part, the higher frequency of such intraoperative complications may be associated with entry into the abdominal cavity and the need to perform adhesiolysis [331]. Enterotomies are practically not found in the cohort of patients with primary hernias. In a number of studies, this indicator is very close to the indicator for Sublay surgery (0.79% vs. 0.52%, respectively). In some cases, such complications are associated with a violation of the technique of surgical intervention or arose at the stage of mastering the technique [362; 71].

Systematic reviews and meta-analyses of recent years indicate the absence of significant differences in this indicator [125].

Seroma

The incidence of seroma in IPOM hernioplasty ranges from 0 to 17,4% [132; 231; 212]. They occur in about half of all complications [205]. This indicator in a number of studies turns out to be slightly higher than in other interventions. For example, when comparing the results in groups of patients after IPAM hernioplasty and intracorporeal aponeurotic plastic surgery, the incidence of seromas 1 month after surgery was 17% and 11.1%, respectively [212]. This percentage is even higher when using polytetrafluoroethylene endoprostheses, which create a closed, non-drainable space between the surface of the peritoneum and the implant [289]. As a rule, seromas resolve on their own and do not require any conservative or surgical interventions.

Late complications

Despite the fact that cases of such serious complications as mesh migration or intestinal fistulas are rare, their treatment can be quite a difficult and expensive task. The implant can lead to the appearance of an external fistula [272] or move entirely into the lumen of the intestine, causing intestinal obstruction [233].

Relapses

The recurrence rate in IPOM plastic surgery increases with a hernial defect size of more than 10 cm, and therefore the use of the technique for such hernias is not recommended [153; 154; 152]. The risk of recurrence is increased by repeated intervention [307]. The recurrence rate decreases with an increase in the overlap of the defect with the grid. According to K. LeBlanc et al., this reduces the recurrence rate from 9 to 4% [262].

Pain syndrome

A comparative study of the results of IPOM and vTAPP showed that both at rest and during movement, the pain syndrome was significantly more pronounced with the first method ($p = 0.008$ at rest, $p = 0.023$ during movement) [281]. The same is noted when comparing pain after IPOM and transabdominal retromuscular plastic

surgery performed in a robotic version [173]. In this study, the need to use TAP block or epidural analgesia for analgesia occurred much more often with IPOM plastic surgery (43.7% vs. 3.7%; P = 0.002). Recent studies comparing IPOM Plus and TAPP also show that by the time of 1 month, the pain syndrome between the groups of operated patients no longer has significant differences [124].

Comparing the pain parameters during IPOM surgery with other methods of treatment of ventral hernias also turns out to be not in favor of the first method. For example, this is clearly shown by a study conducted by W. Reinpold et al., in which the technique was compared with Sublay hernioplasty from minimally invasive access (MILOS) [319].

The severity of chronic pain syndrome depends on the etiology of the hernia. After 6 months, its frequency is higher in postoperative hernias – 5.6%, lower in primary hernias – 2.7% [71]. The severity of the pain syndrome is also associated with the use of stapler fixators and transfascial sutures in IPOM [223; 158]. Adhesive fixation, recently used in IPOM hernioplasty, significantly reduces the severity of pain syndrome, however, in some cases it gives a greater number of relapses [170; 307].

Consequences of implant contact with abdominal organs

Concerns about the long-term results of placing mesh endoprostheses in the abdominal cavity have been expressed since the beginning of the application of the technique. As an argument, opponents cite isolated cases of complications such as intestinal obstruction, bedsores or intestinal fistulas [259; 276; 371; 366].

Indeed, spikes in IPOM are more common than in other surgical methods [210; 208]. However, some modern works devoted to the MRI diagnosis of adhesions provide data indicating the same number of them with IPOM and Sublay [245]. There is also an indication in a number of publications that adhesions with an implant are asymptomatic [372].

It is no secret that spikes complicate repeated operations [127; 357]. The structure of the implant has the greatest influence on their formation. Maximum adhesion is caused by non-composite prostheses made of polypropylene and

polyester [216; 234; 210; 26; 70]. At the moment, these materials are used only as the basis of a composite prosthesis.

Initially, polytetrafluoroethylene implants were proposed, which did not cause adhesions, but did not integrate into the abdominal wall, often encapsulated and caused periprosthetic infection [209]. Subsequently, due to the creation of a composite prosthesis having a microporous and macroporous layer, the severity of encapsulations was reduced, but the frequency of adhesions with hollow organs reached up to 18% [372]. A number of studies devoted to the study of composite meshes with an anti-adhesive non-absorbable layer have shown satisfactory results [276; 301], while others have unsatisfactory results comparable to polypropylene implants [208].

Composite endoprostheses with a resorbable anti-adhesive layer are the most in demand. When using implants coated with oxidized reduced cellulose, adhesions occur in 10-95% of cases [308; 197; 334; 378]. When using implants with a collagen coating, the frequency of detection of adhesions is lower and ranges from 8.3 to 52.9% [279; 169]. Endoprostheses coated with sodium hyaluronate and carboxymethylcellulose also significantly reduce, but do not prevent, adhesions. In terms of anti-adhesive properties, in some cases they surpass prostheses coated with collagen and polytetrafluoroethylene [344; 209].

A number of other authors also, based on isolated cases of clinically significant complications, associate similar problems with viscero-parietal adhesions in the implant fixation zones [147; 322]. Also, adhesions are more often localized in the area of the edges of the implant [170].

Limitations of the use of the technique related to the size of the defect

Unfortunately, IPOM plastic surgery without hernia gate suturing in the laparoscopic version is not applicable for large abdominal wall defects [353]. A study by M. Toffolo Pasquini et al. It was shown that the recurrence rate after IPOM hernioplasty with a defect size of less than 80 cm2 is 13%, while with large sizes it is 24% [361]. The same study showed that when using the IPOM Plus technique, this difference is significantly reduced. A later study by the same authors showed

that the optimal size of the hernial defect with the IPOM technique should be no more than 63 cm^2, while with IPOM Plus it can already reach 168 cm^2, which significantly expands the indications for the use of the method [360].

The cost of the operation

From the point of view of economic efficiency, the IPOM technique in most cases loses to other endosurgical treatment methods. For example, when comparing the cost of consumables for surgery for median ventral hernias, the latter for IPOM was 742.57 ± 128.44 euros, while for TAPP it was 34.37 ± 4.0 euros ($p = 0.001$) [281]. However, it is worth considering that the main cost part is the price of a composite mesh endoprosthesis and a device for fixing it.

1.2. Modern composite implants. The body's reaction to a foreign body as the main cause of adverse reactions and complications in IPOM

1.2.1. Endoprostheses and their main characteristics

Currently, more than 200 types of surgical meshes are produced, most of which are not suitable for performing IPOM hernioplasty [4]. In this case, composite endoprostheses are used, in most cases having a protective anti-adhesive layer. The mesh base of most composite endoprostheses consists of polypropylene or polyethylene terephthalate. The composite layer can be both biodegradable and non-biodegradable [5]. The first includes oxidized reduced cellulose, collagen, a combination of sodium hyaluronate with carboxymethylcellulose and a number of others, the second – polytetrafluoroethylene. Also, implants may not be composite and consist of only one material, such as polyvinylidene fluoride.

In 1959, F. Usher, together with colleagues, conducted an experiment in which fragments from various polymers such as polypropylene, nylon, dacron, Teflon and a number of others were placed in the abdominal cavity of dogs. The results of their use were evaluated by the severity of the inflammatory reaction, the amount of exudate and adhesions in the area of each sample. The experiment showed that the least pronounced inflammation is observed when using polypropylene and Teflon [70].

According to V.A. Zhukovsky [54], endoprostheses are divided according to:

• chemical composition (polypropylene, polyvinylidene fluoride, polyethylene terephthalate, polytetrafluoroethylene);

• material consumption (ultralight, light, medium light, heavy, superheavy);

• destruction index (absorbable, partially absorbable, non-absorbable, combined);

• * structure (mesh, basally knitted, film-porous);

• the structure of the filaments (monofilament, polyfilament);

• pore size (microporous, macroporous);

• structures (flat, three-dimensional).

Polypropylene endoprostheses are most widely used in the treatment of abdominal wall hernias. They have high biocompatibility, strength and are resistant to infection [112; 28]. However, the use of such prostheses in IPOM hernioplasty is not recommended, as they lead to a pronounced adhesive process with internal organs.

Endoprostheses made of polyethylene terephthalate (polyester) are also widely used, which are structurally softer than an implant made of polytetrafluoroethylene. Despite good integration into tissues, such implants are more susceptible to infection and also provoke an adhesive process in contact with abdominal organs [17; 181]. Applying a protective fluoropolymer coating to polyester makes it possible to neutralize these negative effects, however, it leads to an increase in the cost of products [284].

Polytetrafluoroethylene endoprostheses are used much less frequently, as they are poorly integrated into tissues, encapsulated, and eventually often undergo pronounced retraction [309]. Polyvinylidene fluoride is more promising, surpassing polypropylene in terms of biocompatibility and elasticity, having the same parameters of strength and resistance to infection. However, a number of authors express the opinion that the material causes a lesser inflammatory reaction, which negatively affects the strength of the formed scar [145; 60].

The main characteristics of endoprostheses

One of the main characteristics of the endoprosthesis is the material consumption. This concept refers to the amount of polymer mass per unit area (g/m^2). A decrease in this indicator leads to a decrease in the amount of foreign material. Therefore, in modern herniology, the creation of lightweight grids has become one of the main trends [37; 23; 111]. Currently, mesh prostheses are divided into superheavy (100 g/m^2 or more), heavy (70-100 g/m^2), medium–light (50-70 g/m^2), light (25-50 g/m^2) and ultralight (> 10 g/m^2) [187].

Reducing the material consumption of implants makes it possible to reduce both the pain syndrome and the frequency of wound complications [27; 348]. Reducing the amount of polymer, in turn, leads to a decrease in the strength of the prosthesis and the stability of its structure [78; 90; 28; 38]. The introduction of lightweight meshes, in some cases reinforced with threads of higher density or the use of absorbable fibers in their composition, makes it possible to find a golden mean [80; 49]. Unfortunately, the use of light or absorbable nets increases the recurrence rate to 8 – 10% [4; 47; 383]. This is due to the low strength of the material and the hypoplastic reaction in the implantation zone, which disrupts the formation of the connective tissue capsule [63; 77; 104].

Another important characteristic of implants is their structurality. According to this parameter, implants are divided into mono- and multifilament implants. As a rule, meshes consisting of a single strand turn out to be more rigid and skeletal, while multifilament meshes are softer and have greater congruence with the surface in the implantation zone. The latter property is preferable, however, multifilament meshes have a larger surface area than monofilament meshes, which increases the risk of infectious complications [239].

The size of the prosthesis pores is also important. The small size of the pores in some cases limits cell migration, in this case even a light microporous endoprosthesis may have less biological compatibility than a heavy macroporous one [246; 375]. At the end of the last century, P. Amid proposed a classification of endoprostheses depending on the size of the pores [119].

Prostheses with a pore size of more than 75 microns (macroporous prostheses) were classified as type I. When using them, there were favorable conditions for the migration of macrophages and fibroblasts, the germination of collagen fibers and blood vessels, which significantly accelerated the integration of the prosthesis. At the same time, these properties contributed to the appearance of pronounced adhesions when the implant came into contact with internal organs. Another significant disadvantage was pronounced retraction, which in some cases led to a relapse of the disease [174; 272].

Implants with a pore size of less than 10 microns in at least one of the 3 planes were classified as type II. The main problem of such prostheses is their encapsulation, associated with a weak proliferative reaction and lack of connective tissue germination [49].

Type III included macroporous implants with the presence of multifilament or microporous components. With good integration, endoprostheses of this type increase the risk of wound infection due to a larger surface [238].

Prostheses with submicron pore size were classified as type IV. They have unsatisfactory indicators of integration into tissues, but practically do not cause adhesions. It was precisely such prostheses that were the precursors of composite prostheses for intraperitoneal hernioplasty.

In addition to good integration characteristics on the one hand and minimal risks of adhesions with internal organs on the other, endoprostheses should also have the necessary physical properties. First of all, this concerns the mechanical strength, which depends on the structure and composition of the material [55]. Based on the indicators of maximum intra-abdominal pressure with an average abdominal diameter of 32 cm, the force applied to the abdominal wall is about 16 N/cm [60; 35; 113]. Thus, the minimum breaking load of the endoprosthesis for small hernias should be at least 16 N/cm, and for large ones – at least 32 N/cm [58; 35; 41; 83].

1.2.2. Problems of biological compatibility of the basis of composite endoprostheses and their anti-adhesive coating

The effectiveness of surgical treatment of ventral hernias depends on the correct choice of the volume and type of surgical intervention, the quality of the materials used and the level of surgical technique [155]. With regard to the well-standardized intraperitoneal plastic surgery IPOM, the issue of the quality of the consumables used comes first. First of all, these are composite endoprostheses and fixation devices.

The main properties of composite implants are biocompatibility and resistance (stability, stability). On the one hand, the material should be inert, integrate well into tissues and not have carcinogenic properties, on the other hand, it should be moderately elastic and durable [70; 53]. Combining all these characteristics is quite a difficult task. At this point in time, this task has not been resolved.

The biological compatibility of endoprostheses depends on the body's reaction to their presence in tissues, that is, on the reaction to a foreign body. Difficulties in the development of composite prostheses lie in the fact that they are located on the border of tissues with different properties. On the one hand, they interact with the muscular-aponeurotic framework of the abdominal wall, while requiring good integration into the tissues. On the other hand, with tissues of the abdominal cavity organs, which differ in a softer structure. If inflammation, due to more pronounced scarring, to a certain extent favors the insertion of the prosthesis into the abdominal wall, then inflammation can also lead to more pronounced adhesions with the organs of the abdominal cavity.

It is also necessary to take into account the fact that the mesh implant is present in the body throughout life and the severity of chronic inflammation can also vary along with the reactivity of the body. The granuloma formed in response to the finding of the mesh, which is a cluster of giant cells resulting from the death of monocytes and macrophages [134], is characterized by increased cellular activity even after a considerable time after implantation [250].

The body's reaction to the prolonged presence of a foreign body has not been fully studied [84; 90; 25]. The very concept of biocompatibility is precisely a characteristic of the body's response to the presence of a foreign body. The main manifestation is chronic inflammation with the formation of scar tissue, and the course of the regeneration process differs from the classical one [237; 120; 84; 48]. At the first stage, the body reacts to injury and only later to a foreign body. This allows us to conclude about a smoother course of the process with a decrease in the volume of surgical trauma [55; 14].

At the time of the operation, an alteration phase occurs, during which the release of biologically active peptides occurs, the source of which are neutrophils, macrophages, eosinophils, mast cells, basophils and platelets [57; 58]. The change in vascular permeability in the second phase of inflammation is accompanied by the release of the liquid part of the blood from the intracellular and intercellular space, migration to the focus of inflammation of leukocytes and the process of phagocytosis [79; 59; 68; 73; 31]. Due to changes occurring in the vascular endothelium, proteins are released into the tissues, leading to an increase in oncotic pressure and even more fluid entering the inflammatory zone [120; 348; 55; 85; 101]. Neutrophils, monocytes and lymphocytes migrating to the focus consistently affect microorganisms, fragments of foreign bodies, and destroyed cells of the body [94; 31]. These mechanisms lead to wound cleansing within a few days [94; 237].

During the proliferation phase, the number of stromal cells increases, and fibrin formed from fibrinogen thickens and fixes the endoprosthesis [94; 68]. Due to the release of collagenase by fibroblasts, which is responsible for the synthesis of collagen structures, granulation tissue with collagen filaments is formed around the implant [76; 62; 69]. The germination of granulation tissue between the pores of the endoprosthesis, the compaction of collagen filaments and the replacement of fibrin with connective tissue fibers eventually leads to the formation of mature connective tissue [94; 68; 67]. It forms a connective tissue capsule with a thickness of 50 to 200 microns around the implant [363; 76; 110].

In some cases, the processes of transition from one phase of inflammation to another are sharply slowed down or remain incomplete, that is, they turn into sluggish chronic inflammation. It is possible to explain the occurrence of such changes from a pathophysiological point of view due to the interaction of the immune system with free radicals present on the surface of the endoprosthesis, triggering the process of lipid peroxidation [99; 51]. In response to the installation of the endoprosthesis, activation of the humoral link of immunity is noted, the level of cytokines, acute phase proteins of inflammation and immunoglobulins increases [166; 36; 247]. Prolonged circulation of these proinflammatory mediators causes damage to biological structures, activation of peroxide and immunopathological processes [81].

A number of researchers note that in response to implantation, a rejection-type reaction occurs, as evidenced by signs of pronounced granulomatous inflammation and the proliferation of scar tissue around the prosthesis, which tends to encapsulate it [89; 102]. In some cases, these processes are the cause of unsatisfactory results of intraperitoneal hernioplasty [247].

The body's reaction to a foreign body after implantation of composite prostheses can occur in the form of such phenomena as local inflammation, infection, severe fibrosis, and adhesions. Complications of these processes may include wrinkling or dislocation of the mesh with the development of recurrence or penetration into surrounding tissues [282; 130], intestinal obstruction [141; 223], formation of intestinal fistulas [302]. The causes of pathological reactions can be both the mechanical and chemical structure of the implant base or the anti-adhesive layer [237; 120].

Retraction and dislocation of the implant

Retraction and dislocation of the prosthesis are quite often the causes of hernia recurrence [2; 282; 130]. The rate of reparative processes in the area of a tighter fit of the implant along the edge of the mesh is higher than in its center. At the same time, the cells on the periphery expand more often, and their size decreases in the center, which provokes the process of its retraction [109]. The causes of

endoprosthesis deformation can be different [66]. There is evidence of mesh retraction with an increase in the level of interleukin I and a decrease in the level of type I collagen, as well as the ratio of collagens I and III [356]. To date, there is no consensus on the factors triggering this process. Among the possible causes, uneven and excessively tight fixation of the prosthesis is noted [98]. Also, wrinkling and deformation of the implant in some cases are the result of periprosthetic infection, leading to severe scarring [16].

Any endoprostheses are more or less susceptible to deformation and retraction processes. For example, some authors claim that after 4 weeks, polypropylene nets can decrease in size by 30-50% of the original [105; 81]. In part, the process of retraction and dislocation of prostheses containing polypropylene in the base may be associated with an increase in the stiffness of polypropylene fibers over time [15]. At the same time, in the presence of a composite coating of sodium hyaluronate or collagen, the retraction process is less [236].

Unlike polypropylene, polyvinylidene fluoride does not contain plasticizers and stabilizers, as a result of which it does not undergo hydrolysis and remains in a stable state for a much longer time [364]. The material causes a significantly lower cellular reaction compared to polypropylene [246].

Endoprostheses with polytetrafluoroethylene in their composition are most susceptible to retraction. The material undergoes encapsulation, which in the long term leads to a significant, sometimes twofold decrease in the implant area [338].

Acute and chronic seroma

The increase in serom frequency was directly related to the introduction of prosthetic hernioplasty [240]. The largest number of them is observed when the implant is located in the Onlay and Inlay positions [87; 254; 21]. At the same time, the main reason for their formation is a significant area of damage to the subcutaneous tissue and its contact with the implant [61; 97; 172; 288; 108]. To a certain extent, the formation of seromas can also be influenced by other implantable material, for example, various fixators used to hold the implant in the required position [329]. Another factor contributing to the formation of seromas during IPOM

hernioplasty is the appearance of a closed non-drainable space, which is especially characteristic of polytetrafluoroethylene endoprostheses [75].

Periprosthetic infection

Composite endoprostheses with polyester in the base are most susceptible to infection [367]. Due to the small size of the pores that prevent phagocyte migration, the material has significantly lower resistance to infection compared to polypropylene [17]. Polyvinylidene fluoride, like polypropylene, has a sufficiently high biological inertia and is resistant to infection [93]. Also, in conditions of infection, removal of biological prostheses is not required [209].

Spike formation

The main causes of adhesions in IPOM, as in other surgical interventions, are ischemia and inflammation resulting from invasion and the presence of a foreign body [217]. These processes reduce the fibrinolytic activity of the peritoneum, as a result of which the fibrin formed between the organs and the implant is not destroyed, but participates in the formation of adhesions [221].

In addition, other common factors such as age [188], gender [264], obesity [268], diabetes [214], and elevated cholesterol levels [117] can influence the processes of adhesion formation. Another group is surgical factors such as the type and duration of the intervention [188], the use of irrigation [325] and a number of others [265].

Effective reduction of adhesions is the most important characteristic of a modern endoprosthesis for IPOM hernioplasty. The most pronounced adhesion formation is observed when using materials that integrate well into the abdominal wall, such as polypropylene and polyester [216; 27]. One of the reasons for the formation of adhesions when using polypropylene is persistent inflammation caused by myeloid cells [225]. Attempts to separate the polypropylene implant from other abdominal organs with an omentum do not prevent the appearance of adhesions with hollow organs [205]. At the moment, polypropylene is used only as the basis of a composite prosthesis [70].

The use of bioabsorbable implants such as Vicryl Mesh for intraperitoneal hernioplasty also proved to be ineffective. Despite the fact that a number of early studies noted a more than twofold decrease in adhesion formation compared to polypropylene prostheses [210], subsequent studies failed to confirm the results. The main cause of adhesions is a chronic inflammatory process, the duration of which is determined by the period of degradation of the material [365].

Polytetrafluoroethylene implants did not cause adhesions, but they also did not integrate into the abdominal wall, encapsulated, and decreased in size, which led to the formation of hernia recurrence [210]. Subsequent modernization of the implants made it possible to reduce the scale of the problem. This was achieved by creating two layers – a microporous anti-adhesive and a porous one for better integration into the abdominal wall tissues and implemented in a Dual Mesh prosthesis. Despite the presence of an anti-adhesive coating, the frequency of detection of adhesions in a number of studies reaches 83% [252; 372], up to 99.9% [208], and the incidence of adhesions with hollow organs is up to 18% [372]. A number of studies have shown much better results, up to the complete absence of adhesions [276; 301]. At the same time, such implants are less effective in preventing adhesion compared to composite implants with a bioabsorbable protective layer [234, 208].

The most advanced in terms of adhesion formation are composite implants with a biodegradable coating. Such a coating can be oxidized reduced cellulose (OVC), collagen, a combination of sodium hyaluronate with carboxymethyl cellulose, and a number of others [5]. The main task of the anti-adhesive layer of a composite prosthesis is the temporary separation of the implant base from the abdominal organs. During the period from 5 to 8 days, the parietal peritoneum is restored and there is no need to further protect the structural basis of the implant [123; 5].

The deep mechanisms of the anti-adhesive effect of the protective layer of composite implants have not been practically studied. At this point in time, researchers are following the path of simply selecting the most effective

components. In this regard, the question arises of creating a unified scheme for evaluating the anti-adhesive effectiveness of the prosthesis [243].

The only OVC-coated implant is the Proceed prosthesis, which has a polypropylene and polydioxanone base. In early experimental studies, the incidence of adhesion when using it is about 10% [301]. However, more recent experimental and clinical studies give much larger numbers – from 29 to 95% [308; 197; 334; 378]. The authors attribute higher adhesion figures to the impregnation of the SHEEP layer with blood, which significantly reduces the adhesive properties.

The inclusion of an anti-adhesive coating made of collagen in the implant structure provides an advantage in the prevention of adhesion formation compared to both traditional prostheses made of polypropylene and composite prostheses with an anti-adhesive layer made of polytetrafluoroethylene and OVC. The detection of signs of adhesion ranges from 8.3 to 52.9%, and in most patients there are only loose clinically insignificant adhesions. The positive effect may be associated with the thickness of the resulting peritoneum, since this indicator is higher when using implants with a collagen coating [279; 169; 324].

The coating of implants, including sodium hyaluronate and carboxymethylcellulose (commercial name Sepra), allows to obtain results comparable to the coating of collagen and significantly better when compared with prostheses made of polypropylene [147]. A systematic review and meta-analysis evaluating data from 9 experimental studies comparing the results obtained using Sepra-coated prostheses and polypropylene implants showed a decrease in the degree of adhesion formation by more than 2.5 times [270]. In a number of studies, the coating surpasses collagen and polytetrafluoroethylene in terms of anti-adhesive properties [344; 210]. Since, according to a number of authors, adhesion formation is significantly influenced not only by the structure of the material, but also by the shape of the implant and the condition of its edges [372], one of the mechanisms of the anti-adhesive effect is the flow of the components of the Sepra coating, which increase in volume upon contact with liquid, fixators, uneven edges or folds formed on the surface of the implant [156].

Fistulas

The formation of intestinal fistulas and fistulas is most often associated with the physical properties of the prosthesis, primarily with its density. As a result of contact of the dense edges of the implant, damage to the intestinal wall occurs with the development of chronic inflammation, which ultimately leads to perforation [165]. Inadequate fixation of the endoprosthesis or its retraction also contribute to the migration of the mesh [177]. Cases of finding part or even the entire mesh in the small intestine or colon have been described [302; 233]. Fortunately, such cases are rare.

Relapses

As a rule, the recurrence rate in IPOM hernioplasty increases with an increase in the size of the hernial gate. Most authors recommend using the technique with a transverse defect size of no more than 8 cm [71]. For patients with herniated defects of greater width, who have lateralization of the rectus muscles, performing IPOM-plasty is not recommended. The results of a study of prognostic factors that increase the risk of recurrence showed that the presence of a postoperative hernia (15%), a BMI of more than 35 (21%), a defect width of more than 4 cm (27%), a defect area of more than 20 cm^2 (27%), mesh overlap of less than 5 cm (32%), the ratio of the mesh area to the defect area is less than 12 (48%) [219]. Multidimensional analysis showed that only the last factor was the only independent one. With a ratio of less than 8, the recurrence rate was 70%, from 9 to 12 – 35%, from 13 to 16 – 9%, more than 17 – 0% ($p < 0.001$).

In addition to these reasons, incorrect fixation and retraction of the endoprosthesis often leads to relapses [305; 304; 49; 141]. The refusal to use bioabsorbable implants in IPOM hernioplasty is also primarily associated with relapses that occur in almost all patients [209; 365].

1.2.3. Mechanisms of development of adverse events associated with the option of fixation of a composite endoprosthesis

There are few studies evaluating the effect of fixation on the results of IPOM hernioplasty. In this regard, it is premature to draw unambiguous conclusions about

the advantages of a particular method. Much attention has been paid to the effect of fixation type on postoperative pain and the number of relapses [223; 345; 167; 9]. At the same time, clinical studies on the effect of fixators on adhesion formation are rare [379; 232]. For example, a systematic review conducted by V.P. Armashov et al., evaluating studies examining the effect of the fixation method on spike formation, showed that only 3 experimental studies out of 22 have a low risk of systematic error, and there are no evidence-based clinical studies on this problem [6]. The difficulties of evaluation are also partly due to the presence of various fixation methods (suture, stapler, adhesive, etc.), a wide variety of designs of the clamps themselves and the materials from which they are made.

Transfascial sutures

Non-absorbable stapler fixators and transfascial sutures are most often used to fix the endoprosthesis to the abdominal wall [131; 345; 171]. The latter greatly facilitate the positioning of the prosthesis, moreover, complete rejection of them leads to a more pronounced retraction of the latter [296; 135]. The advantage of transaponeurotic sutures is the high strength of fixation. In the work of M. van't Riet et al. It is noted that the fixation strength when using them is 2.5 times higher than when using stapler staples [367].

The main disadvantage of transfascial sutures is the pain syndrome in the areas of their localization, which occurs due to the stitching of a significant array of tissues. The incidence of postoperative pain ranges from 1 to 3% of cases [223; 158; 131; 345] and in most patients it is stopped during the first 2 months. The use of a limited number of sutures in combination with other fixation methods allows to reduce the severity of pain [321; 187; 171].

It is impossible to reliably judge the recurrence rate with the isolated use of transfascial sutures, since such a technique was used only at an early stage of the introduction of IPOM hernioplasty. Some authors claim that their use does not reduce the number of relapses [347]. It is interesting to note that transfascial ligatures can lead to the occurrence of such a rather rare type of recurrence as a "suture" hernia ("suture" hernia), which forms at the sites of transfascial sutures [295; 9]. The causes

of such hernias are damage by sutures to the muscular-aponeurotic structures of the abdominal wall or the endoprosthesis itself, as well as excessive tension [263; 352]. Another unfavorable moment that occurs when using transfascial sutures is local ischemia associated with their excessive tightening and leading to the appearance of local tissue necrosis, which, in turn, slows down the integration of the implant and provokes the formation of adhesions [328].

According to a number of authors, adhesion formation does not differ when comparing the results of isolated use of transfascial sutures and titanium fixators [335; 168], while others – transfascial sutures have an advantage [242; 228]. One of the works indicated that absorbable transfascial ligatures are also better than titanium spirals in terms of adhesion formation parameters [334]. The causes of adhesions when using transfascial sutures are ischemia [261; 328] and bleeding occurring in the area of their application [379].

Non-absorbable stapler clamps

The number of recurrences in the use of titanium spiral fixators corresponds to the general recurrence rate in IPOM hernioplasty, as they are used in most clinical studies. Unlike fixation with biodegradable staples or glue, metal clamps continue to hold the implant in its original position throughout the patient's life. The migration of fixators may partly influence the number of relapses [6]. The number of migrated fixators can range from 12.5 to 50% [256; 334]. It should be said that there are isolated publications describing cases of intestinal obstruction associated with the migration of non-absorbable fixators. P.A. Yartsev et al. A clinical case of acute intestinal obstruction is described due to the migration of fixators and their introduction into the wall of the small intestine [114].

As with the use of transfascial sutures, metal spirals in some cases lead to recurrent pain syndrome, which is the main reason for the search for alternative fixation methods [331; 321]. The main pathogenetic cause of pain syndrome is the contact of fixators with nerve endings in the tissues of the abdominal wall [198]. The number of fixators can increase the severity of pain, as well as adhesions, while reducing their number can lead to relapse [333; 167].

In most experimental studies, the severity of adhesive adhesions when using non–absorbable fixators does not differ from the isolated use of transfascial sutures [235; 257], in isolated cases they have an advantage [256]. The addition of transfascial sutures to titanium fixation either does not affect adhesion formation [175] or enhances it. Also, a number of authors have not identified a difference between non-absorbable fixatives and fixatives made of polylactic acid [162; 241]. However, there are works where non-absorbable fixatives lead to increased adhesion formation [283], this is especially noticeable when compared with fibrin glue [335].

The adhesion formation is also influenced by the design of the retainer. Thus, according to K. LeBlanc et al., Q-shaped rings cause less adhesion formation than titanium spirals [260]. Also, fewer adhesions are formed when using spiral fixators coated with a polyesterephyrketone head [274]. Some authors claim that adhesion formation is more influenced by the shape of the retainer than the material from which they are made [372].

Absorbable stapler clamps

A number of studies indicate that absorbable fixatives increase the risk of recurrence [307]. The results of one of the latest systematic reviews comparing implant fixation methods for primary and postoperative hernias, including evaluating the results of IPOM plastic surgery, did not reveal a difference in the recurrence rate when using absorbable and non-absorbable fixators [275]. At the same time, to work [in the review? Only 2 studies involving 101 patients were included, which indicates an extremely small number of such studies. The same review indicated that due to the low reliability of the evidence, it is impossible to judge the difference in the recurrence rate when using non-absorbable and absorbable stapler fixators, non-absorbable and absorbable threads. From a pathophysiological point of view, a slightly higher recurrence rate can be explained by a decrease in the strength of mechanical fixation after their resorption [168].

Absorbable fixers often do not show differences in the parameters of adhesion formation with titanium fixers. In one of the works, absorbable fixators led to less formation of adhesions [228], and in 2 more works – to a greater one [168; 241].

These parameters often do not differ when compared with other fixation methods [193; 321; 241]. Recent authors associate a higher frequency of adhesions with a longer inflammatory process when using them.

Suture fixation

The use of intracorporeal sutures allows you to perform good fixation and reduce pain in the postoperative period. Pain reduction is due to the absence of stitching of all layers of the abdominal wall. At the same time, the presence of suture threads can be considered as additional factors provoking adhesions. This may be due to their direct contact with the abdominal organs and their traumatization [147; 322]. For example, in an experimental study by M.L.P. Biondo-Simões et al. more adhesions were formed with the use of polyglactin 910 than with the use of catgut [148].

Another disadvantage of intracorporeal suture fixation is a significant lengthening of the operation time [329]. As for spike formation, such studies are isolated and do not allow us to draw any unambiguous conclusions. More often, the number of adhesions when using non-absorbable and absorbable sutures does not differ [235; 334].

Adhesive fixation

The active introduction of adhesive fixation during IPOM surgery was facilitated by the presence of a sufficiently pronounced pain syndrome in the early postoperative period [178]. Despite the fact that fixation with fibrin glue reduces the severity of pain syndrome and adhesions, however, it gives a greater number of relapses [170; 151]. This is due to the fact that the specified adhesive does not allow for satisfactory fixation to the peritoneum [199].

An increase in their frequency when using any type of adhesive is more associated with migration and retraction of the implant [175]. Also, a number of types of glue, such as latex or "Sulfacrylate", cause more pronounced scar fibrosis [86].

However, not all authors agree with the position of inefficiency of adhesive fixation. Thus, according to S. Harsløf et al., using cyanoacrylate glue, non-

absorbable and absorbable fixators in 75 patients with ventral hernias showed no differences in the severity of postoperative pain, quality of life and the number of relapses [218].

The severity of adhesion formation when using glue depends on its chemical composition. The adhesive process is least pronounced when using fibrin glue [168], slightly more so when using cyanoacrylates [191]. There are works in which the simple application of fibrin glue to the surface of the peritoneum did not lead to any adhesions. More pronounced adhesion formation when using cyanoacrylate glue is associated with a more intense inflammatory reaction [257], and in some cases, with its contact with the peritoneum covering the nearby abdominal organs [320].

1.3. Clinical and economic efficiency of laparoscopic interventions for ventral hernias

Endoscopic access in the treatment of hernias of the anterior abdominal wall in any of its variants provides a number of undeniable advantages. These are improved visualization, small size of postoperative wounds, minimal pain severity and reduced risk of infectious complications [144; 116; 251; 74]. However, with the introduction of modern technologies, the cost of the operation itself and the total cost of hernia treatment significantly increases. So, the survey conducted by N.L. Matveev et al., showed that 55% of surgeons performing inguinal hernia interventions from traditional approaches justify their position by the significant high cost of mini-invasive techniques [74]. When assessing the position on postoperative hernias, the figures were even higher – 58%.

IPOM hernioplasty is the most technologically advanced and, as a result, the most expensive of all modern herniological operations. To perform it, in addition to endovideosurgical equipment, expensive disposable consumables are also needed, in particular composite implants and herniators. In a number of regions, the costs of its implementation are higher than the rates of compulsory medical insurance for the treatment of certain hernia variants. This leads to a restriction or complete shutdown of the purchase of such consumables, which affects the number of operations performed using this technique and in some cases leads to an increase in the number

of complications due to the loss of surgical skills by surgeons. Limiting the number or exclusion of endovideosurgical operations from the list of performed operations ultimately leads to an increase not only in the number of complications, the number of which is higher with traditional approaches, but also to lengthening the duration of treatment and rehabilitation of patients [381].

In a study conducted by V. Shubinets et al., the burden on hospitals associated with the treatment of postoperative hernias in the United States was studied [342]. Analyzing national databases of inpatient patient samples from 2007 to 2011, the authors determined annual cost indicators related to the treatment of postoperative hernias, hospitalization and serious adverse events. The number of completed cases of inpatient treatment with a diagnosis of "postoperative hernia" over these years amounted to 583,054, while 81.1% of patients underwent hernioplasty. The authors noted that the number of hospitalizations of patients with this nosology increased by 12% from 2007 to 2011 ($p = 0.009$), and the number of hernioplasty by 10% ($p < 0.001$). At the same time, the index of concomitant diseases increased from 3.0 to 3.5 ($p < 0.001$) and the frequency of serious adverse events increased from 13.5% to 17.7% ($p < 0.001$), which led to a disproportionate increase in treatment costs by 37% ($p < 0.001$). The study clearly showed that cost reduction is impossible without the prevention of postoperative hernias, one of the ways of which is the introduction of endovideosurgical techniques.

Assessment of the economic burden in the treatment of recurrent ventral hernia in the work of D. Davila et al. It has shown that the cost of treatment after laparoscopic surgery is lower than after open surgery [181]. The authors used data from the Premier Alliance database from 2009 to 2014. When analyzing the results of treatment of 1077 patients with a total recurrence rate of 3.78%, it was found that the cost of surgery using traditional access is $ 21,726, and laparoscopic surgery is $19484 ($p < 0.0001$). When using laparoscopy, costs did not increase, even when the severity of pathology during repeated hospitalization according to the Charlson comorbidity index was higher (0.92 vs. 1.06; $p = 0.0092$).

A retrospective study conducted by B. Ecker et al. based on the evaluation of the results of treatment of 13,567 patients with ventral hernia using the open and laparoscopic method, it was shown that laparoscopy was accompanied by a lower frequency of repeated operations (OR 0.29; CI 0.12 – 0.58; p = 0.001), wound discrepancies (OR 0.35; CI 0.16 – 0.78; p = 0.01), wound infectious complications (OR 0.50; DI 0.25 – 0.70; p <0.001), the need for blood transfusion (OR 0.47; DI 0.36 – 0.61; p <0.001), acute respiratory distress syndrome (OR 0.74; DI 0.54 – 0.99; p <0.05), a significant decrease in the number of repeated hospitalizations (OR 0.81; CI 0.75 – 0.88; p <0.001) [189]. The total cost of treatment, taking into account the treatment of complications, when followed for 1 year with laparoscopic interventions was lower (12881 ± 13254 dollars versus 14468 ± 19702 dollars, p <0.001).

A study by R.F. Lobato and co-authors conducted in a cohort of 140 patients with ventral hernias and also comparing the cost of open and laparoscopic interventions showed that laparoscopy reduces the number of postoperative complications and mortality (p <0.001), and also ultimately turns out to be cheaper (2865 euros versus 4125 euros) [271].

If there are a sufficient number of publications on the cost-effectiveness of laparoscopic treatment of ventral hernias in comparison with traditional methods, then publications justifying the cost-effectiveness of IPOM in comparison with other endovideosurgical techniques are very rare. One of them, conducted by a group of authors led by A. Moreno-Egea, showed that the cost of treatment of spigelial hernia is lower when using IPOM than eTEP (1260 vs. 2200 euros, p <0.001) [290]. Fixation in both cases was carried out using stapler staples using the "double crown" technique or a combination of staples and n-hexyl-α-cyanoacrylate, and the difference in cost arose due to the use of a dissector balloon during eTEP.

Despite the lower cost of consumables for eTEP, it can be assumed that the total cost of treatment can be comparable to the IPOM method, since a more extensive dissection and duration of surgery increases the risks of complications and,

accordingly, re-hospitalization. Unfortunately, there are no evidence-based comparative studies of the cost of the methods.

1.4. The main ways to solve the problems of biological compatibility of endoprostheses and fixators, prevention of relapses and pain syndrome, options for optimizing economic costs during IPOM surgery

The main problems that arise after IPOM hernioplasty are postoperative viscero-parietal adhesions and pain syndrome. The first problem is usually related to the structure of the implant, the second is related to the fixation method used.

Postoperative adhesions have a large number of etiological factors. These include mechanical, thermal, and chemical effects on serous integuments, ischemia of organs and tissues of the abdominal cavity, resulting from exposure to vascular structures. In IPOM hernioplasty, in addition to these factors, the effect of a foreign body – an implant is added. Thus, the main ways to prevent adhesions are to influence these etiological causes.

According to B.S. Sukovatykh et al., in the prevention of adhesions during any operation, there are 4 main directions: 1) reduction of peritoneal injury; 2) reduction of inflammatory response in the area of surgery; 3) drug effect on the balance of fibrin formation and destruction; 4) delineation of damaged serous surfaces through the use of barrier agents [104]. In IPOM hernioplasty, in addition to these areas, there is a need to optimize the anti-adhesive properties of composite endoprostheses and fixators. It is the introduction of new technologies and materials used in their manufacture that can minimize this problem.

In the problem of pain syndrome, the main etiological cause is not the structure of the implant, but the method of its fixation. That is why one of the main modern directions of pain prevention is the rejection of stapler fixation with non-absorbable spirals in favor of fixation with absorbable screw-like fixators or intracorporeal sutures, as well as the introduction of adhesive fixation methods. These methods also have their drawbacks. For example, when using sutures, the operation time is significantly prolonged, and when using glue, the number of

relapses increases, however, which can be eliminated by combining with other traditionally used fixation methods.

1.4.1. Improvement of the implant structure

As already mentioned in the previous sections, composite implants often have a two–layer structure, one of which allows for the necessary integration, the other minimizes the likelihood of adhesions. However, attempts are being made to create prostheses that do not have a separate anti-adhesive layer. They are based on traditionally used polypropylene and polyester, and anti-adhesive properties are provided by applying various polymer or metal coatings to their surface [332; 284]. The main difference from traditional two-layer composite prostheses is the preservation of the mesh structure, which does not prevent the integration of the implant into the abdominal wall. The complexity of the production technology in most cases causes an increase in the cost of the product, but it remains below the price of composite endoprostheses.

Titanium-coated implants

Initially, such solutions were implemented in the TiMesh prosthesis by applying a titanium layer to the surface. As is known, the presence of titanium in implants significantly reduces the severity of the body's immune response and the severity of aseptic inflammation, which ultimately leads to the formation of a more complete connective tissue capsule [332; 92]. A comparison of retraction indices in the experimental study by H. Scheidbach showed that titanization of the implant reduces retraction from 14.9% to 8.8% ($p < 0.05$) [332]. The authors also noted that the volume of inflammatory infiltration in the prosthesis installation area decreases. In addition to good integration into tissues, the problem of recurrence can also be solved by reducing the risk of infection. According to L. Miao et al., the application of titanium coating polyester implant filaments to the surface significantly increases the resistance of the mesh to infection [284].

A study by A. Moreno-Egea et al. It has been shown that the frequency of postoperative complications and relapses after two years of follow-up does not differ when using polypropylene mesh with titanium coating and polyester mesh with

collagen coating [291]. At the same time, the pain syndrome in the early postoperative period and after 1 month turns out to be less when using the first implant ($p = 0.029$), which leads to a difference in the time of patients' return to their usual lifestyle. At a later date of observation, the indicators are leveled.

When comparing adhesion formation after IPOM-plasty with titanium-coated endoprostheses and polytetrafluoroethylene prostheses, there is a significant decrease in adhesions when using the former [338]. The authors also found a significant difference in retraction (43.5% in polytetrafluoroethylene versus 18% in titanium prostheses, $p = 0.006$). The use of such grids in an experiment conducted by S. Delibegovic et al., also revealed a significant decrease in the number of adhesions when compared with Ultrapro polypropylene and polyglecapron prostheses and polypropylene implants with polydioxanone and oxidized reduced cellulose Proceed [185]. Another study noted that the use of an additional anti-adhesive coating of polylactide applied to the TiMesh implant during intraperitoneal plastic surgery does not provide an advantage in reducing adhesion formation, which indicates sufficient anti-adhesive properties of the implant itself [337].

Dentures with fluoropolymer coating

If the effectiveness of titanium-coated endoprostheses approved for use in intraperitoneal hernioplasty has been studied to a certain extent, then there are very few publications on the results of intra-abdominal placement of fluoropolymer-coated prostheses. At the same time, fluoropolymers in their physical and biological properties may not be inferior to implants containing titanium [16].

Endoprostheses with fluoropolymer coating cause significantly less local inflammation than prostheses made of polypropylene, which is their basis [15]. In addition, the coating has high thrombosis resistance, which can potentially help reduce adhesion formation [14].

The use of fluoropolymer-coated mesh endoprostheses can significantly reduce the risks of infection by closing the gaps between the filaments with fluoropolymer [284]. This creates a smooth surface that does not allow exudate or cellular elements to penetrate into the inter-fiber spaces and gives the prosthesis

greater elasticity and, accordingly, greater inertia [56]. When compared with polypropylene endoprostheses, it was shown that the local inflammatory reaction in the early postoperative period and the phenomenon of fibrosis in the long term significantly decreases, and when compared with polyester endoprostheses, the resistance of the material to infection increases [55].

Combined endoprostheses

An alternative direction is the use of endoprostheses in IPOM, consisting of layers woven from different threads. The most famous of these two-component implants is DynaMesh, consisting of polypropylene and polyvinylidene fluoride. The peculiarity of this prosthesis is the presence of polypropylene filaments on one side, and anti–adhesive filaments of polyvinylidene fluoride on the other. According to some authors, the use of an endoprosthesis makes it possible to obtain adhesion figures comparable to implants with a collagen coating and to halve adhesion formation compared to polypropylene [238], according to others, it does not lead to a significant decrease in adhesion formation [204].

Interesting data were obtained in the work of A. Tandon et al. when comparing the results of using DynaMesh-IPOM and Parietex Composite grids in IPOM [355]. The first one had an advantage in the frequency of relapses (3.8% vs. 12.9%), the number of seromas (0% vs. 6.4%), but its installation led to a significant increase in the frequency of intestinal obstruction (11.5% vs. 0%, $p = 0.006$). In a study by T. Sommer et al. Of the 181 patients operated with the DynaMesh implant, 11 had repeated mesh–related operations, of which 3 had intestinal obstruction, and 1 had a colonic fistula [349]. The frequency of severe complications casts doubt on the expediency of intraperitoneal use of such an implant.

Biological prostheses

Another promising area is the use of biological prostheses, which can reduce the number of adhesions even in infected conditions [209; 210]. A systematic review conducted by N.J. Slater et al., which included 25 retrospective studies involving at least 7 patients, showed that the overall recurrence rate with the use of various biological implants was 13.8% (95% CI, 7.6–21.3), and with contaminated or

purulent operations – 23.1% (95% CI; 11.3 – 37.6). Infection occurred in 15.9% of patients (95% DI; 9.8 – 23.2), and removal of the prosthesis was required only in 4.9% of cases [346].

A systematic review by C.F. Bellows et al., which has lower selection criteria, allowed us to evaluate the results of 60 publications, of which about half indicate the use of a grid in infected conditions [138]. The authors indicate that complications such as infection (16.9%) or seroma (12.0%) were most common. With an average follow-up period of 13.6 months, the recurrence rate of hernias was 15.2%. The review conducted by S. Morales-Conde et al., showed that the recurrence rate when using biological prostheses in infected conditions is lower than that of synthetic ones [287]. However, these data do not allow us to reliably judge the effectiveness and safety of such prostheses, since no evidence-based studies have been conducted due to their high cost.

1.4.2. Development of new materials and methods used to fix the endoprosthesis

It is no secret that various mesh endoprostheses can be unsatisfactorily fixed with certain stapler fixators. In this regard, one of the areas of research is to substantiate the criteria for choosing a fixation method for a particular implant. The next direction is the search for new design solutions and materials that allow maintaining the mechanical strength of the joint and do not affect the surrounding organs and tissues. Another direction is the search for alternative fixation methods, the next stage of which was the introduction of various biological and chemical adhesive compositions.

Transfascial sutures and non-absorbable stapler retainers

If transfascial sutures and non-absorbable titanium spiral fixators were traditionally used for fixation, then over time other fixators appeared that differ in design and composition. Of the permanent ones, the most promising are stainless steel spirals coated with caps made of polyester etheric ketone, the distinctive feature of which is a softer effect on the implant base and an anti-adhesive layer. Another advantage of such fixators is a more pronounced anti-adhesive effect, achieved due

to the biological inertia of the polymer and the elimination of bleeding from its installation site [274; 241]. In addition, screw-like permanent fixators made of PermaFix polyester are being actively introduced, the distinctive feature of which is the presence of a hollow lumen through which connective tissue germination occurs [162].

Absorbable fixators

The introduction of absorbable fixators also made it possible to eliminate such a negative factor as the lifelong presence of additional foreign bodies in the tissues of the abdominal wall in addition to the implant. This made it possible to reduce the risks of their negative impact, such as migration and organ perforation. Unfortunately, despite a number of positive effects, absorbable fixators do not allow to achieve significant mechanical strength of the joint, which negatively affects primarily when working with scarred tissues or when fixing at an acute angle to the surface of the peritoneum [327].

There is also a need to develop new materials for such fixators, since a number of studies have noted an increase in viscero-parietal adhesion formation when using polylactic acid staples [168; 241].

Adhesive fixation

The idea of using fixation with adhesive compositions arose in response to a rather pronounced pain syndrome when using transfascial sutures and non-absorbable stapler fixators [158; 320]. Another problem was a certain relationship of adhesion with the localization zones of fixators [6].

The use of glue has significantly reduced the pain syndrome [377]. This is due to the absence of mechanical damage to the structures of the abdominal wall and less pronounced ischemia occurring in the areas where traditional fixators are located [377]. However, the use of cyanoacrylates in some cases is accompanied by a more pronounced local inflammatory reaction and adhesions [256]. The results of the effect of cyanoacrylates on the severity of adhesions are still ambiguous [256; 321; 168]. At the same time, the use of fibrin glue leads to a decrease in the severity of adhesions [198; 168].

The results of the use of adhesives consisting of human or bovine blood serum and glutaraldehyde/polyaldehyde or polyethylene glycol are interesting. Their use in IPOM hernioplasty gives encouraging results, leading to a significant reduction in chronic postoperative pain when compared with mechanical fixation methods, while not increasing the number of complications and relapses [121].

Despite the good results in the prevention of postoperative pain and adhesions, when using glue, there is a significantly lower fixation force of the prosthesis to the abdominal wall, which often leads to its retraction, dislocation or recurrence [256]. A study by C. Schug-Pass et al. It showed insufficient fixation strength of the TiMesh titanium-coated implant to the peritoneum with fibrin glue [336]. The authors compared the strength of fixation to the peritoneum and muscle tissue, obtaining a significant difference not in favor of fixation to the peritoneum (11.86 N vs. 47.88 N; $p = 0.001$). In a clinical trial, some of the meshes were not integrated into the structures of the abdominal wall, and another part turned out to be displaced.

At this point in time, it is the above factor that hinders the active implementation of this fixation method in IPOM plastic surgery. However, alternative points of view appear in a number of works. So, in the work of P. Wilson et al. In the treatment of 137 patients using n-butyl-2-cyanoacrylate for intraperitoneal mesh fixation, only 2% of relapses were noted [377].

The search for new glue options and application techniques continues. An interesting adhesive method was proposed by R. Lanzafame et al., in which the mesh was either filled with molten collagen or pressed into it [258].

Suture fixation

An alternative to adhesive fixation is intracorporeal suture fixation. A return to this technique occurred in the treatment of inguinal hernias and was associated with severe pain syndrome when using staplers. Currently, only single sutures are used to fix the implant with TAPP, or they are not used at all, and the parietal peritoneum is restored only with sutures. By analogy, the use of sutures in IPOM also makes it possible to solve one of the main problems of the technique – pain syndrome in the early postoperative period.

The main disadvantage of intracorporeal suture fixation is its duration [294]. For suture fixation, threads with a long period of biodegradation are more often used. However, when using a thread made of absorbable material, a longer period of chronic inflammation is noted, which primarily increases the risk of adhesions [320; 241].

It can be assumed that the use of filaments with different coatings can solve the problem of local adhesions to a certain extent. The most promising is the use of filaments coated with fluoropolymers. Similar threads have been used in surgery for a long time. Like implants with a similar coating, they have a high biological inertia. They combine the properties of mono- and multifilament filaments, have good biological compatibility, high strength and good manipulation qualities. Due to the coating, there is no capillary effect in such threads, moreover, they pass through the tissues much more easily without having a "sawing" effect.

The most common filaments are made of polyester, depending on the structure they can be twisted (Fluoroest), braided (Fluorex) or twisted and braided (Fluorolan). In some cases, a nylon thread (Fluoroline) is used as a base. Threads are used in all types of tissue approximation, including when performing operations on organs of the cardiovascular system and nervous tissues.

Conclusion

According to the results of the literature review, it is quite obvious that current trends in herniology tend towards minimally invasive treatment methods. At the same time, the gaze of many, especially young surgeons, is directed towards the not fully studied eTEP technique. However, the existing IPOM operation has proven its effectiveness and safety over 30 years of existence. The search for new options for anti-adhesive materials, as well as options for fixing the endoprosthesis, will overcome a number of limitations associated with adhesions, pain syndrome and cost.

Chapter 2. MATERIALS AND METHODS OF RESEARCH

2.1. Materials and methods of experimental research

2.1.1. Methods of studying the structural and physical properties of modern synthetic mesh endoprostheses of various types

Since one of the main tasks of the endoprosthesis used in the treatment of hernias is to create a physical framework on the basis of which the formation of its own tissues takes place, at the first stage, a study of the structural and physical properties of a number of ex vivo implants was performed. In a comparative aspect, the properties of both polypropylene and polyester endoprostheses traditionally used in IPOM hernioplasty with a separate resorbable and non-resorbable anti-adhesive layer and new endoprostheses without a separate protective layer, the anti-adhesive properties of which are provided by applying fluoropolymer both to individual threads and to the mesh web as a whole, have been studied.

The study was conducted with the direct participation of the author on the basis of the scientific and production laboratory of LLC Cardioplant (Penza) and LLC Lintex (St. Petersburg). 5 variants of samples of synthetic endoprostheses with differences in design, chemical composition and production technology were taken into the work. All samples were sterilized at the factory and were in packages.

The studied products were represented by the following endoprostheses:

1) polyester coated with synthetic fluorinated rubber-like copolymer of vinylidene fluoride with hexafluoropropylene (SKF–26) - Fluorex (Lintex, Russia);

2) made of polyester coated with a synthetic fluorinated rubber-like copolymer of vinylidene fluoride with hexafluoropropylene (SKF–26) - Fluorex and an additional anti-adhesive layer of carboxymethylcellulose (Lintex, Russia);

3) made of monofilament polyester coated with acellular pig collagen – Symbotex (Medtronic, USA);

4) made of polypropylene and polyglycolic acid coated with chemically modified sodium hyaluronate, carboxymethylcellulose and polyethylene glycol – Ventralight ST (Bard, USA);

5) made of lightweight polypropylene with an anti–adhesive coating of poly (oligouretanacrylate) - Reperen-16-2 (Ikon Lab, Russia).

The following parameters were evaluated:

The type of base, anti-adhesive coating and a separate anti-adhesive layer, the surface density, thickness, breaking load and tensile elongation declared by the manufacturer.

Research methods

The study was carried out in accordance with the regulatory documentation of the textile industry. The average figures were presented based on the results of three measurements. All physical parameters were determined both along the loop row and along the loop column.

Data on the composition of the base, anti-adhesive coating or a separate anti-adhesive layer, according to the manufacturer's declared surface density in g/m2, were taken from the instructions for use or from the manufacturer's website.

The thickness of the endoprosthesis was measured in mm using the Mitutoyo series 7 thickness gauge, modification 7327 with disc ceramic measuring tips (Mitutoyo Corporation, Japan).

The breaking load P in Newtons (H) and the elongation distance of the sample at maximum load in mm were determined using a universal desktop electromechanical testing machine Instron 5900 series (Instron-division of ITW Ltd., USA) (Fig. 2.1.1.1). The width of the studied samples was 10 mm, the distance between the clamps was 25 mm, the speed was 50 m/min.

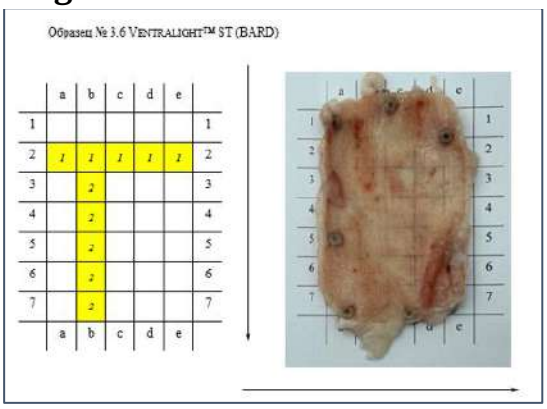
After receiving the measurement data (Fig. 2.1.1.2), the tensile elongation was calculated ε in % according to the formula,

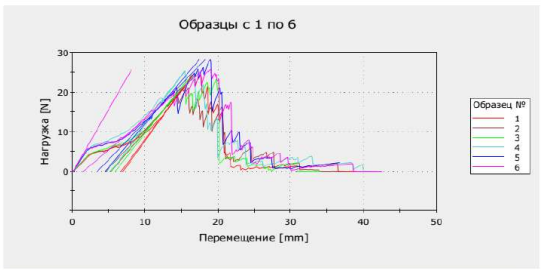
$$\varepsilon = \frac{a \times 100\%}{b}$$

where ε is the tensile elongation (%), a is the distance by which the sample was extended at maximum load (mm), b is the length of the sample fragment initially fixed between the clamps of the testing machine (mm).

Statistical analysis was carried out using descriptive statistics methods.

Figure 2.1.1.1 – Conducting physical and mechanical tests of the sample using the Instron 5900 testing machine.





	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,50000	12,79586	17,66033	4,86689
2	25,00000	10,00000	0,50000	9,79344	15,99528	4,22950
3	25,00000	10,00000	0,50000	11,74242	19,81684	4,65201
4	25,00000	10,00000	0,50000	12,65812	15,41071	5,06788
5	25,00000	10,00000	0,50000	10,91204	18,98687	5,63888
6	25,00000	10,00000	0,50000	16,05659	19,07349	5,13999

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	24,13443	10,91482	21,20000	
2	21,14751	10,62576	19,20000	
3	23,26004	14,56962	23,79200	
4	25,13941	10,64846	18,50000	
5	28,19439	15,51153	22,79400	
6	25,69996	17,54157	22,90000	

Figure 2.1.1.2 is an example of the protocol of physical and mechanical tests of samples carried out using the Instron 5900 machine.

2.1.2. Methods for studying the biomechanical properties and biocompatibility of modern synthetic mesh endoprostheses of various designs in animal experiments

The study consisted of 3 series of experiments conducted on the basis of LLC Center for Preclinical Research (Technopark of High Technologies, Penza). The animals were kept in the conditions of a subsidiary farm of the Penza State Agrarian University. The work was performed in compliance with the rules of good laboratory practice GLP (Good Laboratory Practice). Photo and video recording of the results was carried out at all stages of the study.

Before the operation, the animals were isolated and dosed for 3 weeks. At the initial stage, laparoscopy and intraperitoneal installation of endoprostheses were performed under combined endotracheal anesthesia. Surgical intervention was performed by surgeons with experience in performing more than 50 laparoscopic hernioplasty IPOM using endovideosurgical equipment and Karl Storz instruments (Germany).

In the 1st series (pilot part), the possibility of safe intraperitoneal use of modern mesh endoprostheses of domestic production Fluorex polyester with fluoropolymer coating (Lintex, Russia) and Fluorex with an additional anti-adhesive layer of carboxymethylcellulose (Lintex, Russia) was evaluated in comparison with other widely used modern implants of domestic and foreign production. This stage also allowed us to evaluate the prospects of using a biological plate made of decellularized peritoneum (Cardioplant, Russia) in order to create an anti-adhesive layer of a composite implant.

The second series of the experiment was aimed at evaluating the effectiveness and safety of a full-size fluoropolymer-coated implant under conditions of modeling a situation with the presence of a bruised defect of anterior abdominal wall aponeurosis. The next goal was to select the most suitable retainer (spiral or harpoon) and fixation device in terms of performance characteristics for this model of mesh endoprosthesis. Another goal was to study the possibility of using cyanoacrylate surgical glue for fixation of mesh endoprostheses with fluoropolymer coating.

The third series of the experiment was aimed at confirming the effectiveness and safety of fluoropolymer-coated implants on a larger volume of experimental

material. It also allowed us to study the effectiveness of using fluoropolymer-coated filaments for fixing implants.

2.1.2.1. Pilot stage (1st series of the experiment). Assessment of biomechanical properties and biocompatibility of various endoprostheses and decellularized porcine peritoneum

The pilot stage of the experiment was performed on 3 pigs of both sexes of the Russian white breed. The age of the animals was 6 months, the average weight was 71.0±3.2 kg. The stage started on April 30, 2022, and ended on August 10, 2022.

The technique of primary surgical intervention

In the position of the animal on its back, a 12 mm optical trocar was installed in an open manner along the midline. An abdominal cavity revision was performed at a pressure of 8 mmHg. The next step was to install two 5 mm trocars along the middle line, retreating 7 cm to the sides from the optical trocar. Implants with rounded corners measuring 5 by 7.5 cm (36.6 cm^2), selected at random, were placed on the anterolateral walls of the abdomen on both sides. Symmetrically from the middle line, 3 samples were placed at a distance of at least 2.5 cm from each other. Thus, 18 implants were installed in 3 animals. Fixation was performed at 8 points with a herniator, transfascial sutures were not used. One fixation point accounted for 4.6 cm^2 of the prosthesis area. After fixation of the implants, desufflation and suturing of trocar wounds were performed.

Relaparoscopy technique

In the position of the animal on its back, a 12 mm optical trocar was installed in an open manner along the midline outside the zone of postoperative scars. An abdominal cavity revision was performed at a pressure of 12 mmHg. If necessary, a 5 mm trocar was installed along the middle line, retreating at least 7 cm from the optical trocar. When manipulating the clamp, damage to the existing adhesive joints was avoided. After completion of relaparoscopy, desufflation and suturing of trocar wounds were performed.

Implants and fixators

During the 1st series of the experiment, 6 implant variants were used: from polyester with fluoropolymer coating Fluorex (Lintex, Russia) and Fluorex with an additional anti-adhesive layer of carboxymethylcellulose (Lintex, Russia), from lightweight polypropylene with anti-adhesive coating Reperen-16-2 (Ikon Lab, Russia), from monofilament polyester with collagen coated with Symbotex (Medtronic, USA), polypropylene coated with hyaluronic acid and carboxymethylcellulose Ventralight ST (Bard, USA), biological plate made of decellularized peritoneum (Cardioplant, Russia). Implants were fixed with absorbable spirals made of poly-D, L-lactide – SorbaFix (Bard, USA) or non-absorbable spirals made of polyesterephyrketone and stainless steel – CapSure (Bard, USA). The number of implants with absorbable or non-absorbable fixators was the same. The fixation option for one or another variant of the implant was chosen randomly (Fig. 2.1.2.1.1).

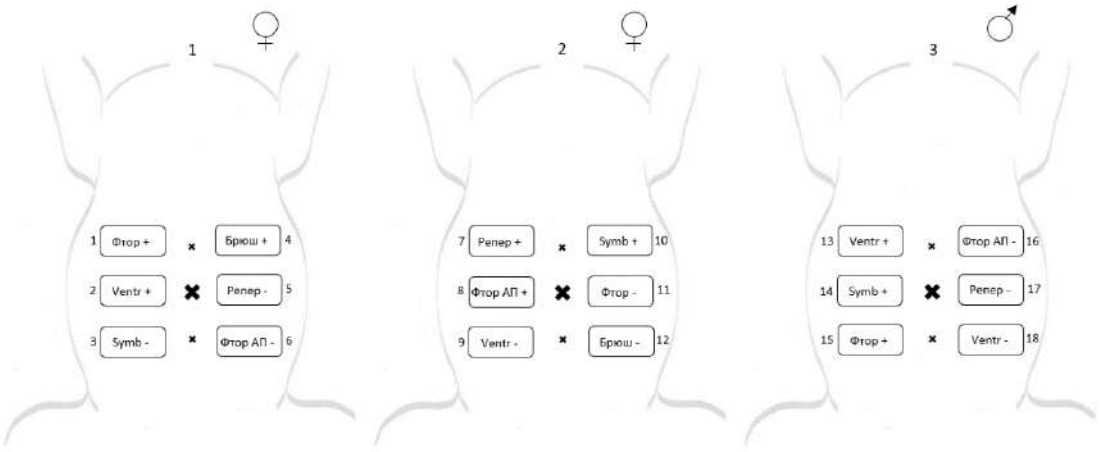


Figure 2.1.2.1.1 is a diagram of the arrangement of trocar ports, the location of implants and fixation options

Implants: Fluoro – Fluorex with fluoropolymer coating; Fluoro -Fluorex with fluoropolymer and additional anti–adhesive coating; Reper – Reperen-16-2 with Reperen coating; Symb – Symbotex with collagen coating; Ventr – Ventralight ST with hyaluronic acid and carboxymethylcellulose coating; Peritoneum – decellularized peritoneum. Fixation: + absorbable spirals made of poly-D, L-lactide (SorbaFix); – non-absorbable spirals made of polyester etheric ketone and stainless steel (CapSure). × - port installation points.

Stages of observation

Relaparoscopy and revision of abdominal organs were performed 45 days after the start of the experiment.

The animals were removed from the experiment after 90 days. Euthanasia was performed by administering submaximal doses of drugs for anesthesia. The abdominal cavity was opened with a longitudinal median incision from the xiphoid process to the pubic articulation. A preliminary visual inspection was performed with an assessment of adhesive joints. In each animal, 2 sections of the abdominal wall with implants were excised in single blocks on each side of the midline of the abdomen. In the case of adhesions, abdominal organs involved in the adhesive process were excised.

2.1.2.2. Evaluation of the effectiveness and safety of the use of full-size fluoropolymer-coated implants and various fixation methods in the conditions of modeling a hernial defect of the abdominal wall (2nd series of the experiment)

The second series of the experiment was performed on 3 pigs of both sexes of the Russian white breed. The age of the animals was 14 months, the average weight was 122.0±5.1 kg. The stage started on September 17, 2022, and ended on December 30, 2022.

The technique of primary surgical intervention

In the position of the animal on its back, a 12 mm optical trocar was installed in an open manner along the midline. An abdominal cavity revision was performed at a pressure of 12 mmHg. The next step was to install a 12 mm optical port and two 5 mm trocars in the left mesogastric zone according to the principle of triangulation. The laparoscope was wound through a side optical port, the 12 mm port along the middle line was removed, the trocar wound was sutured with a 2-0 polypropylene thread. 1 mesh endoprosthesis with an area of 150, 300 or 400 cm^2 was placed symmetrically above the sutured defect relative to the midline in each animal. Fixation was performed according to a standard procedure using transfascial

ligatures, hernia staplers or surgical cyanoacrylate glue. After fixation of the endoprostheses, desufflation and suturing of trocar wounds were performed.

Relaparoscopy technique

In the position of the animal on its back, a 12 mm optical trocar was installed in an open manner along the midline outside the zone of postoperative scars and localization of the endoprosthesis. An abdominal cavity revision was performed at a pressure of 12 mmHg. If necessary, a 5 mm trocar was installed. When manipulating the clamp, damage to the existing adhesive joints was avoided. After completion of relaparoscopy, desufflation and suturing of trocar wounds were performed.

Implants, transfascial sutures and fixators

During the 2nd series of the experiment, 1 variant of the endoprosthesis was used – made of polyester with fluoropolymer coating Fluorex (Lintex, Russia). The thickness of the endoprostheses was 0.3-0.4 mm, the surface density was 36-42 g/m^2. Before insertion into the abdominal cavity, 4 ligatures made of polypropylene 3-0 thread were fixed at the edges of each implant for subsequent transfascial fixation. After the endoprosthesis was inserted into the abdominal cavity and positioned on the abdominal wall with previously fixed ligatures, it was fixed to the muscular-aponeurotic tissues of the abdominal wall.

In the 1st animal, an endoprosthesis with an area of 300 cm^2 (15 by 20 cm) was additionally fixed with 3.8 mm high titanium spirals – ProTack (Medtronic, USA) (Fig. 2.1.2.2.1). In the 2nd animal, the implant with an area of 400 cm^2 (20 by 20 cm) was fixed with absorbable harpoon fixators with a height of 6.7 mm from a mixture of polydioxanone and a copolymer of L-lactide and glycolide - SecureStrap (Ethicon, USA). In the 3rd animal, an endoprosthesis with an area of 150 cm^2 (10 by 15 cm) was additionally fixed with butyl-2-cyanoacrylate surgical glue Glubran 2 (GEM, Italy). A device for atraumatic laparoscopic fixation of Glutack mesh (GEM, Italy) was used to deliver the glue.

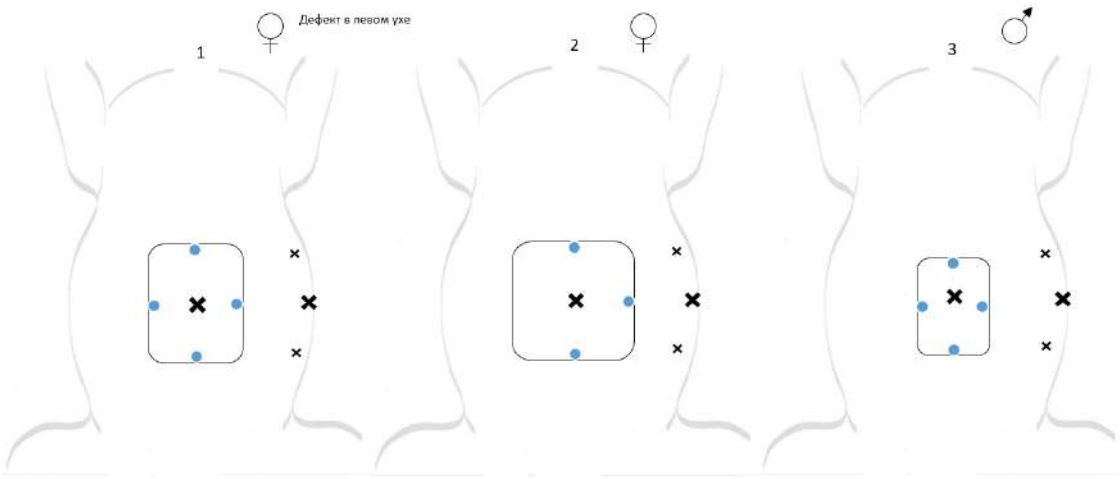


Figure 2.1.2.2.1 is a diagram of the arrangement of trocar ports, the location of implants and transfascial sutures
The blue dots are the locations of the transfascial sutures. × – port installation points.

Stages of observation

Diagnostic laparoscopy and removal of animals from the experiment were performed after 90 days. Euthanasia was performed by administering submaximal doses of drugs for anesthesia. The abdominal cavity was opened with an incision bordering the zone of installation of the endoprosthesis without damage to the latter, after which a visual examination was performed with an assessment of adhesive joints. The section of the abdominal wall with the implant was excised in a single block. In the case of adhesions, abdominal organs involved in the adhesive process were excised.

2.1.2.3. Comparative assessment of biomechanical properties and biocompatibility of endoprostheses with fluoropolymer coating and composite endoprostheses with anti-adhesive collagen layer, as well as fixing filaments with fluoropolymer coating (3rd series of the experiment).

The 3rd series of the experiment was performed on 2 female pigs of the Russian white + Landrace + Duroc breed. The age of the animals was 6 months, the average weight was 60.0 ± 0.5 kg. The stage started on May 20, 2023, and ended on July 4, 2023.

Surgical intervention technique

In the position of the animal on its back, a 12 mm optical trocar was installed in an open manner along the midline. An abdominal cavity revision was performed at a pressure of 12 mmHg. The next step along the middle line, retreating 7 cm to the sides from the optical trocar, a 12 mm trocar was installed in the mesogastric zone, and a 5 mm trocar in the hypogastric zone. Implants with rounded corners measuring 5 by 7 cm (33.6 cm^2), randomly selected, were placed on the anterolateral walls of the abdomen on both sides. Symmetrically from the middle line, 3 samples were placed at a distance of at least 2.5 cm from each other. Thus, 12 endoprostheses were installed in 2 animals. Transfascial sutures were not used. Fixation was performed either with a herniator or with nodular sutures. After fixation of the implants, desufflation and suturing of trocar wounds were performed.

Implants and fixators

In the 3rd series of the experiment, 2 variants of endoprostheses were used: from polyester with fluoropolymer coating Fluorex (Lintex, Russia) and from monofilament polyester with collagen coating Symbotex (Medtronic, USA). The thickness of endoprostheses with fluoropolymer coating was 0.3-0.4 mm, the surface density was 36-42 g/m^2.

In the first 2 animals, 5 Fluorex endoprostheses and 3 Symbotex prostheses were fixed with nodular sutures, 3 more Fluorex endoprostheses and 1 Symbotex prosthesis were fixed with stapler fixators (Fig. 2.1.2.3.1). Stapler fixation was performed at 4 points with absorbable harpoon fixators 6.7 mm long from a mixture of polydioxanone and a copolymer of L-lactide and glycolide – SecureStrap (Ethicon, USA). Suture fixation with nodular sutures was performed with non-absorbable braided polyester thread with fluoropolymer coating Fluorex (Lintex, Russia). One fixation point accounted for 8.4 cm^2 of the prosthesis area.

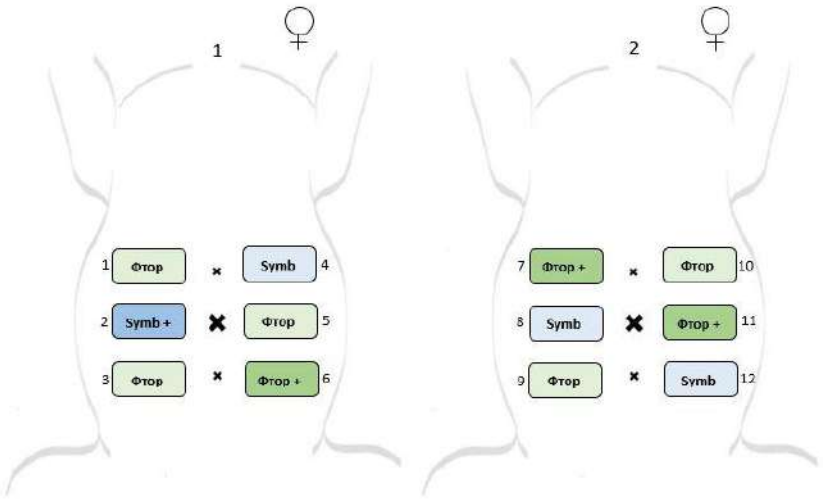


Figure 2.1.2.3.1 – Diagram of the arrangement of trocar ports, the location of implants and the fixation option
Implants: Fluoro – Fluorex with fluoropolymer coating; Symb – Symbotex with collagen coating
Fixation: + SecureStrap fixation; in other cases, fixation with Fluorex thread
× – Port installation points

Stages of observation

The animals were removed from the experiment after 45 days. Euthanasia was performed by administering submaximal doses of drugs for anesthesia. The abdominal cavity was opened with a longitudinal median incision from the xiphoid process to the pubic articulation. Preliminary visual examination, manual examination and measurement of the size of the endoprostheses were performed. After excision of the prosthesis-tissue complex, further evaluation was performed by straightening the implant on the plane. In the case of adhesions, abdominal organs involved in the adhesive process were excised.

2.1.2.4. Investigated parameters

During the experimental study, the following indicators were taken into account and evaluated:

Animal health parameters:

Breed, age, gender, initial weight, weight change at the stages of the study.

Parameters related to the operation:

The duration of the operation, adverse events during the operation, the peculiarities of the course of the postoperative period.

Parameters related to the endoprosthesis and the method of fixation:

Structure, base, visceral layer, area, localization of the endoprosthesis, distance between implants, number of transfascial sutures, method of fixation of the endoprosthesis, design of the fixation device, number of fixators, area of the implant fixed with one fixator, damage to the visceral layer of the endoprosthesis.

Performance characteristics of the endoprosthesis:

The time and features of the endoprosthesis installation.

Biocompatibility parameters of the endoprosthesis:

General assessment of the animal's health status, complications of the early (up to 30 days) and late postoperative period, elimination of complications, duration of postoperative follow-up, signs of inflammation, deformation, retraction of the prosthesis, migration of fixators, the size of the prosthesis before and after excision.

Parameters for assessing adhesions in the implant area and in the abdominal cavity:

The presence and localization of adhesions on the surface of the endoprosthesis, the area of the implant involved in adhesions, the type and strength of adhesions, the involvement of organs in the adhesive process, an integral assessment of adhesions in the implant area, adhesions in other parts of the abdominal cavity associated with the use of the implant.

Biomechanical parameters of endoprosthesis integration:

Manual assessment of the elasticity and strength of the prosthesis-tissue complex, the thickness of the prosthesis-tissue complex, the average breaking load, breaking load along the loop row and the loop column, the average breaking elongation of the prosthesis-tissue complex, breaking elongation along the loop row and the loop column.

Morphological parameters of endoprosthesis integration:

Assessment of the following parameters: inflammation, fibrosis, vascular proliferation, severity of macrophage-histiocyte-fibrocyte infiltration, cellular

composition of the prosthesis-tissue complex, assessment of the neoperitoneum layer on the prosthesis-tissue complex.

2.1.2.5. Research methods

Parameters related to the endoprosthesis and the method of fixation

The area of the endoprosthesis in cm^2 was calculated after transferring the contour to a graduated film.

The area of the implant per retainer was calculated in cm^2 according to the formula

$$S = \frac{S(\text{имп})}{n}$$

where S is the area of the endoprosthesis per 1 fixator (cm^2), S (imp) is the total area of the endoprosthesis (cm^2), n is the number of fixators (pcs.).

Performance characteristics of the endoprosthesis

The time of installation of one endoprosthesis was calculated in minutes from the moment of its introduction into the abdominal cavity until the installation of the last fixator.

Biocompatibility parameters of the endoprosthesis

The number of endoprostheses with inflammation, deformation and retraction, implants with migration of fixators was calculated in absolute and relative values. Inflammation was determined visually by the presence of edema and hyperemia in the area of the endoprosthesis. It was believed that there was a deformation when the presence of folds was noted in the implant and the rectangular shape was disturbed.

After the autopsy, the area of retraction of the endoprosthesis in % was calculated using the formula

$$x = \frac{S(\text{имп}45) \times 100\%}{S(\text{имп})}$$

where x is the retraction area (%), S (imp) is the area of the endoprosthesis at the time of installation (cm^2), S (imp45) is the area of the endoprosthesis at the time of autopsy on day 45 (cm^2). The area of the endoprosthesis in cm2 was calculated after transferring the contour to a graduated film.

The migration of fixators was assessed at the time of autopsy. It was believed that migration exists in the absence of at least one fixator.

Parameters for assessing adhesions in the implant area and in the abdominal cavity

During the autopsy, a macroscopic assessment of the degree of adhesions was performed both in the area of the implant localization and in other parts of the abdominal cavity.

The number of endoprostheses with adhesion phenomena was calculated in absolute and relative values.

When evaluating the coverage of the surface of the implant with adhesions in absolute and relative values, the number of endoprostheses with a single mooring, adhesions at the edges and splices at the edges and in the center was calculated.

The implant area involved in adhesions was calculated using an adapted scale by P.A. Lucas et al. [273]: 0 – there are no adhesions, 1 – adhesions occupy from 1 to 24%; 2 – adhesions occupy from 25 to 49%; 3 – adhesions occupy from 50 to 74%; 4 – adhesions they occupy from 75% to 100% of the surface of the endoprosthesis.

The type of adhesion was assessed according to the scale of M.D. Mueller et al. [292]: 0 – absence of adhesions; 1 – thin, avascular adhesions; 2 – thick, avascular adhesions; 3 – very dense, vascularized adhesions.

The density of adhesions was assessed according to the scale of H.V. Zühlke et al. [382]: 0 – lack of adhesion; 1 – filmy, easily removable adhesions; 2 – adhesions can be separated bluntly; 3 – to eliminate adhesions, it is necessary to resort to acute dissection; 4 – a pronounced process, the separation of which may damage internal organs.

It was believed that the internal organs were involved in the adhesive process when they were fixed by adhesions to the area of the endoprosthesis installation.

An integral assessment of spike formation in scores from 0 to 11 was carried out using an adapted scale by M.P. Diamond et al. [189]. Quantitative assessment of the area of adhesions: 0 – there are no adhesions, 1 – adhesions occupy less than

25%; 2 – adhesions occupy from 25 to 50%; 3 – adhesions occupy from 50 to 75%; 4 – adhesions occupy an area of more than 75% of the surface of the endoprosthesis. Qualitative assessment by appearance: 0 – no adhesions; 1 – filmy, transparent, avascular adhesions; 2 – opaque, avascular adhesions; 3 – dense, opaque, weakly vascularized adhesions; 4 – dense, well-vascularized joints. Qualitative assessment of the density of adhesions: 0 – there are no adhesions; 1 – the adhesions are separated without effort; 2 – the adhesions are separated during traction; 3 – an acute dissection is required for separation.

Adhesions in other parts of the abdominal cavity that occurred after the use of an endoprosthesis were recorded in case of their appearance during repeated laparoscopy or autopsy.

For scales with a point score, the average score for each variant of the implant was calculated by dividing the sum of points scored by endoprostheses of this variant by their number. The results were evaluated at all stages by two researchers. Disagreements were resolved after viewing photos and videos with the involvement of a third researcher.

Biomechanical parameters of endoprosthesis integration

Manual assessment of the elasticity and strength of the prosthesis-tissue complex: 0 – no integration (the implant lies freely in the abdominal cavity), 1 – weak (the implant is easily separated from the abdominal wall by a blunt path), 2 – medium (separated by a blunt path with effort), 3 – good (it is difficult to separate by a blunt path), 4 – very good (it is impossible to separate without cutting).

The thickness of the endoprosthesis and the prosthesis-tissue complex, the breaking load P in Newtons (H) and the elongation distance of the sample at maximum load were measured using the methods described above.

Morphological parameters of endoprosthesis integration

6 fragments of the abdominal wall taken from each animal with elements of each variant of the mesh implant and adhesions, if any, were immersed in containers with a 10% solution of neutral formalin. Histological examination was performed at the Interregional Laboratory Center LLC (St. Petersburg).

At least five interval sections of tissue from different fragments of the material samples provided for the study of each animal were placed in two or more histological cassettes (Fig. 2.1.2.5.2). Sections of the endoprosthesis with surrounding tissues were taken subtotally in cross section. The analysis was carried out based on the totality of the detected changes at all levels of the endoprosthesis extension in the fragment under study.

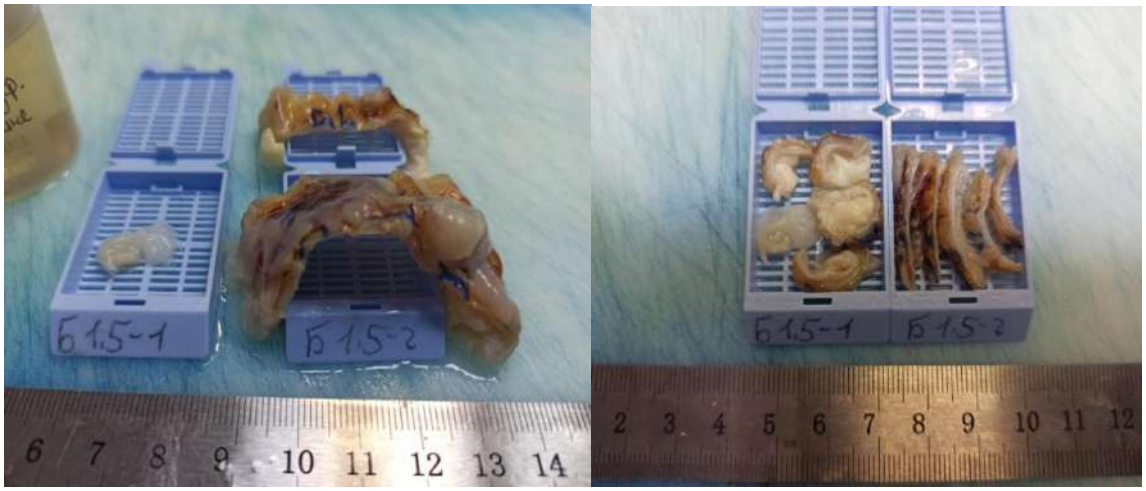


Figure 2.1.2.5.2 – Cutting and placing the material in cassettes

a – the material before the cuts; b – the material after the cuts.

The material in the cassettes went through the stages of sample preparation. Dehydration and paraffin impregnation were performed according to a standardized technique in an Excelsior AS automatic histological processor (Thermo, USA) in a ready-made IsoPREP solution (Biovitrum, Russia) and HISTOMIX paraffin medium (Biovitrum, Russia). Using the NM 325 rotary microtome (Thermo, USA), sections with a thickness of 2-3 microns were made, which were further dewaxed, dehydrated, stained with histological methods according to the generally accepted standardized technique with hematoxylin-eosin in accordance with the manufacturer's recommendations (Biovitrum, Russia). An immunohistochemical study with the PCK marker (AE1/AE3) was performed using the Masson trichrome PAS method to visualize the mesothelium in assessing the growth of the neoperitoneum, preservation of the initial peritoneum and fouling of adhesions (Fig. 2.1.2.5.3).

Figure 2.1.2.5.3 – Immunohistochemical study with an antibody to pan-cytokeratins (PCK, clone AE1/AE3)
There is a positive staining of mesothelial cells located on the surface of the neoperitoneum (H) and the base peritoneum (P) under the structures of the endoprosthesis (E). ×200.

Microscopic examination was performed on an AXIO LAB.A1 microscope (Carl Zeiss, Germany) at magnification ×40, ×100, ×200, ×400, ×1000 (Fig. 2.1.2.5.4, 2.1.2.5.5, 2.1.2.5.6). The results of the analysis were entered into the developed technological maps reflecting the main visualized pathological patterns in the form of semi-quantitative values of deviations from the norm of histological structure.

As a result of a preliminary analysis of the microscopic picture of the visualized changes (pilot study), a possible range of visualized patterns, their severity, the possibility of their quantitative or qualitative assessment, their significance for achieving the effectiveness of the study, the possibility of using histochemical dyes to objectify the detected morphological patterns were determined.

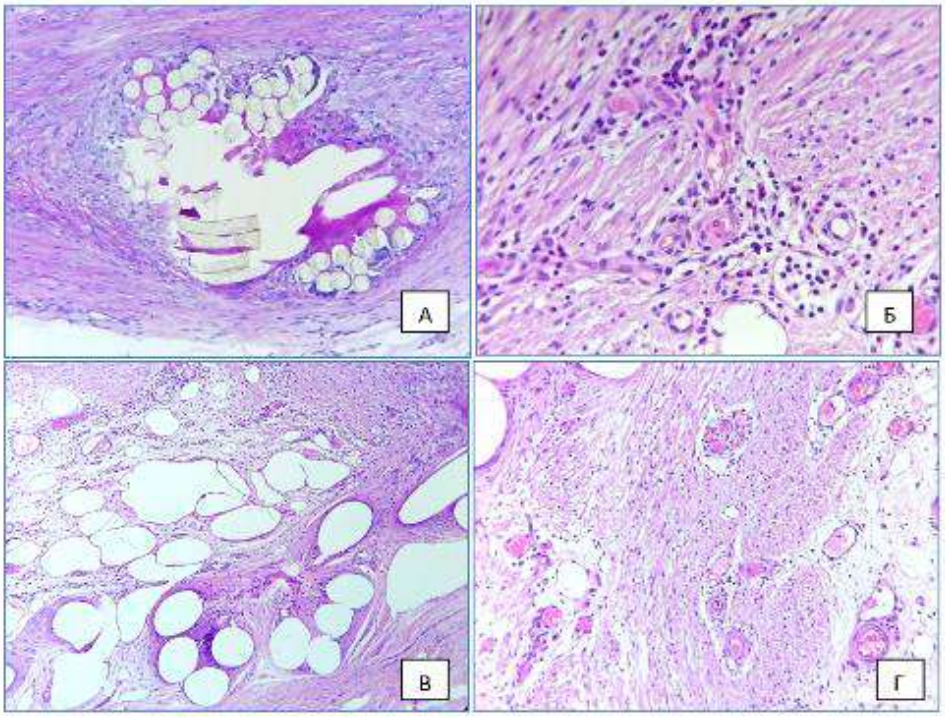


Figure 2.1.2.5.4 – Micrographs (Example No. 1)

a – mesh filaments surrounded by macrophages, multinucleated giant cells, fibroblasts and fibrocytes, collagen fibers forming a capsule (PAS reaction. × 100); b – the area around the implant, newly formed arterial and venous vessels of small caliber, capillaries, lymphatic vessels surrounded by lymphocytes and eosinophils (stained with hematoxylin and eosin. ×200); b is a zone at the border of the implanted mesh and the underlying peritoneum, newly formed arterial and venous vessels of small caliber surrounded by lymphocytes, a collector network of lymphatic vessels (stained with hematoxylin and eosin. ×100); g – zone at the border of the implanted mesh and the underlying peritoneum, newly formed tangles of small-caliber arterial and venous vessels, capillaries surrounded by lymphocytes, dilated lymphatic vessels (stained with hematoxylin and eosin. ×200).

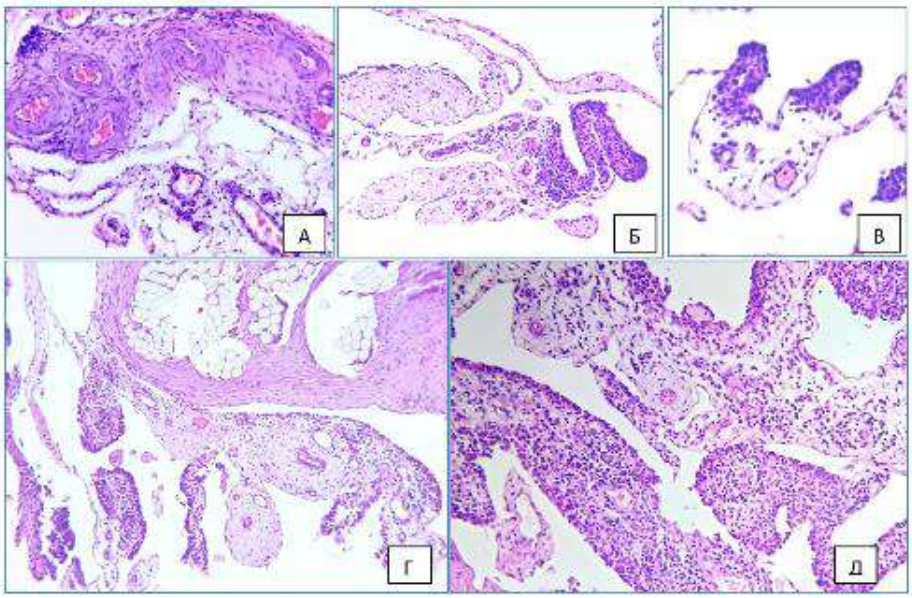


Figure 2.1.2.5.5 – Micrographs (Example No. 2)

a – mature vessels of medium caliber in the composition of adhesions (stained with hematoxylin and eosin. ×200); b – formed adhesions with newly formed small-caliber vessels, moderately pronounced stroma fibrosis and focus of the growing kidney adhesions with lymphocytic infiltration of the stroma and immature capillary vessels (stained with hematoxylin and eosin. ×100); b – immature growth buds of adhesions with reactive mesothelium (stained with hematoxylin and eosin. ×200); g – adhesions of various maturity with pronounced stroma fibrosis and mature vessels and growing young adhesions with reactive mesothelium and small immature capillary vessels (stained with hematoxylin and eosin. ×100); d – adhesions of various maturity with mild stroma fibrosis and mature vessels and growing young adhesions with reactive mesothelium and small immature capillary vessels (stained with hematoxylin and eosin. ×100).

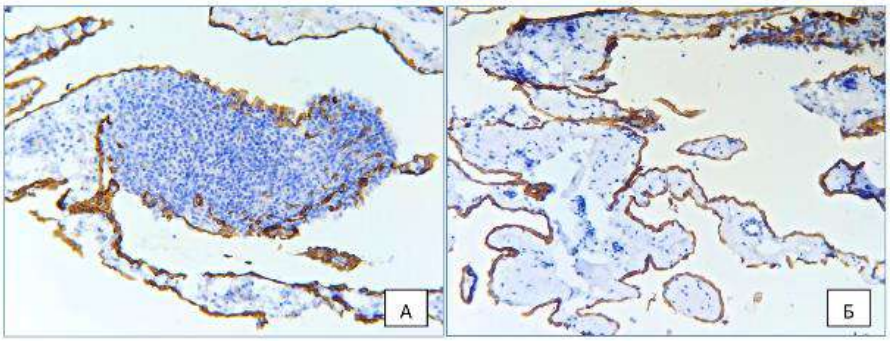


Figure 2.1.2.5.6 – Micrographs (example No. 3)

a – a young growing spike with a reactively altered mesothelium; b – formed spikes covered with a calm mesothelium. IHC reaction with PCK marker AE1/AE3. ×200.

Quantitative morphometry was performed on digitized images of histological preparations (WSI, Panoramic MIDI) stained with hematoxylin and eosin using freely distributed programs Pannoramic Viewer Version 1.15.4 and Orbit Image Analysis Version 3.64.

To assess the thickness of the briquette (Fig. 2.1.2.5.7 a), the peritoneal plate (Fig. 2.1.2.5.7 b), the implant (Fig. 2.1.2.5.7 c), fibrosis around the filaments (Fig. 2.1.2.5.7 d) on digitized histological preparations stained with hematoxylin and eosin, heights at 10 loci in the projection of the filaments were measured for each of the parameters with using Panoramic Viewer Version 1.15.4. The absolute values for each indicator were entered into an Excel spreadsheet, where primary statistical data processing was performed – the average (M) and standard deviation (± SD) for each animal were calculated.

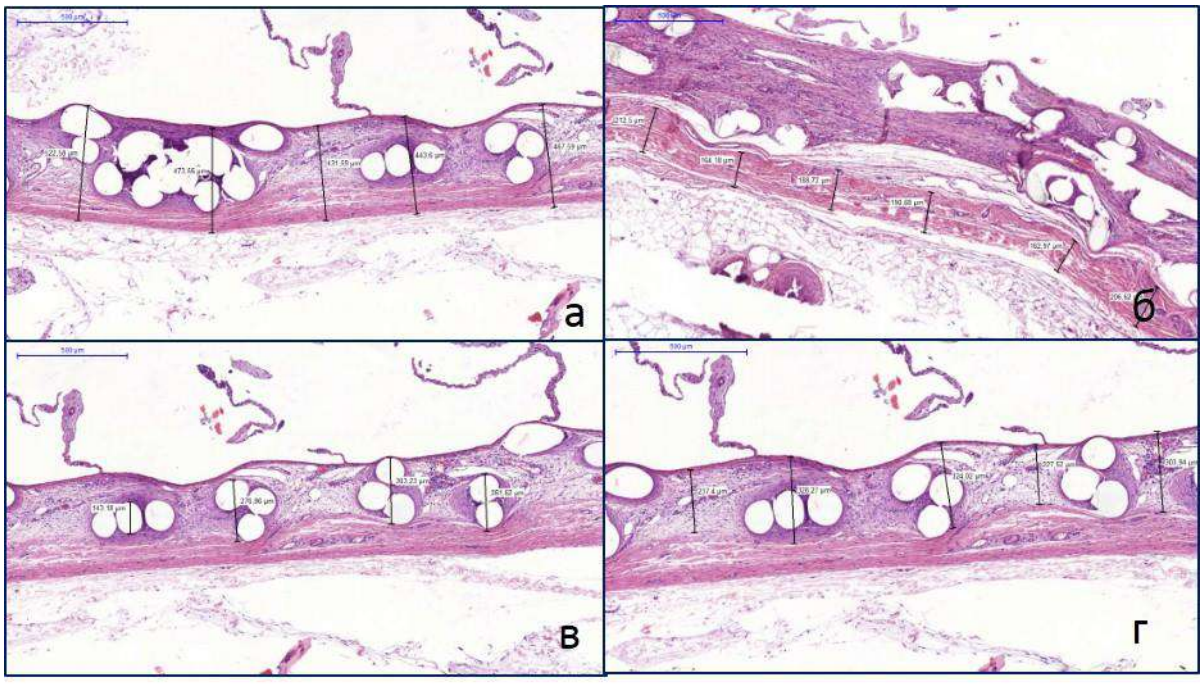


Figure 2.1.2.5.7. An example of height measurement in the Panoramic Viewer program on a digitized histological preparation
a – the height of the briquette (implant with fibrosis around the threads and peritoneum); b – the height of the peritoneum; c – the height of the implant threads; d – the height of fibrosis around the threads with the implant. Staining with hematoxylin and eosin. ×30.

The implant area was measured on a 5 mm^2 tissue area (Fig. 2.1.2.5.8a, 2.1.2.5.8b), as well as in a 10 mm long tissue area (Fig. 2.1.2.5.8c, 2.1.2.5.8d) on digitized preparations using Panoramic Viewer Version 1.15.4. For each measurement variant, the proportion of the implant area from the tissue area (S^2 grid/ S^2 of fabric, %).

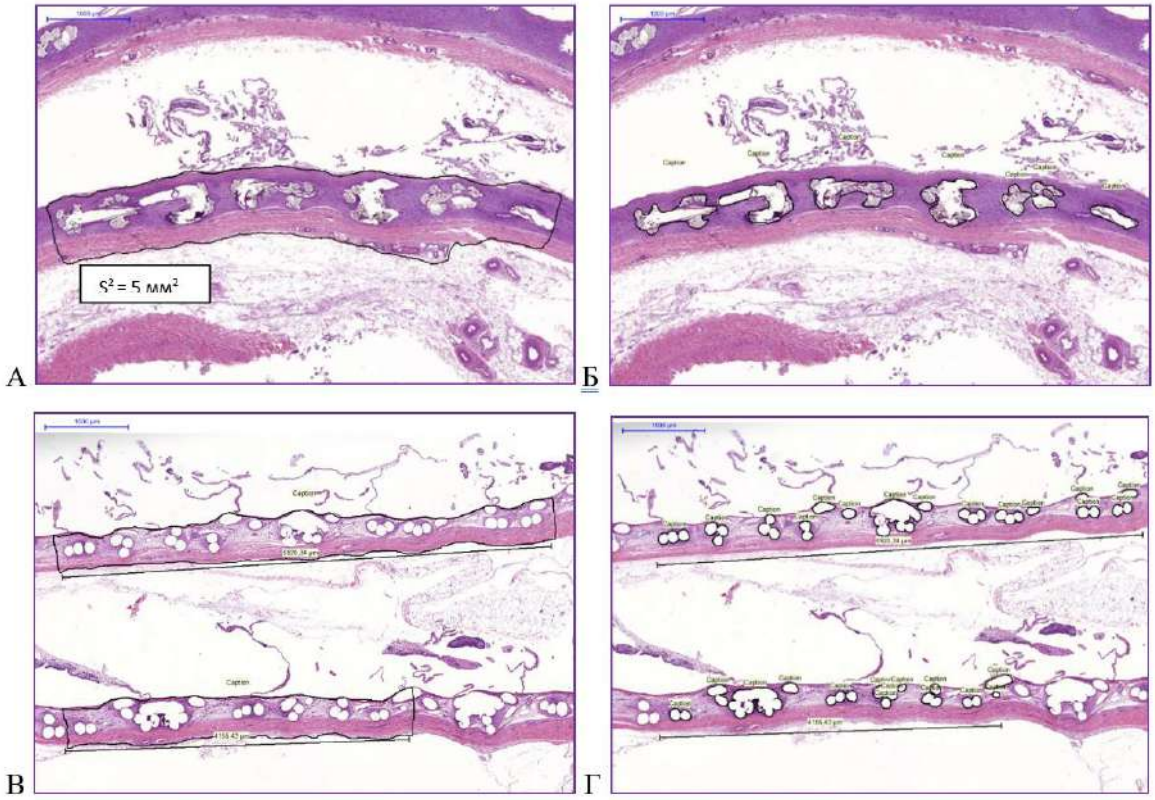


Figure 2.1.2.5.8 is an example of measuring the area of an implant on a digitized histological preparation in the Panoramic Viewer program.
Measuring the area of the implant (a) on a 5 mm^2 area of tissue (b); measuring the area of the implant (c) and the area of the tissue on a 10 mm (10,000 microns) long area (d). Staining with hematoxylin and eosin. ×20.

In the study of changes in the parameters of the vascular system, in each histological preparation, the number of arteries and arterioles, veins and capillaries, lymphatic vessels and their total number in five fields of view were calculated separately in the peritoneum and implant areas (Fig. 2.1.2.5.9).

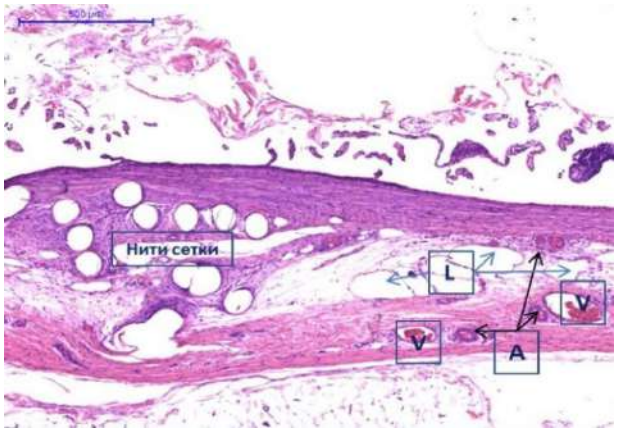


Figure 2.1.2.5.9 is a digitized micrograph of the thickness of the newly formed tissue complex around the filaments of the endoprosthesis with the underlying peritoneum.

Newly formed arterioles (A), venules (V) and lymphatic vessels (L) are well visualized. Staining with hematoxylin and eosin. ×30.

The count of the number of cells in the interstitium was performed automatically, using the Orbit Image Analysis Version 3.64 program, separately on the implant and peritoneum sections (Fig. 2.1.2.5.10) in five fields of view for each (×200). The number of cells was expressed as their absolute values in the field of view, and also standardized to the area of the tissue (the ratio of the number of cells to the proportion of the area of the tissue).

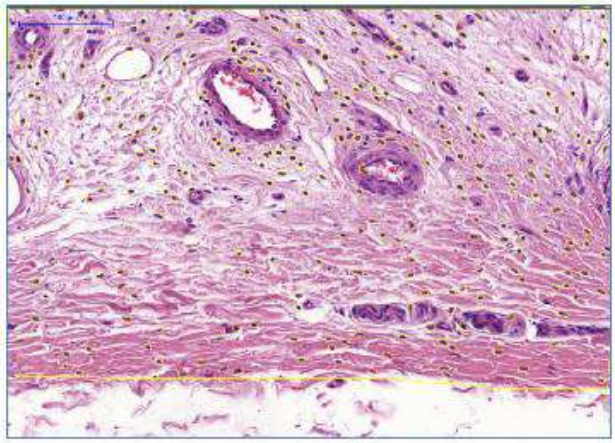


Figure 2.1.2.5.10 is an example of an automated calculation of the number of cells in the peritoneum using the Orbit Image Analysis morphometric image analysis program

Stained with hematoxylin and eosin. ×200.

2.2. Materials and methods of clinical research

The main goal of the first stage of the clinical trial was to confirm the need to find the most effective and safe implant and a method of its fixation, the use of which would reduce or eliminate a number of disadvantages of intraperitoneal hernioplasty. For this purpose, in a retrospective analysis, the results were evaluated depending on the anti-adhesive coating option and the type of fixation. Also at this stage, the influence of various factors on the most significant indicators of the effectiveness and safety of surgery, such as postoperative pain, adhesions, recurrence rate and overall quality of life, was studied.

The purpose of the second stage was to substantiate the effective and safe clinical use of endoprostheses and filaments with fluoropolymer coating Fluorex. The results of their use were compared with other endoprostheses and fixation options used in IPOM hernioplasty.

2.2.1. General characteristics of patient groups

Before being included in the study, all patients gave written voluntary informed consent to participate.

2.2.1.1. Investigation of the clinical efficacy and safety of various endoprostheses and methods of their fixation used in IPOM hernioplasty: a multicenter, retrospective study

The selection for a multicenter, retrospective, one-stage study was carried out from a pre-formed group including 137 patients with primary or postoperative ventral hernias who had previously been operated on using the IPOM method from laparoscopic access. The operations were performed from 2011 to 2023 on the basis of 4 medical institutions in St. Petersburg, Moscow, Moscow region ("Clinic of High Medical Technologies named after N.I. Pirogov" St. Petersburg State University, GBUZ "Moscow Clinical Scientific Center named after A.S. Loginova" DZM, GBUZ MO "Vidnovskaya district clinical hospital", GBUZ MO "Lyubertsy regional hospital").

The following procedures were performed during one patient visit:

1. Assessment of compliance with the inclusion criteria.

2. Signing of informed consent (Appendix 1).

3. Collection of anamnestic data.

4. A questionnaire to assess postoperative reactions or complications and determine the overall quality of life.

5. General clinical examination.

6. Investigation of the local status.

7. Ultrasound diagnostics of viscero-parietal adhesions.

Criteria for inclusion in a retrospective clinical trial:

1. Age from 18 to 75 years.

2. Signed informed consent for the study.

3. Elective surgery for primary or postoperative ventral hernia.

4. Laparoscopic hernioplasty using the IPOM and IPOM Plus techniques.

Criteria for exclusion from a retrospective clinical trial:

1. Age less than 18 and over 75 years old.

2. The patient's refusal to participate in the study.

3. Operations for inguinal, femoral, lumbar, perineal, hiatal hernia.

4. Previously performed planned surgical interventions using IPOM techniques from traditional access, Onlay, Sublay, TAR, TAPP, TEP, eTEP, SCOLA.

After the exclusion of patients who did not pass the selection criteria for inclusion and exclusion, as well as did not show up for examination, the study groups were formed. Depending on the anti-adhesive coating option, 3 groups of patients were identified who previously had endoprostheses coated with collagen (group 1), hyaluronic acid and carboxymethylcellulose (group 2) and poly(oligouretanacrylate) (group 3). Depending on the type of fixation, 3 groups of patients were also identified who had previously used non-absorbable (group 1), absorbable (group 2) and adhesive (group 3) fixation. The assessment was carried out without dividing patients into groups with primary and postoperative ventral hernias.

2.2.1.2. Evaluation of the effectiveness and safety of fluoropolymer-coated composite endoprostheses and methods of their fixation in intra-abdominal plastic surgery (IPOM): a multicenter, non-randomized, controlled, clinical trial

A multicenter, non-randomized, controlled clinical trial included 79 patients of both sexes operated on using the IPOM technique from laparoscopic access for primary or postoperative ventral hernia. The duration of observation is from 3 months to 1 year.

The study was conducted from January 2023 to January 2024. The operations were performed on the basis of 4 medical institutions in St. Petersburg, Moscow, Moscow region ("Clinic of High Medical Technologies named after N.I. Pirogov" St. Petersburg State University, GBUZ "Moscow Clinical Scientific Center named after A.S. Loginov" DZM, GBUZ MO "Vidnovskaya regional clinical hospital", GBUZ MO "Lyubertsy regional Hospital").

The following procedures were performed during 4 patient visits:

During visit 1 (hospitalization and surgical treatment):

1. Assessment of compliance with the inclusion criteria.
2. Signing of informed consent (Appendix 1).
3. Collection of anamnestic data.
4. A survey to determine the overall quality of life (Appendix 2).
5. Clinical examination.
6. Investigation of the local status.
7. Evaluation of laboratory and instrumental examination data.
8. Ultrasound diagnosis of viscero-parietal fusion.
9. Laparoscopic surgery using the IPOM or IPOM Plus technique.
10. Assessment of the results of follow-up in the early postoperative period.
11. A questionnaire to assess the severity of early postoperative pain syndrome.

During visits 2 (after 1 month), 3 (after 3 months) and 4 (after 12 months):

1. Collection of anamnestic data.

2. A questionnaire to assess postoperative reactions or complications and determine the overall quality of life and pain.

3. General clinical examination.

4. Investigation of the local status.

5. Ultrasound diagnostics of viscero-parietal adhesions.

Unplanned visits (which do not coincide in time with Visit 2, 3 or 4) were initiated either by the researcher or by the patient himself in case of any deviations from the normal course of the postoperative period.

Criteria for inclusion in a prospective clinical trial:

1. The age of the patient is from 18 to 75 years old.

2. Signed informed consent for the study.

3. The presence of a small (small), medium (medium), large (large) primary ventral hernia; small (W1) or medium (W2) postoperative ventral hernia (according to EHS classifications) [286] – with a maximum transverse size of the hernial gate of no more than 8 cm

. 4. Elective surgery.

5. The physical status of the patient I – III according to the ASA classification [270].

6. IPOM hernioplasty from laparoscopic access.

Criteria for exclusion from a prospective clinical trial:

1. The age is less than 18 years old or more than 75 years old.

2. The patient's refusal to participate in the study.

3. The presence of a large primary ventral hernia or postoperative ventral hernia of medium size (W2) with a transverse hernial gate size of more than 8 cm, postoperative ventral hernia of large size (W3) (according to EHS classifications), inguinal, femoral hernia, lumbar, perineal, hiatal hernia.

4. Emergency surgical intervention.

5. The physical status of the patient is ASA IV and more.

6. Previously performed hernioplasty using IPOM techniques from traditional access, Onlay, Sublay, TAR, TAPP, TEP, eTEP, SCOLA.

After the exclusion of participants who were not selected according to the inclusion and exclusion criteria, as well as who did not show up for examination, the study groups were formed separately for patients with primary and postoperative hernias. For the purpose of comparison, patients were selected from a retrospective cohort who used prostheses with an anti-adhesive coating of collagen (Parietene Composite, Parietex Composite and Symbotex) during IPOM plastic surgery.

2.2.2. Surgical intervention technique

Laparoscopic hernioplasty IPOM was performed under combined endotracheal anesthesia in the position of the patient on the operating table on his back with his arms brought to the body. The first 10- or 12-mm trocar was installed in an open manner in an area remote from the edge of the hernial gate at a distance of at least 5-10 cm. As a rule, the installation was performed laterally to the edge of the rectus abdominis muscles in the left or right mesogastric zone. Another one or two 5 mm trocars were installed under visual control according to the principle of triangulation, departing from the first trocar by 5-8 cm. Front-side vision optics of 30° were used (Karl Storz, Germany).

After performing blunt or acute access using an electrosurgical or ultrasound dissector, adhesions (if any) were separated from the hernial sac and the edges of aponeurosis, and the circular ligament of the liver was mobilized. Hernial gate suturing (IPOM-Plus technique) was performed with non-absorbable standard polypropylene thread or thread with notches of type V-Loc PBT or Stratafix 0 (3.5 Metric) or 1 (4 Metric). The implant was inserted into the abdominal cavity through a 10 or 12 mm port. The endoprosthesis was positioned on the abdominal wall in such a way that there was an overlap of at least 5 cm from the edges of the hernial gate in all directions. Preliminary fixation of the implant was performed with single transfascial ligatures. The next step was fixation using herniated staples with resorbable or nonresorbable staples, surgical intracorporeal suture or glue.

The following modifications of endoprostheses were used:

from polypropylene coated with collagen Parietene Composite (Medtronic, USA), from multifilament polyester coated with collagen Parietex Composite

(Medtronic, USA), from monofilament polyester coated with collagen Symbotex (Medtronic, USA), from polypropylene coated with sodium hyaluronate and carboxymethylcellulose Ventralight ST (Bard, USA), made of polypropylene coated with poly(oligouretanacrylate) – Reperen-16-1, Reperen-16-2 (with threads), (Ikon Lab, Russia), made of multifilament polyester with fluoropolymer coating Fluorex (Lintex, Russia).

Fixation of small endoprostheses was performed without the use of transfascial sutures. When fixing large implants, from 2 to 4 polypropylene transfascial sutures were used, previously fixed at the edges of the implants. Suturing through abdominal wall tissues was performed using a disposable needle for suturing trocar wounds EndoClose (Medtronic, USA) or a reusable suture tool for closing subcutaneous fascia according to Berci (Karl Storz, Germany).

The following methods of fixation of the endoprosthesis were used:

Non-absorbable stapler: ProTack titanium spirals (Medtronic, USA), L-0129 titanium fixers (PPP, Russia), polyester etheric ketone and stainless steel CapSure spirals (Bard, USA).

Stapler absorbable: paper clips from polymolactic acid AbsorbaTack (Medtronic, USA), from polyglycolic acid ReliaTack (Medtronic, USA), spirals from poly-D, L-lactide SorbaFix (Bard, USA), harpoon fixers from polydioxanone and copolymer L(-)-lactide and glycolide (SecureStrap, Ethicon).

Suture: non-absorbable braided polyester thread with fluoropolymer coating Fluorex (Lintex, Russia).

Adhesive: butyl-2-cyanoacrylate surgical glue Glubran 2 (GEM, Italy). A device for atraumatic laparoscopic fixation of Glutack mesh (GEM, Italy) was used to deliver the glue.

2.2.3. Research methods

Demographic indicators and initial parameters of patient health

The patients included in the study had their personal data recorded (surname, first name, patronymic, date of birth, age, gender, place of residence, phone number, name of the hospital where the operation will be performed or has already been

performed, medical history number, date of operation). When collecting anamnesis, attention was paid to such criteria as primary or postoperative hernia, duration and complications of herniation, previously performed operations and features of the course of the postoperative period, concomitant diseases, risk factors affecting the formation of a hernia. In order to obtain an overall assessment of the patient's health, examination, palpation, percussion, auscultation, height and weight measurement were performed.

The body mass index (BMI) in kg/m^2 was calculated using the formula

$$I = \frac{m}{h^2}$$

where I is the body mass index, m is body weight (kg), h is height (m) [Garrow J.S., Webster J., 1985]. According to BMI, patients were divided into groups in accordance with WHO recommendations: lack of body weight (<18.5 kg/m^2), normal body weight (18.5 – 24.9 kg/m^2), overweight (25 – 29.9 kg/m^2), grade I obesity (30 – 34.9 kg/m^2), obesity of the II degree (35 – 39.9 kg/m^2), obesity of the III degree (> 40 kg/m^2).

Parameters associated with the presence of hernia

The study of the local status was performed in the vertical and horizontal position of the patient. The localization, the size of the hernial sac and hernial gate, the number of aponeurosis defects, the fixability of the hernia, the presence of diastasis of the rectus abdominis muscles, signs of damage to the skin (maceration, dermatitis, fistula passages, etc.) were determined. In case of difficulties in determining the size of the aponeurosis defect or the presence of multiple defects, preference was given to instrumental studies (ultrasound or CT).

The area of the hernial gate was calculated according to the recommendations of the European Society of Herniology (EHS) in cm^2 as the area of an ellipse according to the formula

$$S = \pi \times a \times b$$

where S is the area (cm^2), π is the number "pi", a is the length of the small semi–axis (cm), b is the length of the large semi–axis (cm). In the presence of

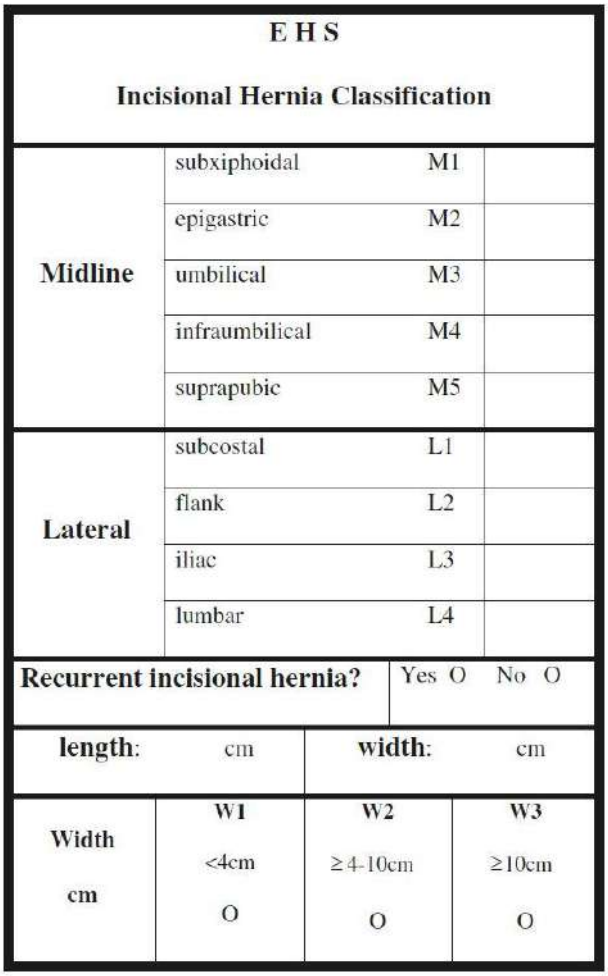
multiple aponeurosis defects, the total size of the hernial defect was determined by the boundaries of the edges of all insolvent sites (Fig. 2.2.4.1) [286].

Figure 2.2.4.1 – Determination of the length and width of the defect in single and multiple hernias.

After determining the hernia parameters, patients were divided into groups according to the classifications of primary (EHS Primary Abdominal Wall Hernia Classification) (Fig. 2.2.4.2) and postoperative hernias (EHS Incision Hernia Classification) (Fig. 2.2.4.3) of the European Society of Herniology [293].

EHS Primary Abdominal Wall Hernia Classification		Diameter cm	Small <2cm	Medium ≥2-4cm	Large ≥4cm
Midline	Epigastric				
	Umbilical				
Lateral	Spigelian				
	Lumbar				

Figure 2.2.4.2 – Classification of primary hernias of the European Society of Herniologists.



EHS Incisional Hernia Classification			
Midline	subxiphoidal	M1	
	epigastric	M2	
	umbilical	M3	
	infraumbilical	M4	
	suprapubic	M5	
Lateral	subcostal	L1	
	flank	L2	
	iliac	L3	
	lumbar	L4	
Recurrent incisional hernia?		Yes O	No O
length:	cm	width:	cm
Width cm	W1 <4cm O	W2 ≥4-10cm O	W3 ≥10cm O

Figure 2.2.4.3 – Classification of postoperative hernias by the European Society of Herniologists.

In case of detection of diastasis of the rectus abdominis muscles, its type was determined according to F.X. Nahas [296]: A – isolated diastasis of the rectus abdominis muscles that occurred after pregnancy; B – diastasis of the rectus abdominis muscles in combination with relaxation of the lateral and lower abdominal wall; C – diastasis that occurred due to congenital lateral attachment of the rectus muscles to the costal arch; D – diastasis of the rectus abdominis muscles in combination with a bad waistline. The classifications recommended by the working group of the German Society of Herniologists (DHG) and the International Society of Endogerniologists (IEHS) were also used (Fig. 2.2.4.4) [319], as well as the classification recommended by the European Society of Herniology (EHS Rectus Diastasis Classification) (Fig. 2.2.4.5) [224].

Rectus Diastasis Classification			
Midline	M1 subxiphoidal		
	M2 epigastric		
	M3 umbilical		
	M4 infraumbilical		
	M5 suprapubic		
Length: cm		Width: cm	
Width cm	W1 < 3 cm	W2 3 - ≤ 5 cm	W3 > 5 cm

Figure 2.2.4.4 – Classification of diastasis of the rectus abdominis muscles of the German Society of Herniologists and the International Society of Endogerniologists

T Type	D Inter-rectus distance	H Concomitant umbilical and/or epigastric hernia
T1 = after pregnancy	D1 = >2–3 cm	H0 = without
	D2 = >3–5 cm	
T2 = with adiposity	D3 = >5 cm	H1 = present

Figure 2.2.4.5 – Classification of diastasis of the rectus abdominis muscles of the European Society of Herniologists

Parameters related to hospitalization and surgery

Standard laboratory and instrumental examination before surgery

Before performing surgery, all patients underwent a standard laboratory and instrumental examination (general and biochemical blood analysis, coagulogram, blood group analysis, Rh factor, Kell phenotyping, antibodies to HIV, HBs-Ag, antibodies to hepatitis C virus antigens, general urinalysis, ECG, lung X-ray or fluorography, ultrasound abdominal wall, abdominal organs, veins of the lower extremities). The patients were consulted by a therapist or cardiologist, and the women by a gynecologist. If indicated, EGDS, CT scans of the abdominal wall and

abdominal organs were performed, and the function of external respiration was studied. If necessary, a standard laboratory and instrumental examination was performed after the operation (general and biochemical blood analysis, general urine analysis, ultrasound of the abdominal wall and abdominal organs).

The assessment of the patient's physical status was carried out according to the classification of the American Society of Anesthesiologists (ASA Physical Status Classification System): I – a healthy patient, II – a patient with a mild systemic disease, III – a patient with a severe systemic disease, IV – a patient with a severe systemic disease that poses a constant threat to life, V – a dying patient, the operation is performed according to vital indications, VI – brain death was diagnosed [Mayhew D. et al., 2019]. Patients with ASA IV and higher were not included in the study.

Parameters related to the endoprosthesis and the method of fixation

The area of the rectangular implant in cm^2 was calculated using the formula

$$S = a \times b$$

where S is the area (cm^2), a is the length of the smaller side (cm), b is the length of the larger side (cm).

The area of the round–shaped implant in cm^2 was calculated using the formula

$$S = \pi \times r^2$$

where S is the area (cm^2), π is the number "pi", r is the radius (cm).

The ratio of the implant area to the area of the hernial gate was calculated in relative units using the formula

$$x = \frac{S(\text{имп})}{S(\text{грвор})}$$

where x is the ratio of the area of the endoprosthesis to the area of the hernial gate, S (imp) is the total area of the endoprosthesis (cm^2), S (gr vor) is the area of the hernial gate (cm^2).

The area of the implant per fixator was calculated in cm^2 according to the formula

$$S = \frac{S(\text{имп})}{n}$$

where S is the area of the endoprosthesis per 1 fixator (cm^2), S (imp) is the total area of the endoprosthesis (cm^2), n is the number of fixators (pcs.).

When conducting a composite endoprosthesis through a trocar and positioning it in the abdominal cavity, the appearance of damage to the visceral layer was taken into account. The zones (edges, center, edges and center) and the degree of damage (mild, moderate, pronounced) were evaluated.

Parameters for assessing the safety of surgical intervention

The severity of the pain syndrome and its duration in the early postoperative period were assessed using the NRS Digital Pain Rating Scale (Numeric Rating Scale for Pain), where 0 is the absence of pain and 10 is the maximum pain. The study was performed by questionnaire before surgery, 6 hours after surgery, on the 1st, 2nd, 3rd, 4th, 5th day of the postoperative period (Appendix 3). The duration of the pain syndrome in the early postoperative period was calculated in days. The criterion for the absence of pain was considered to be zero on the NSR scale.

The safety of the performed interventions was assessed based on the number of early and late reactions and complications. During the patient's stay in the hospital and after discharge, in case of repeated treatment, reactions or complications were detected based on complaints, clinical examination, laboratory and instrumental data. Reactions and complications that occurred in the patient after discharge from the hospital, diagnosed in other medical institutions, were taken into account retrospectively based on a questionnaire 1, 3 and 12 months after surgery. The classification of surgical complications proposed by D. Dindo et al. (Clavien-Dindo Classification) was applied (Table 2.2.4.1).

Table 2.2.4.1 – Classification of surgical complications

Class	Identification
I	Any deviation from the normal course of the postoperative period without the need for medical treatment or surgical, endoscopic, radiological interventions. Pro-motility, antipyretic drugs, analgesics, diuretics, electrolyte solutions, physiotherapy are used. Wound infections eliminated during bandages are also included.

II	Any deviation from the normal course of the postoperative period requiring treatment with medications, in addition to those used for class I complications. Blood transfusion and general parenteral nutrition are included.
III	Requiring surgical, endoscopic, and radiological interventions.
IIIA	Interventions without general anesthesia.
IIIB	Interventions under general anesthesia.
IV	Life-threatening complications (including complications from the central nervous system, such as cerebral hemorrhage, ischemic stroke, subarachnoid hemorrhage, but excluding transient ischemic attack) requiring treatment in intensive care or intensive care units.
IVA	Dysfunction of one organ (including hemodialysis).
IVB	Multiple organ failure.
V	Fatal outcome.
Suffix «d»	If the patient had complications that led to disability, the suffix "d" is added to the appropriate complication class.

To assess postoperative seromas, the S. Morales-Conde classification recommended by the EHS working group [288] was used: type 0 – seroma without clinical signs; type I – clinically significant seroma lasting less than 1 month; type II – seroma lasting more than 1 month; type III – seroma lasting more than 6 months, which does not allow the patient to lead a habitual lifestyle (accompanied by discomfort, pain, cellulite phenomena), which may require treatment; type IV – seroma, accompanied by complications (chronic infection, relapse, implant rejection) and requiring treatment. Seroma was considered as a complication only in its types III and IV.

Quality of life assessment parameters

The quality of life was assessed using the EuraHS-QoL (EHS Quality of Life Scale) questionnaire recommended by the working group of the European Society of Herniologists (EHS) [294] before surgery, 1, 3 and 12 months after surgery. Parameters such as pain, activity restriction, and cosmetic dissatisfaction were evaluated on a scale from 0 to 10 (Appendix 2). In a retrospective study, the questionnaire was conducted once, in a prospective study – before surgery, 1, 3 and 12 months after surgery.

Methods for assessing spike formation

Intraoperative assessment of adhesions

During laparoscopic hernioplasty, a macroscopic assessment of the degree of adhesions was performed both in the area of hernia localization and in other parts of the abdominal cavity. The degree of adhesion was assessed according to the M.D. Mueller et al. scale: 0 – absence of adhesions; 1 – thin, avascular adhesions; 2 – thick, avascular adhesions; 3 – very dense, vascularized adhesions. The density of adhesions was assessed according to the scale of H.V. Zühlke et al. [382]: 0 – lack of adhesion; 1 – filmy, easily removable adhesions; 2 – adhesions can be separated bluntly; 3 – to eliminate adhesions, it is necessary to resort to acute dissection; 4 – a pronounced process, the separation of which may damage internal organs. During the examination of the abdominal cavity, special attention was paid to the involvement of parenchymal and hollow abdominal organs in the adhesive process.

Ultrasonic assessment of adhesion formation

To determine the optimal way to diagnose the adhesive process in the abdominal cavity, we analyzed the available radiation diagnostic methods [7, 10] and chose ultrasound diagnostics as the most affordable, standardized and economically justified method.

Ultrasound of the abdominal cavity, abdominal wall and hernial protrusion with diagnosis of viscero-parietal fusion was performed in a retrospective study once, in a prospective study – before surgery, 1 week, 1, 3 and 12 months after surgery.

The study was performed in the patient's back position with a 3.5 and 7.5 MHz sensor in In-mode on Logiq-400 devices (General Electric, USA). Viscero-parietal fusion was assessed in each of the 9 zones of the abdominal wall. The area of the hernial gate was subjected to the most careful study at the preoperative stage, and the area of the endoprosthesis installation was examined in the postoperative period. During ultrasound diagnostics of adhesions, other changes in the implant placement area were simultaneously detected, the width of the white line of the abdomen was measured, the size of the endoprosthesis was fixed with good visualization, the

volume of the liquid barrier drug was controlled in case of its recent use, in some cases a comprehensive examination of the abdominal organs was performed.

In order to facilitate the process of fixing the results obtained, the abdominal wall was divided into 9 zones: epigastrium, left and right hypochondrium, umbilical, right and left mesogastric zones, suprapubic, right and left iliac zones (Appendix 4).

The following ultrasound signs were taken into account when diagnosing adhesions:

1) rectilinear longitudinal sliding of the abdominal cavity organs (visceral slide, English visceral slide test) is the distance traveled by the underlying internal organs relative to the abdominal wall during the respiratory cycle [343]. The test was considered negative for the presence of adhesions at a distance of at least 1 cm with calm breathing and at least 2.5 cm with forced breathing or a Valsalva sample.

2) "angular" displacement is a phenomenon that occurs when the subject organs located at different depths pass through during the respiratory cycle at different distances and manifests itself as a visual effect of a "pendulum–like" movement centered at the point of localization of adhesions with the abdominal wall.

3) disturbed contour of the parietal peritoneum and transverse fascia – union, deformation or thickening of the hyperechoic line of the peritoneum and transverse fascia, the appearance of areas where this line is interrupted [157].

4) fixation of the intestine to the abdominal wall – there is no change in the contour of the intestinal loop at the height of the peristaltic wave, limitation of its longitudinal sliding, in some cases, deformation of its lumen during breathing [269].

The final assessment of the presence of viscero-parietal junctions was carried out by an ultrasound diagnostic specialist based on a comprehensive assessment of these diagnostic signs according to the methodology developed by our research group.

Clinical and economic parameters

The cost index of consumables needed to perform the operation was calculated in rubles as the sum of the cost of the endoprosthesis, fixation device, anti-adhesive barrier agent (if used), consumables, without which it is impossible to

perform surgery. Next, a direct comparison of the ratio of funds spent to the cost of the tariff was carried out, depending on the manufacturer of the endoprosthesis.

Statistical methods

The statistical analysis was carried out using the StatTech 2.8.8 program (Stattech, Russia). Quantitative indicators were evaluated for compliance with the normal distribution using the Shapiro-Wilk criterion or the Kolmogorov-Smirnov criterion. Quantitative indicators with a normal distribution were described using arithmetic averages (M) and standard deviations (SD). In some cases, with a small sample, only the arithmetic mean was calculated. Categorical data were described with absolute values. Comparison of three or more groups by a quantitative indicator, the distribution of which differed from the normal one, was performed using the Kraskel-Wallis criterion, a posteriori comparisons were performed using the Dunn criterion with the Hill correction. The comparison of percentages in the analysis of multipole conjugacy tables was performed using Pearson's chi-squared criterion.

Chapter 3. RESULTS OF THE STUDY OF STRUCTURAL, PHYSICAL, BIOMECHANICAL PROPERTIES AND BIOCOMPATIBILITY OF MODERN SYNTHETIC MESH ENDOPROSTHESES OF VARIOUS TYPES

3.1. Structure and physical properties of modern synthetic mesh endoprostheses of various types ex vivo

At the first stage of the experimental study, a selective assessment of a number of structural and physical properties was carried out in endoprostheses planned for installation in vivo.

3.1.1. A brief description of the characteristics of the examined endoprosthesis samples

Sample No. 1 (made of polyester with fluoropolymer coating)

Name: FLUOREX.

Manufacturer: Lintex (Russia).

Base material: polyester.

Coating: synthetic fluorinated rubber-like copolymer of vinylidene fluoride with hexafluoropropylene (SKF-26).

Anti-adhesive layer: no.

The thickness of the endoprosthesis: 0.31 mm.

Surface density: 36-42 g/m^2.

This sample consists of a mesh woven from biocompatible non-absorbable complex polyethylene terephthalate filaments and having a fluoro-rubber anti-adhesive coating over the entire surface of the filaments. The endoprosthesis has stable dimensions and physico-mechanical properties, the basally bonded structure provides shape stability, optimal extensibility, atraumatic, non-permeable edges when cutting, optimal volumetric porosity.

Unlike endoprostheses traditionally used in intraperitoneal hernioplasty, this implant does not have a separate biodegradable or permanent anti-adhesive layer. The originality of the solution lies in the manufacture of a mesh made of filaments

already coated with fluoropolymer. Another feature is the additional application of a fluoropolymer to an already bonded web, which allows you to eliminate inter-fiber gaps in the area of thread contact. This allows you to get rid of the wickedness effect inherent in polyester, as well as increase the elasticity of the product.

Sample No. 2 (made of polyester with a fluoropolymer coating and an additional anti-adhesive layer of carboxymethylcellulose)

Name: FLUOREX.

Manufacturer: Lintex (Russia).

Base material: polyester.

Coating: synthetic fluorinated rubber-like copolymer of vinylidene fluoride with hexafluoropropylene (SKF-26).

Anti-adhesive layer: carboxymethylcellulose.

The thickness of the endoprosthesis: 0.32 mm.

Surface density: 36-42 g/m^2.

This sample, like the previous one, is a mesh made of non-absorbable complex polyethylene terephthalate filaments and has a fluoro-rubber coating. A special feature is the presence of a separate additional anti-adhesive layer of carboxymethylcellulose, which can potentially reduce the risk of adhesions with abdominal organs. The endoprosthesis also has stable dimensions and physico-mechanical properties.

Sample No. 3 (made of polyester with an anti-adhesive layer of collagen)

Name: Symbotex.

Manufacturer: Medtronic (USA).

Base material: polyester.

Coverage: none.

Anti-adhesive layer: porcine acellular collagen.

The thickness of the endoprosthesis: 0.59 mm.

Surface density: 66 g/m^2.

This sample has a mesh base of volumetric weaving made of monofilament polyester. The cells have a hexagonal shape without thickened columns. A

transparent protective absorbent layer of collagen, unlike previous models of implants from this manufacturer, Parietex Composite, has increased resistance to mechanical damage, which ensures its greater safety and increases anti-adhesive properties. The mesh is color-coded in the center to facilitate positioning in the area of the abdominal wall defect. At the moment, the effectiveness and safety of this modification of the endoprosthesis, along with the following sample (Ventralight ST), is the most studied.

Sample No. 4 (made of polypropylene and polyglycolic acid with an anti-adhesive layer of Sepra)

Name: Ventralight ST.

Manufacturer: Bard (USA).

Base material: polypropylene and polyglycolic acid.

Coverage: none.

Anti-adhesive layer: chemically modified sodium hyaluronate, carboxymethylcellulose and polyethylene glycol (Sepra).

The thickness of the endoprosthesis: 0.55 mm.

Surface density: no more than 213 g/m^2.

This sample has a mesh base made of polypropylene monofilament with the inclusion of polyglycolic acid filaments, while its surface density is significantly higher than other samples under study. The anti-adhesive surface is represented by a separate absorbable hydrogel layer consisting of chemically modified sodium hyaluronate, carboxymethylcellulose and polyethylene glycol (trademark Sepra). A feature of the layer is its ability to spread to the surrounding tissues, as a result of which the elements fixing the mesh are enveloped and the anti-adhesive protection is increased. This property also allows, if necessary, cutting and cutting of the implant.

Sample No. 5 (made of polypropylene with an anti-adhesive layer of Reperen)

Title: Reperen 16.

Manufacturer: Ikon Lab (Russia).

Base material: polypropylene.

Coverage: none.

Anti-adhesive layer: poly(oligouretanacrylate) (Reperene).

The thickness of the endoprosthesis: 0.63 mm.

The surface density of the reinforcing layer is 38-44 g/m^2.

This sample is a domestic development. It is represented by a mesh base made of lightweight polypropylene and a permanent anti-adhesive layer of monolithic spatially crosslinked poly(oligouretanacrylate) (trademark Reperen). In the manufacture of this prosthesis, the mesh base is poured into a polymer solution, after which UV polymerization is performed. As a result, there is a mesh polypropylene base on the parietal side, which promotes integration into tissues, and a layer on the visceral side that prevents adhesion. The biomechanical properties and biocompatibility of this endoprosthesis, along with the first two samples, are currently the least studied.

3.1.2. Composition, physical properties and mechanical strength of the samples

Of the presented endoprosthesis samples, 3 have a polyester base (both FLUOREX and Symbotex variants), and the distinctive feature of the Symbotex implant was volumetric mesh weaving and the use of monofilament polyester. In 2 more samples, the base is made of polypropylene (Ventralight ST and Reference 16) (Table 3.1.2).

4 endoprostheses have a "classic" anti-adhesive layer, and one of them (Reperen 16) has a permanent one, the other 3 (FLUOREX with an additional protective layer, Symbotex and Ventralight ST) have a temporary one. One of the prostheses (FLUOREX) does not have a traditional separate anti-adhesive layer. Anti-adhesive properties are achieved due to the presence of a fluoropolymer coating for each thread and the implant web as a whole. Sample No. 2 (FLUOREX with an additional anti-adhesive layer), in addition to the carboxymethylcellulose plate, also has a fluoropolymer coating.

The Ventralight ST endoprosthesis has the maximum surface density declared by the manufacturer. It is more than 213 g/m^2. Both FLUOREX prostheses have the

lowest surface density – from 36 to 42 g/m^2. According to this indicator, Symbotex and Reperen implants occupy an intermediate position. The largest thickness is the Reperen 16 endoprosthesis – 0.63 mm, the smallest FLUOREX endoprosthesis – 0.31 mm.

After the studies carried out on a bursting machine, the Ventralight ST endoprosthesis had the greatest bursting load, along the loop row it was 31.3 N, along the loop column it was 48.3 N. It turned out to be slightly less at the Reperen implant 16 - 27.5 N in both directions. In the Symbotex endoprosthesis, unlike others, this indicator along the loop row turned out to be less than along the loop column – 24.5 N versus 21.1 N. FLUOREX implants along the loop row had the lowest breaking load among all endoprostheses – 15.1 N, and along the loop column this indicator was only slightly inferior to the Ventralight ST endoprosthesis – 41.5 N (Fig. 3.1.2.4).

The maximum tensile elongation was also shown by Ventralight ST endoprostheses – 108% along the loop row and 65% along the loop column. High rates were noted in the Reperen implant of 16-96% in both directions. The discontinuous elongation along the loop row of the Symbotex endoprosthesis was 2 times less than that of the Ventralight ST and Reperen endoprostheses, and along the loop column it was slightly lower than that of Ventralight ST and FLUOREX – 52%. The indicators of both FLUOREX endoprostheses along the loop row exceeded only the indicators of Symbotex – 68%, and along the loop column turned out to be the lowest among all the studied samples – 32%.

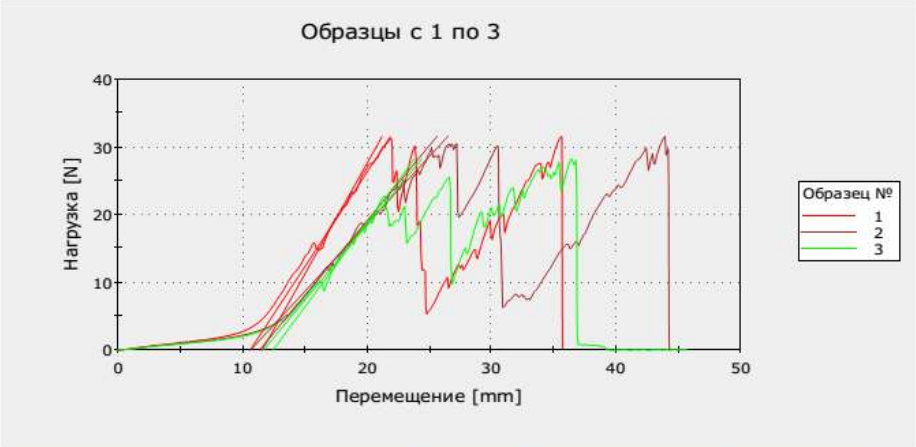
Table 3.1.2 – Composition, physical properties and biomechanical strength of samples under uniaxial tension

Sample number	An endoprosthesis variant	Base	Coating or anti-adhesive layer	Surface density declared by the manufacturer, g/m^2	Number of samples	Parameters				
						Thickness, mm	Along the loop row		Along the looped column	
							Breaking load, N	Breaking elongation, %	Breaking load, N	Breaking elongation, %
1	FLUOREX	PE	SKF-26	36-42	9	0,31	15,1	68	41,5	32
2	FLUOREX with AC	PE	SKF-26 and KMTS	36-42	9	0,32	15,1	68	41,5	32
3	Symbotex	PE	Collagen	66	10	0,59	24,5	53	21,1	52
4	Ventralight ST	PP	GC-CMC	No more than 213	6	0,55	31,3	108	48,3	65
5	Reperen 16	PP	Reperen	64	2	0,63	27,5*	96*	-	-

The width of the sample strip is 10 mm, the clamping length is 25 mm, the speed is 50 m/min

PE – polyester; PP – polypropylene; CMC – carboxymethylcellulose; GC-CMC – hyaluronic acid and carboxymethylcellulose; AC – anti-adhesive layer

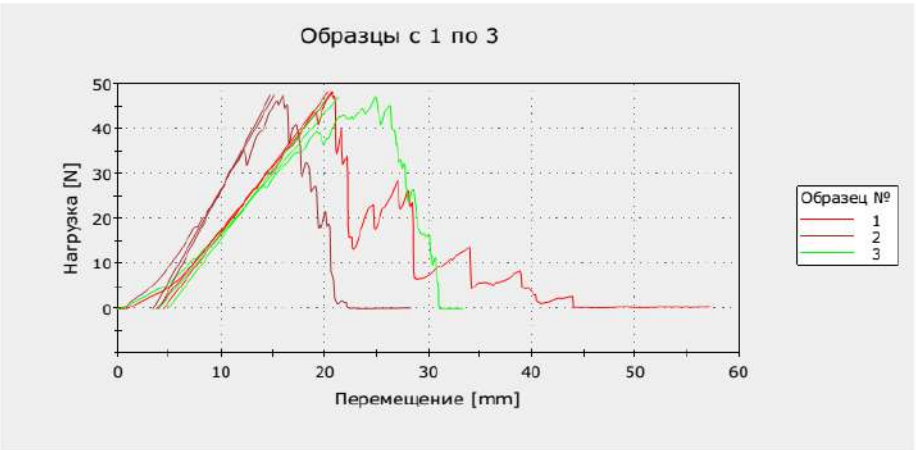
* – tests were carried out for one direction (the structure is homogeneous in two directions)



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,55000	14,94556	35,50564	5,73621
2	25,00000	10,00000	0,55000	10,09555	43,84744	5,74704
3	25,00000	10,00000	0,50000	12,47085	36,36921	5,65217

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	31,54917	24,92296	42,61500	
2	31,60871	33,21253	52,62700	
3	28,26085	24,69534	43,64800	

a

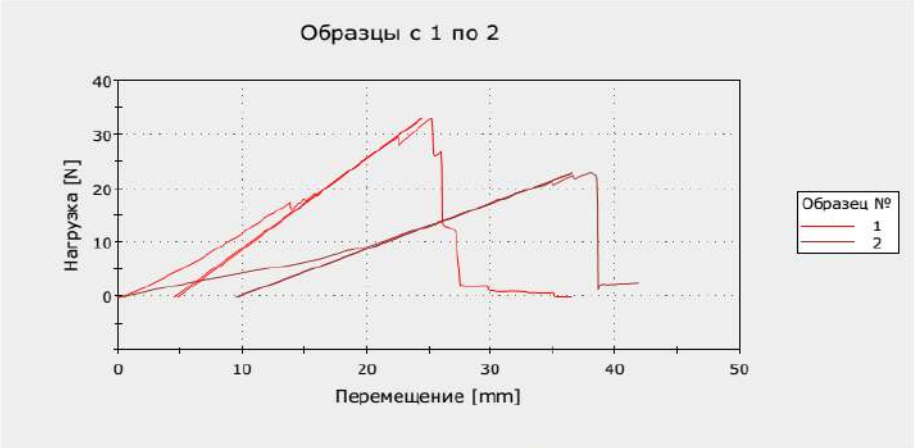


	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,50000	14,11736	20,65721	9,60444
2	25,00000	10,00000	0,50000	22,01303	15,99046	9,46823
3	25,00000	10,00000	0,50000	15,23683	24,82373	9,38703

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	48,02221	16,23829	24,80000	
2	47,34116	12,53069	19,20000	
3	46,93515	20,93151	29,80000	

b

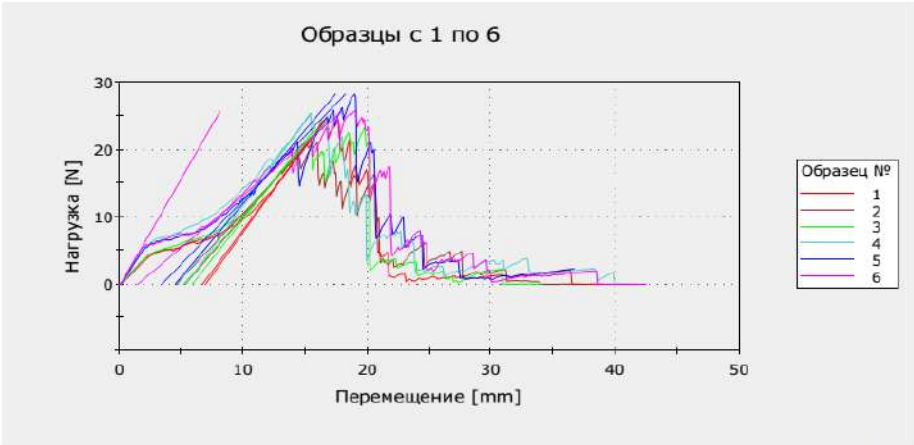
Figure 3.1.2.1 – Indicators of breaking load and tension for Ventralight ST endoprosthesis specimens. *a* – for a loop row; *b* – for a loop column.



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,63000	6,71045	25,16113	5,23991
2	25,00000	10,00000	0,63000	3,36862	38,07389	3,63617

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	33,01141	20,61204	30,20000	
2	22,90786	28,47584	45,70000	

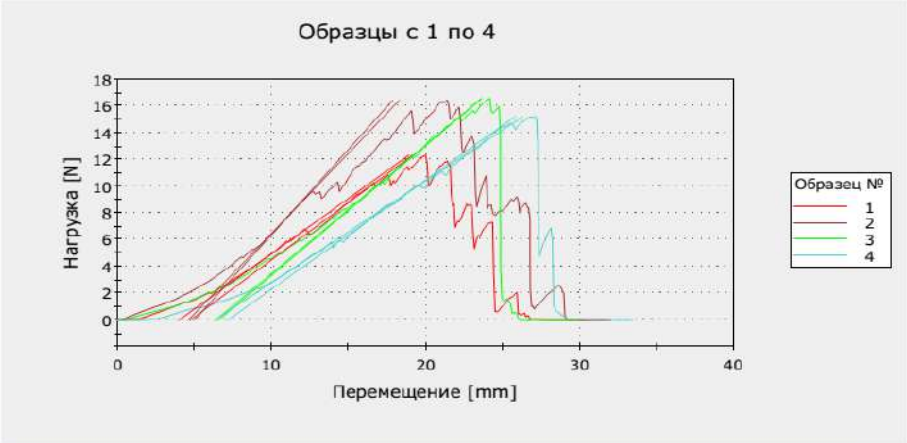
Figure 3.1.2.2 – Indicators of breaking load and tension for the samples of the Reperen endoprosthesis 16.



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,50000	12,79586	17,66033	4,86689
2	25,00000	10,00000	0,50000	9,79344	15,99528	4,22950
3	25,00000	10,00000	0,50000	11,74242	19,81684	4,65201
4	25,00000	10,00000	0,50000	12,65812	15,41071	5,06788
5	25,00000	10,00000	0,50000	10,91204	18,98687	5,63888
6	25,00000	10,00000	0,50000	16,05659	19,07349	5,13999

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	24,33443	10,91482	21,20000	
2	21,14751	10,62576	19,20000	
3	23,26004	14,56962	23,79200	
4	25,33941	10,64846	18,50000	
5	28,19439	15,51153	22,79400	
6	25,69996	17,54157	22,90000	

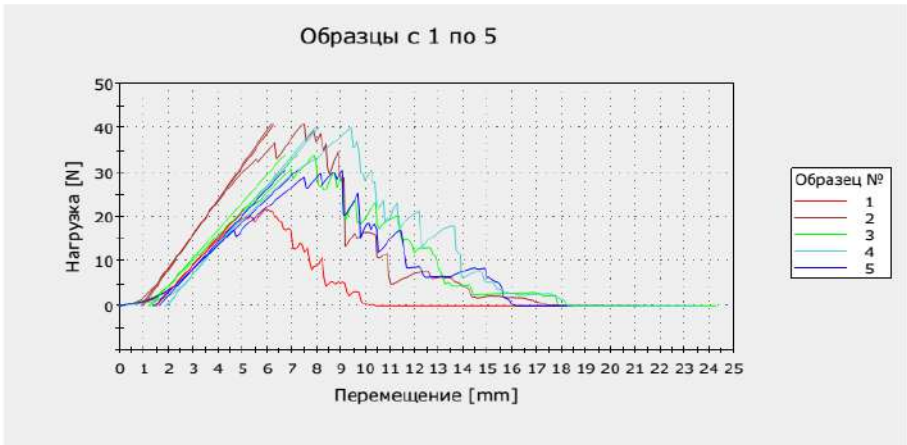
Figure 3.1.2.3 – Indicators of breaking load and tension for Symbotex endoprosthesis samples along the loop row.



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,28000	7,37206	19,99012	4,40584
2	25,00000	10,00000	0,28000	11,40225	21,40724	5,86396
3	25,00000	10,00000	0,28000	8,54696	24,15702	5,91203
4	25,00000	10,00000	0,28000	6,78921	27,07502	5,43214

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	12,33636	15,27032	24,00000	
2	16,41910	16,80443	25,70000	
3	16,55369	17,59666	29,00000	
4	15,21000	19,94183	32,50000	

a



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,28000	54,47262	5,99634	7,73757
2	25,00000	10,00000	0,28000	69,99063	7,49052	14,65342
3	25,00000	10,00000	0,28000	50,19689	7,90718	12,14433
4	25,00000	10,00000	0,28000	59,17457	9,40717	14,30613
5	25,00000	10,00000	0,28000	53,31563	9,07364	10,91047

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	21,66521	4,54351	7,20000	
2	41,02956	6,61797	9,00000	
3	34,00413	6,64209	9,50000	
4	40,05717	7,53416	11,30000	
5	30,54931	7,68027	10,90000	

b

Figure 3.1.2.4 – Indicators of breaking load and tension for FLUOREX endoprosthesis samples. *a* – for a loop row; *b* – for a loop column.

3.2. Biomechanical properties and biocompatibility of modern synthetic mesh endoprostheses of various types in vivo

3.2.1. Assessment of biomechanical properties and biocompatibility of various endoprostheses and decellularized porcine peritoneum (1st series of experiment)

The main task of the 1st series of the experiment was to assess the possibility of safe use of modern mesh endoprostheses of various designs in IPOM hernioplasty [18]. A comparison of the properties of both Symbotex and Ventralight ST implants, which have proven themselves well during long–term clinical use, and the latest domestic developments - FLUOREX endoprostheses made of polyester with a fluoropolymer coating and FLUOREX with an additional anti-adhesive layer of carboxymethylcellulose. Also at this stage, the prospects of using a biological plate from a decellularized peritoneum to create an anti-adhesive layer of a composite implant were evaluated.

3.2.1.1. Operational characteristics

The operation time for the installation of 6 implants ranged from 25 to 40 minutes (average time 31.67±6.24 min.). No gross damage to the base of the prosthesis or visceral anti-adhesive layer, as well as intraoperative complications were noted. In some cases, inadequate screwing of the spiral clamps was observed, which was eliminated by removing them and re-fixing them in this area.

The time of installation of one implant ranged from 2 to 5 minutes (on average 3.06±0.97 minutes) (Fig. 3.2.1.1.1). It was the smallest when using the Symbotex prosthesis (on average 2.33 minutes), the largest was the FLUOREX implant with an additional anti–adhesive layer and a plate made of pork peritoneum (on average 4.0 minutes).

The most convenient implants were Symbotex and FLUOREX, which received 5.0 points each, followed by Reperen 16 and FLUOREX endoprostheses with an additional anti-adhesive layer with 4.67 points (Fig. 3.2.1.1.2). The least

convenient was a biological plate made of pork peritoneum (3.0 points), which has weak rigidity. Less rigidity was observed in both variants of FLUOREX implants, which in some cases was manifested by some deviation of their edges from the peritoneum with stronger screwing of the spiral fixators (Fig. 3.2.1.1.3).

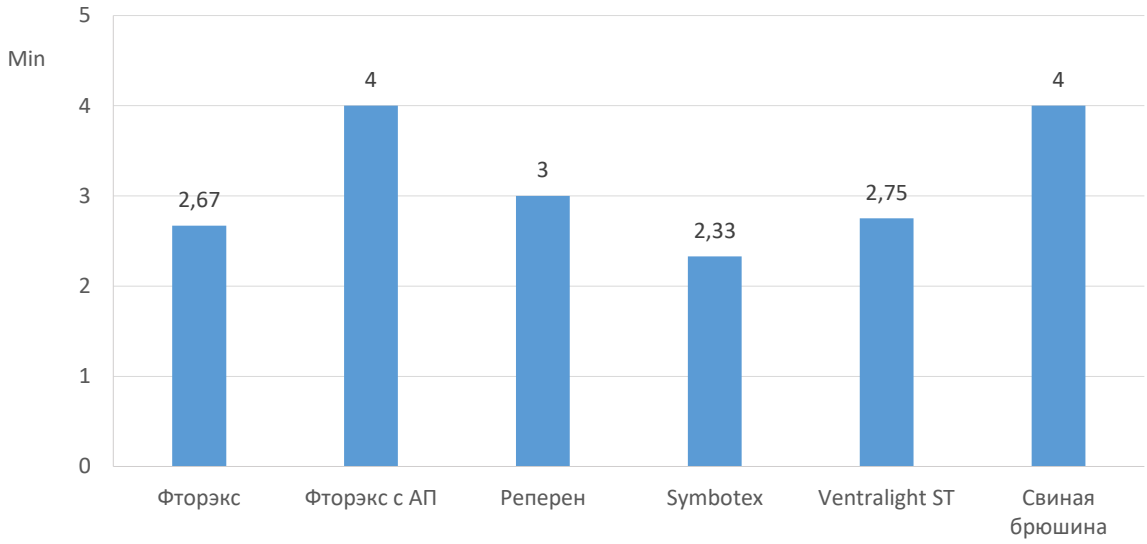


Figure 3.2.1.1.1 – The average time of installation of endoprostheses

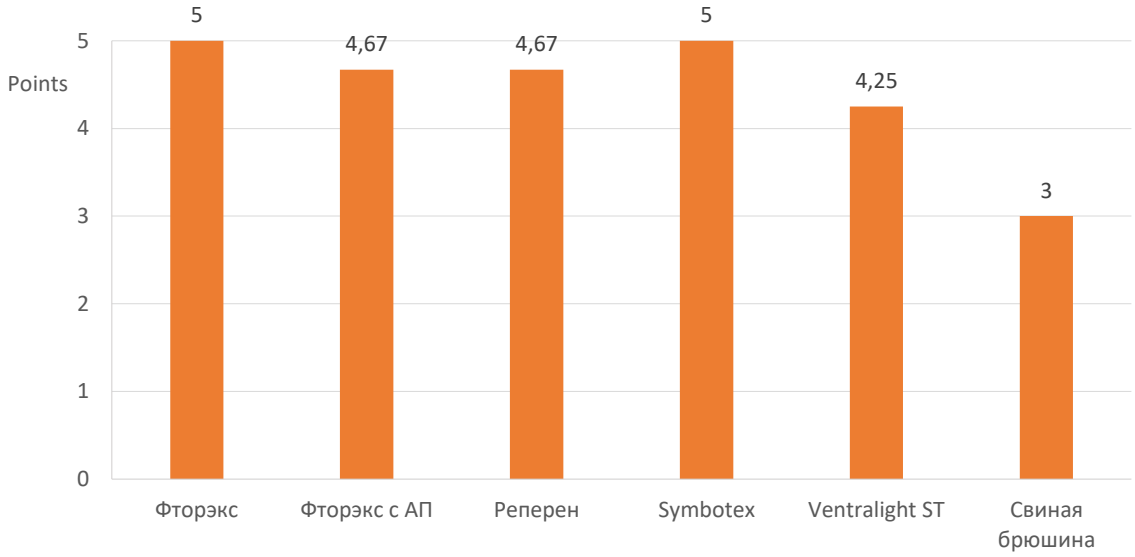


Figure 3.2.1.1.2 – Performance characteristics of endoprostheses. The score is from 0 to 5

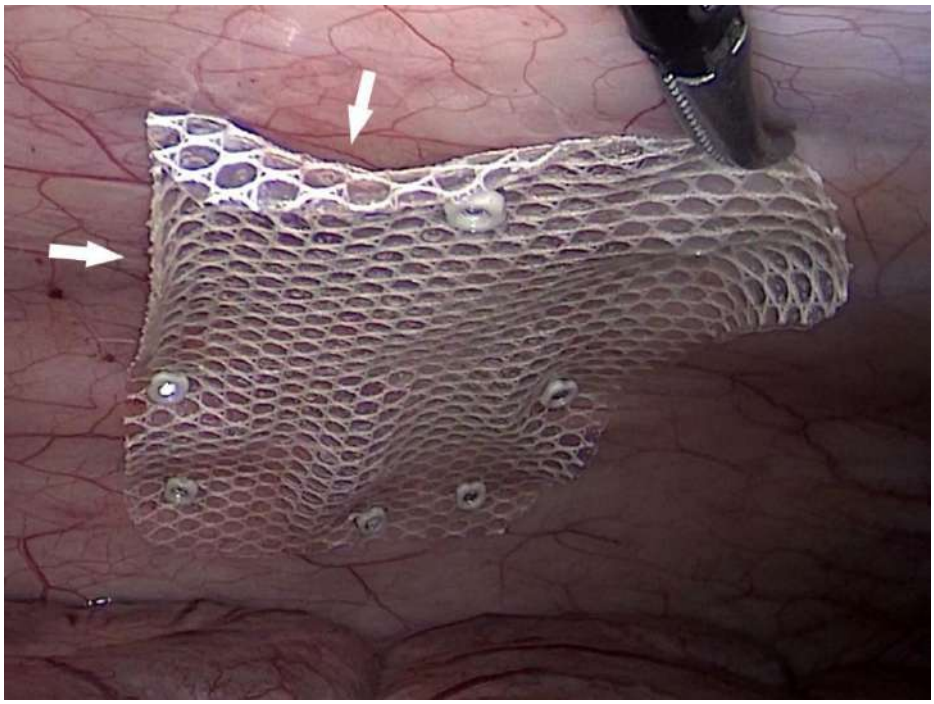


Figure 3.2.1.1.3 – Separation of the edges of the FLUOREX implant with fluoropolymer and additional anti-adhesive coating from the surface of the peritoneum during fixation (intraoperative photograph during installation of the prosthesis). *The arrows indicate the areas where the edges of the endoprosthesis do not fit tightly to the peritoneum.*

3.2.1.2. Inflammation, deformation and retraction

All the animals involved in the experiment survived. They were actively gaining weight in accordance with the growth rate. Early and late reactions and postoperative complications were not observed. Adhesive joints were not detected in the installation area of the trocar ports.

Pronounced visual signs of inflammation in the form of edema and hyperemia in the implant placement area were noted in only one case when using the Reperen 16 endoprosthesis 45 days after the first operation (Fig. 3.2.1.2.1). These changes were resolved by the end of the experiment (Table 3.2.1.2.1).

Deformation by 45 days was observed on the surface of 1 of 3 FLUOREX implants with an additional anti-adhesive layer and 1 of 2 pig peritoneum prostheses. By the 90th day, the deformation process had progressed. Already 2 out of 3 FLUOREX implants with an additional anti-adhesive coating and all plates of the porcine peritoneum had its signs. By the end of the experiment, this process also affected the FLUOREX and Reperen 16 implants. The least pronounced deformation was noted when using endoprostheses with a protective layer of hyaluronic acid and carboxymethylcellulose Ventralight ST, and when using a prosthesis coated with Symbotex collagen, it was absent (Fig. 3.2.1.2.2).

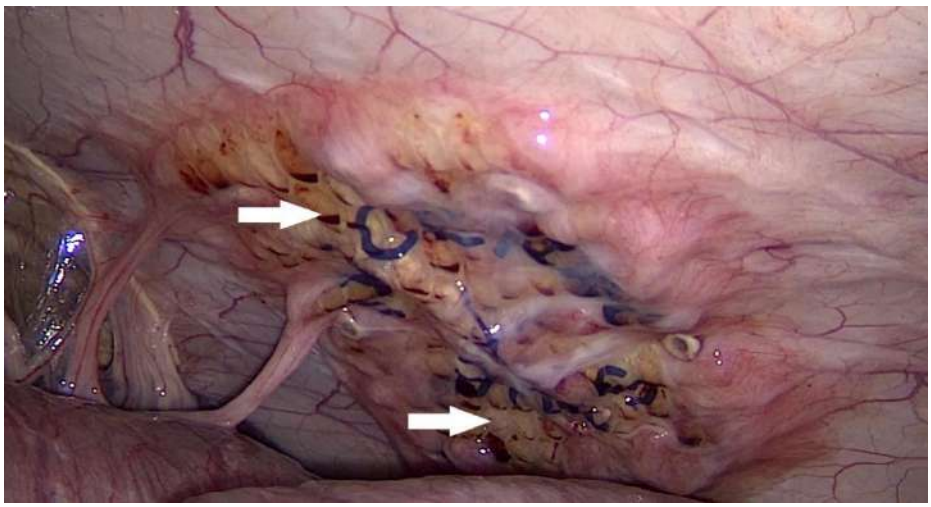


Figure 3.2.1.2.1 – Signs of inflammation in the area of the installation of the Reperen 16 endoprosthesis (intraoperative photo on the 45th day of the experiment). *There are areas of hyperemia and edema. The arrows indicate the areas where the neoperitoneum is absent.*

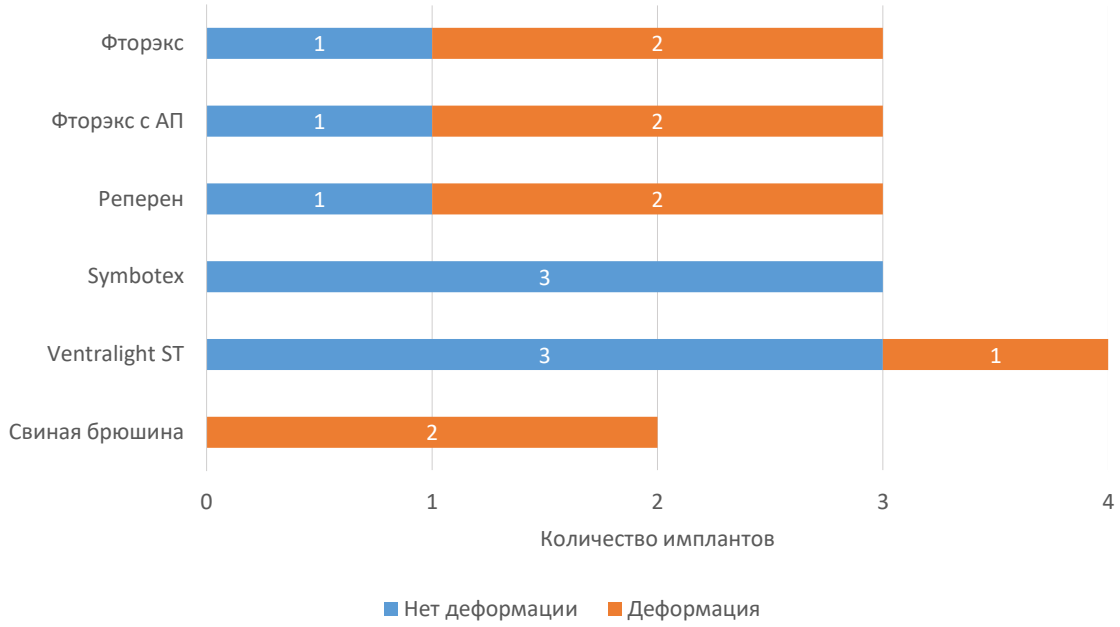


Figure 3.2.1.2.2 – The number of deformed endoprostheses by the 90 days of the experiment

Table 3.2.1.2.1 – Results of evaluation of inflammation, deformation and retraction of endoprostheses at the experimental stages

№	Name of the endoprosthesis	Anti-adhesive coating or layer	Inflammation*		Deformation*		Retraction*		Retraction area, %	
			45 days	90 days	45 days	90 days	45 days	90 days	45 days	90 days
1	FLUOREX (n = 3)	Fluoropolymer	0/3	0/3	0/3	2/3	0/3	3/3	-	21,03
2	FLUOREX with AP (n = 3)	Fluoropolymer and CMC	0/3	0/3	1/3	2/3	0/3	2/3	-	17,30
3	Reperen 16 (n = 3)	Reperen	1/3	0/3	0/3	2/3	1/3	2/3	-	10,93
4	Symbotex (n = 3)	Collagen	0/3	0/3	0/3	0/3	0/3	0/3	-	0
5	Ventralight ST (n = 4)	GC-CMC	0/4	0/4	0/4	1/4	0/4	2/4	-	5,48
6	Pork peritoneum (n = 2)	No	0/2	0/2	1/2	2/2	0/2	0/2	-	0

*AP – anti-adhesive coating; CMC – carboxymethylcellulose; GC-CMC – hyaluronic acid and carboxymethylcellulose; * – the ratio of the number of implants with the presence of changes to the total number of implants*

The retraction of the endoprosthesis during laparoscopy on day 45 was visually clearly determined only in 1 out of 3 Reperen prostheses. At autopsy on day 90, all FLUOREX implants showed signs of retraction, 2 out of 3 Reperen 16 implants and 2 out of 3 FLUOREX prostheses with an additional protective layer (Fig. 3.2.1.2.3c, 3.2.1.2.3d). Ventralight ST endoprostheses showed less pronounced wrinkling (2 out of 4). The best results with complete absence of signs of retraction were noted when using a Symbotex implant and a plate made of pork peritoneum (Fig. 3.2.1.2.3a, 3.2.1.2.3b). The total percentage of implant retraction by 90 days is shown in Fig. 3.2.1.2.4.

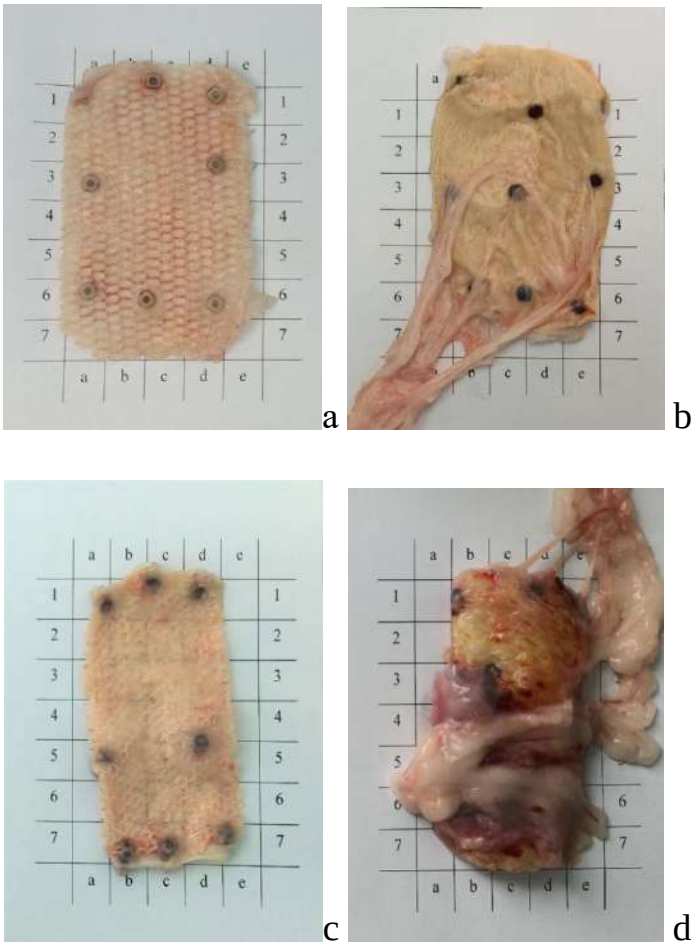


Figure 3.2.1.2.3 – Endoprostheses without retraction and with retraction by 90 days of the experiment. *a, b – absence of retraction in the Symbotex implant and the pork peritoneum plate, c, d – retraction of FLUOREX and Reperen implants 16. The price of dividing the mesh is 1.0 cm.*

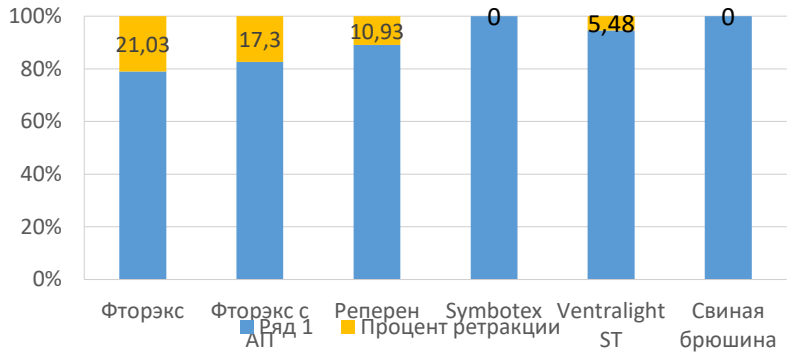


Figure 3.2.1.2.4 – Retraction of endoprostheses by 90 days of the experiment

The absorbable fixators retained their structure by the end of the experiment. In both groups, migration of part of the fixators in 1/3 of the implants (33.3%) was noted by the 90th day. More often, 1 or 2 fixators out of 8 were missing, but in one case, when using a FLUOREX implant with an additional anti-adhesive coating, the number of missing non-absorbable fixators reached 4 (Fig. 3.2.1.2.5).

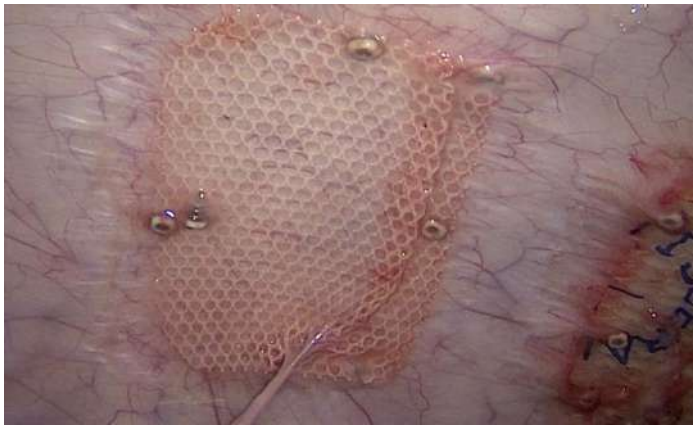
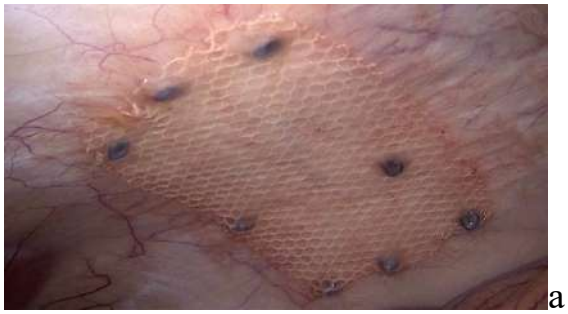


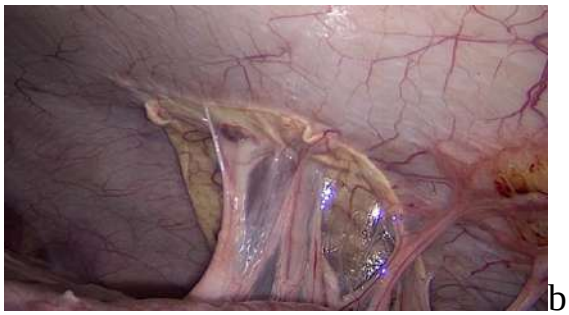
Figure 3.2.1.2.5 – Migration of fixators to 45 days of the experiment (intraoperative photography). *There is a lack of clamps at the bottom edge and in the upper left corner.*

3.2.1.3. Spike formation

During the observation period, no clinical manifestations and behavioral reactions indicating the effect of adhesions on the condition of animals were noted. After 45 and 90 days, adhesion phenomena were detected only in the areas of

installation of a number of implants (Fig. 3.2.1.3.1), no adhesive adhesions were found in other parts of the abdominal cavity.


a


b

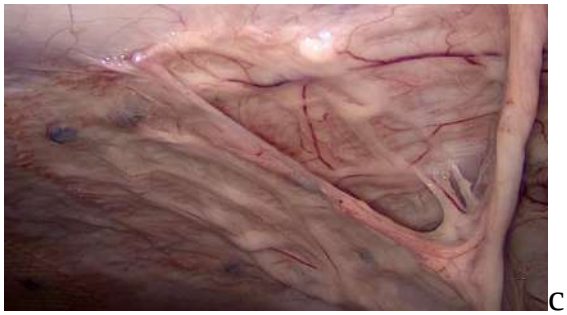

c

Figure 3.2.1.3.1 – The appearance of the localization zone of endoprostheses with varying degrees of severity of the adhesive process. *a – there are no adhesions (FLUOREX endoprosthesis), b – thin omentum adhesions (pork peritoneum plate), c – pronounced adhesions (Symbotex endoprosthesis).*

When assessing the number of implants with adhesion phenomena, FLUOREX implants with an additional anti-adhesive coating (adhesions mainly consisted of single moorings), Reperen 16 and Symbotex (2 out of 3 prostheses) showed the worst results by 45 days. The results were better when using Ventralight ST and porcine peritoneum endoprostheses, in the area of which adhesions were

noted in half of the cases (2 out of 4 and 1 out of 2, respectively). Adhesions were formed less often when using an implant with fluoropolymer coating FLUOREX (1 prosthesis out of 3) (Table 3.2.1.3.1). After 90 days, the number of implants with adhesions decreased. This indicator turned out to be worse when using a Reperen 16 prosthesis (2 out of 3 prostheses) and a pork peritoneum plate (1 out of 2 prostheses). Both fluoropolymer-coated implants and a prosthesis with a protective layer of Symbotex collagen occupied an intermediate position (1 out of 3 prostheses each). The best indicator was found when using implants with a visceral layer of hyaluronic acid and carboxymethylcellulose Ventralight ST (1 prosthesis out of 4).

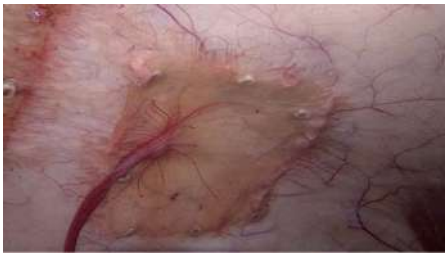
Table 3.2.1.3.1 – The results of the assessment of adhesions in the area of localization of endoprostheses at the stages of the experiment

№	Name of the endoprosthesis	Anti-adhesive coating or layer	The presence of adhesions*		Involvement of organs in the adhesive process*		Localization of adhesions on the implant surface		The area of the implant involved in adhesions (according to P.A. Lucas et al.), points		Type of adhesions (according to M.D. Muller et al.), points		Adhesive strength (according to H.V. Zühlke et al.), points		Integral assessment of spike formation (according to M.P. Diamond), points	
			45 days	90 days	45 days	90 days	45 days	90 days	45 days	90 days	45 days	90 days	45 days	90 days	45 days	90 days
1	FLUOREX (n = 3)	Fluoropolymer	1/3	1/3	0/3	0/3	Edges	Edges and center	0,33	0,33	0,67	0,33	0,67	0,67	1,67	1,67
2	FLUOREX with AP (n = 3)	Fluoropolymer and CMC	2/3	1/3	0/3	0/3	The "mooring" of the edge and the center	Edges and center	0,67	0,33	0,67	0,33	1,00	0,67	2,33	1,67
3	Reperen 16 (n = 3)	Reperen	2/3	2/3	1/3	1/3	Edges Edges and center	"Mooring" Edges and center	1,33	1,33	1,33	1,33	1,67	1,33	4,67	3,67
4	Symbotex (n = 3)	Collagen	2/3	1/3	0/3	0/3	"Mooring" Edges and center	Edges and center	1,00	0,67	1,00	0,67	1,33	0,67	3,33	2,00

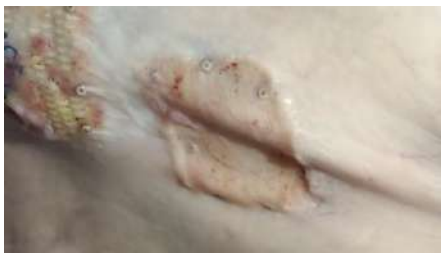
5	Ventralight ST (n = 4)	GC-CMC	2/4	1/4	1/4	1/4	"Mooring" Edges and center	Edges and center	1,25	0,75	0,75	0,50	1,25	0,50	3,25	1,75
6	Pork peritoneum (n = 2)	No	1/2	1/2	0/2	0/2	Edges	Edges and center	0,50	1,00	1,00	1,00	1,00	1,00	2,50	2,50

*AP – anti-adhesive coating; CMC – carboxymethylcellulose; GC-CMC – hyaluronic acid and carboxymethylcellulose; * – the ratio of the number of implants with adhesions to the total number of implants is indicated*

It was not possible to identify the dependence of the area of localization of adhesions on the implant surface on its modification due to a small sample. A decrease in the number of implants with adhesions by 90 days in all cases was associated with the resorption of single "mooring", which were observed by 45 days and were absent by the end of the experiment (Fig. 3.2.1.3.2). At the 45 day stage, in addition to the "mooring", adhesions were noted in 3 cases only along the edges of the implant, in 4 more cases – on the edges and in the center. By the 90th day, adhesions along the edges were no longer detected, and where they had been observed earlier, adhesions also took place in the central implantation zones.



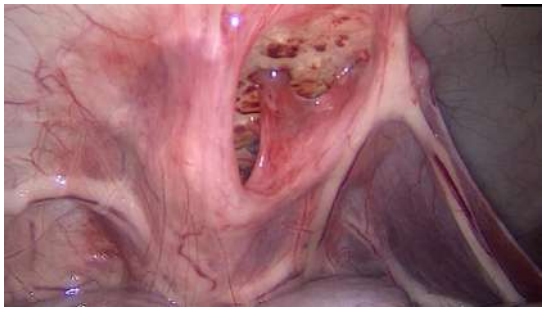
a



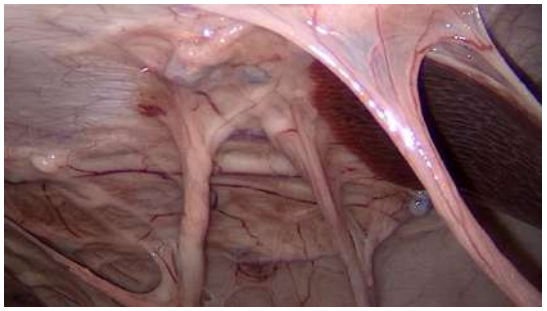
b

Figure 3.2.1.3.2 – Resorption of a single vascularized "mooring" on the surface of the endoprosthesis. *a – "mooring" on the surface of the Ventralight ST endoprosthesis (intraoperative photo on day 45), b – absence of "mooring" (autopsy photo on day 90).*

A pronounced adhesive process involving the right lobe of the liver by 45 and 90 days was noted in 2 cases when implants were installed in the upper floor of the abdominal cavity in close contact with the parenchymal organ [8]. In the first case, the Reperen 16 endoprosthesis was used, in the second – Ventralight ST. Both implants were fixed with absorbable spirals (Fig. 3.2.1.3.3).

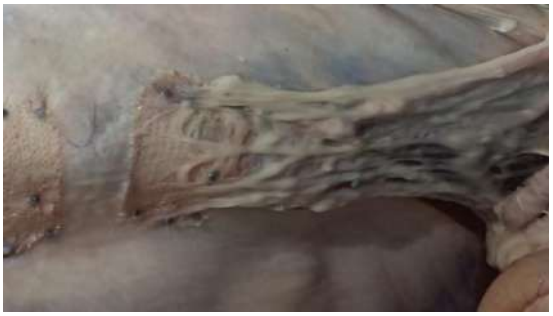


a



b

c



d

Figure 3.2.1.3.3 – Adhesions with the liver during the installation of implants at the border with the upper floor of the abdominal cavity. *a, b – the appearance of the Reperen and Ventralight ST endoprostheses during laparoscopy on day 45; c, d – the same endoprostheses during autopsy on day 90. The implants are completely covered by adhesions.*

The highest average adhesion area, calculated by the method of P.A. Lucas et al., was observed on day 45 when using the Reperen 16 implant. It was 1.33 points. Ventralight ST endoprostheses also showed high figures (1.25 points) at this stage. The lowest results were obtained using both variants of FLUOREX implants (from 0.33 to 0.67 points) and pork peritoneum plates (0.5 points). By 90 days, the area of adhesion to fluoropolymer-coated implants decreased and amounted to 0.33 points for both variants, which turned out to be the best indicators. Ventralight ST endoprostheses also showed a decrease in the area of adhesions. The results of the Reperen 16 implants remained unchanged by 90 days, and the pork peritoneum turned out to be the only one of all implantable materials that showed an increase in the area of adhesions (from 0.5 to 1.0 points). It was noted that the maximum area of adhesion formation on the surface of the endoprosthesis was with the use of absorbable fixators.

The assessment of the appearance of adhesions, carried out according to the method of M.D. Muller et al., took into account the absence of dense vascularized adhesions. In most cases, there were subtle avascular omentum adhesions. The results at all stages of the study were slightly worse for the Reperen 16 implant (1.33 points each) and the pork peritoneum plate (1.0 points each). The best results by 90 days were noted with the use of both variants of endoprostheses with fluoropolymer coating FLUOREX (0.33 points each) and implants with a protective layer of hyaluronic acid and carboxymethylcellulose Ventralight ST (0.5 points).

The adhesive strength, estimated by H.V. Zühlke et al., tended to decrease by the end of the experiment. The indicator at all stages turned out to be higher when using a Reperen 16 implant (1.67 and 1.33 points by 45 and 90 days, respectively) and a pork peritoneum plate (1.0 point each). By day 90, Ventralight ST endoprostheses had the lowest values (0.5 points). Also, good results (0.67 points) were noted when using Symbotex endoprostheses and both variants of FLUOREX implants.

In the integral assessment of adhesion formation according to the M.P. Diamond method, the lowest adhesion formation at all stages was noted when using FLUOREX prostheses (1.67 points at each stage) and FLUOREX with an additional anti–adhesive layer (2.33 and 1.67 points), the highest when using the Reperen 16 prosthesis (4.67 and 3.67 points). As with other parameters of adhesion formation, there was a tendency to decrease the severity of the adhesive process from 45 to 90 days (Fig. 3.2.1.3.4).

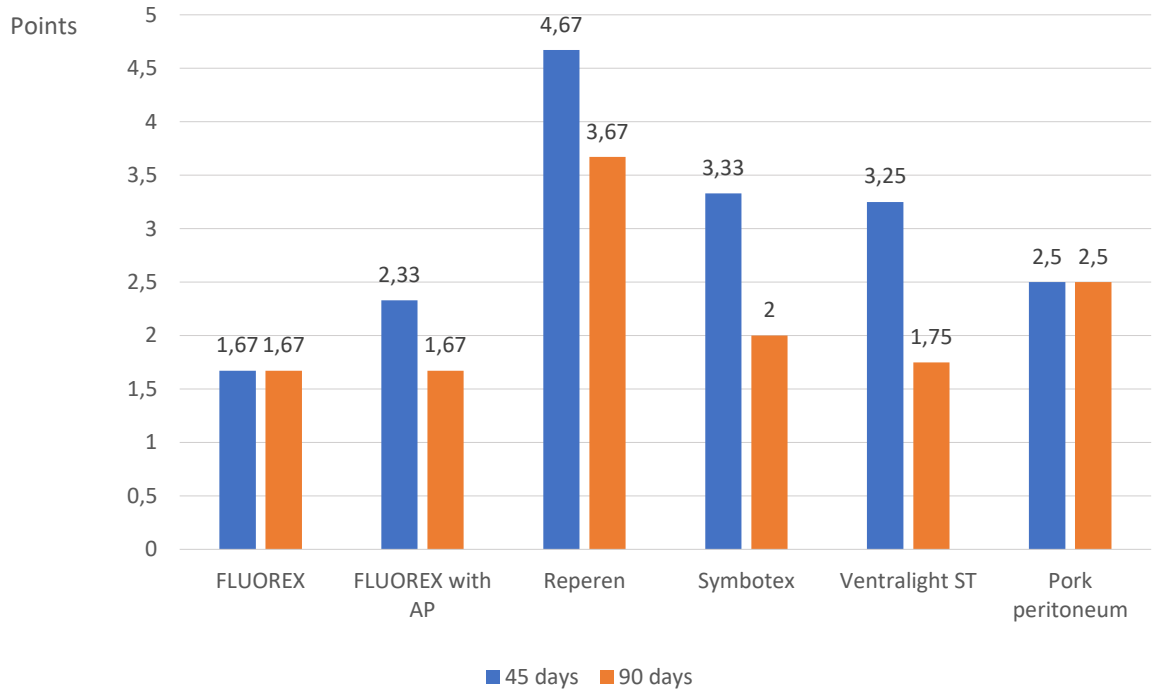


Figure 3.2.1.3.4 – Integral assessment of adhesions in the area of implant localization using the M.P. Diamond technique. *The average score is indicated on a scale from 0 to 11 for all variants of endoprostheses.*

Table 3.2.1.4.1 – The results of the evaluation of the studied parameters depending on the modification of the endoprosthesis

Parameter		Units of measurement	The observation stage	Modification of the endoprosthesis						Reliability (p)
				FLUOREX (n = 3)	FLUOREX with AP (n = 3)	Reperen (n = 3)	Symbotex (n = 3)	Ventralight ST (n = 4)	Pork peritoneum (n = 2)	
Inflammation		Implants Abs. (%)	45 days	0 (0,0)	0 (0,0)	1 (33,3)	0 (0,0)	0 (0,0)	0 (0,0)	0,381
			90 days	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	-
Migration of fixators		Implants Abs. (%)	45 days	-	-	-	-	-	-	-
			90 days	1 (33,3)	1 (33,3)	0 (0,0)	1 (33,3)	3 (75,0)	0 (0,0)	0,344
Deformation		Implants Abs. (%)	45 days	0 (0,0)	1 (33,3)	0 (0,0)	0 (0,0)	0 (0,0)	1 (50,0)	0,288
			90 days	2 (66,7)	2 (66,7)	2 (66,7)	0 (0,0)	1 (25,0)	2 (100,0)	0,221
Retraction		Implants Abs. (%)	45 days	0 (0,0)	0 (0,0)	1 (33,3)	0 (0,0)	0 (0,0)	0 (0,0)	0,381
			90 days	3 (100,0)	2 (66,7)	2 (66,7)	0 (0,0)	2 (50,0)	0 (0,0)	0,123
Retraction area		Percentages Me (Q1 – Q3)	45 days	-	-	-	-	-	-	-
			90 days	19 (16 – 25)	19 (10 – 26)	11 (5 – 16)	0 (0 – 0)	3 (0 – 8)	0 (0 – 0)	0,128
The presence of adhesions		Implants Abs. (%)	45 days	1 (33,3)	2 (66,7)	2 (66,7)	2 (66,7)	2 (50,0)	1 (50,0)	0,952
			90 days	1 (33,3)	1 (33,3)	2 (66,7)	1 (33,3)	1 (25,0)	1 (50,0)	0,911
Localization of adhesions	"Mooring"	Implants Abs. (%)	45 days	0 (0,0)	1 (50,0)	0 (0,0)	1 (50,0)	1 (50,0)	0 (0,0)	0,596
	Edges			1 (100,0)	0 (0,0)	1 (50,0)	0 (0,0)	0 (0,0)	1 (100,0)	

	Edges and center			0 (0,0)	1 (50,0)	1 (50,0)	1 (50,0)	1 (50,0)	0 (0,0)	
	"Mooring"		90 days	0 (0,0)	0 (0,0)	1 (50,0)	0 (0,0)	0 (0,0)	0 (0,0)	0,713
	Edges			0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	
	Edges and center			1 (100,0)	1 (100,0)	1 (50,0)	1 (100,0)	1 (100,0)	1 (100,0)	
The area of the implant involved in adhesions (P.A. Lucas et al.)		Scores Me (Q1 – Q3)	45 days	0 (0 – 0)	1 (0 – 1)	1 (0 – 2)	1 (0 – 2)	0 (0 – 2)	0 (0 – 1)	0,917
			90 days	0 (0 – 0)	0 (0 – 0)	1 (0 – 2)	0 (0 – 1)	0 (0 – 1)	1 (0 – 2)	0,904
Type of adhesions (M.D. Muller et al.)		Scores Me (Q1 – Q3)	45 days	0 (0 – 1)	1 (0 – 1)	2 (1 – 2)	1 (0 – 2)	0 (0 – 1)	1 (0 – 2)	0,948
			90 days	0 (0 – 0)	0 (0 – 0)	2 (1 – 2)	0 (0 – 1)	0 (0 – 0)	1 (0 – 2)	0,806
Adhesive strength (H.V. Zühlke et al.)		Scores Me (Q1 – Q3)	45 days	0 (0 – 1)	1 (0 – 2)	2 (1 – 2)	1 (0 – 2)	1 (0 – 2)	1 (0 – 2)	0,945
			90 days	0 (0 – 1)	0 (0 – 1)	2 (1 – 2)	0 (0 – 1)	0 (0 – 0)	1 (0 – 2)	0,920
Adhesive strength (H.V. Zühlke et al.)		Implants Abs. (%)	45 days	0 (0,0)	0 (0,0)	1 (33,3)	0 (0,0)	1 (25,0)	0 (0,0)	0,600
			90 days	0 (0,0)	0 (0,0)	1 (33,3)	0 (0,0)	1 (25,0)	0 (0,0)	0,600
		Scores	45 days	0 (0 – 2)	3 (2 – 4)	7 (4 – 7)	4 (2 – 5)	2 (0 – 5)	2 (1 – 4)	0,878

Integral assessment of spike formation (M.P. Diamond)	Me (Q1 – Q3)	90 days	0 (0 – 2)	0 (0 – 2)	4 (2 – 6)	0 (0 – 3)	0 (0 – 2)	2 (1 – 4)	0,960

AP – anti-adhesive coating

3.2.1.4. Credibility of the data

According to the results of the study, there was no significant dependence of the indicators of deformation, retraction and adhesion formation on the type of implant. An unreliable dependence was detected by 45 and 90 days according to such indicators as deformation (p = 0.288 and p = 0.221, respectively) and retraction (p = 0.381 and p = 0.123, respectively), by 90 days – according to the parameter retraction area (p = 0.128) (Table 3.2.1.4.1). Migration of fixators by 90 days was also not a risk factor for the development of retraction (OR = 1.0 at 95% CI: 0.141 – 7.099) and adhesions (OR = 0.200 at 95% CI: 0.018 – 2.265) (Table 3.2.1.4.2).

Table 3.2.1.4.2 – Results of the assessment of the effect of migration of fixators on the indices of retraction of endoprostheses and adhesion formation by 90 days of the experiment

Parameter, abs. (%)	Migration of fixators		Reliability (p)	Odds ratio (OR)
	Yes	No		
Endoprostheses with retraction	3 (50,0)	6 (50,0)	1,000	1,0 (95% CI: 0,141 – 7,099)
Endoprostheses with adhesions	1 (16,7)	6 (50,0)	0,316	0,2 (95% CI: 0,018 – 2,265)

3.2.1.5. Physical characteristics and biomechanical strength of the prosthesis-tissue complex

The greatest breaking load of the prosthesis-tissue complex was noted in the Ventralight ST endoprosthesis, along the loop row it was 64.2 N, along the loop column – 65.2 N (Table 3.2.1.5.1, Fig. 3.2.1.5.4). Along the loop row, it turned out to be more than 2 times higher than the load required to rupture only the prosthesis. A slightly lower load in both directions was required to rupture the abdominal wall

tissue complex with a Reperen 16 – 42.7 N endoprosthesis (Fig. 3.2.1.5.5), with FLUOREX implants – 42.0 N and FLUOREX with an additional layer of carboxymethylcellulose – 39.5 N (Fig. 3.2.1.5.1, Fig. 3.2.1.5.2). The lowest breaking load was registered for the complex with the Symbotex endoprosthesis. The indicators were 33.6 N along the loop row and 37.7 N along the loop column (Fig. 3.2.1.5.3). The xenomaterial from the decellularized pork peritoneum was able to rupture at a load of 28.6 N (Fig. 3.2.1.5.6), while the native pork peritoneum ruptured at a force of 12.8 N (Fig. 3.2.1.5.7).

When comparing the rupture load of the prosthesis and the prosthesis-tissue complex, the indicator increased for the Symbotex endoprosthesis along the loop row by 37.1%, along the loop column by 78.7%; for the Ventralight ST endoprosthesis along the loop row by 105.1%, along the loop column by 35.0%; for the Reperen 16 endoprosthesis by 55.3%. At the same time, for both FLUOREX endoprostheses, these indicators have practically not changed. The parameters for the xenomaterial were not compared.

The maximum rupture elongation of the prosthesis-tissue complex was noted when using a Reperen endoprosthesis of 16-212% for both directions, which was more than 2 times higher than the indicator for one prosthesis (Table 3.2.1.5.1). The complex with the Ventralight ST implant showed a slightly lower tensile elongation – 180% along the loop row, 135% along the loop column. For the native peritoneum, the parameter was 126%, while the complex with xenomaterial was only 89%. Also, 89% was the discontinuous elongation of the complex with the Symbotex endoprosthesis along the loop row. For the complex with FLUOREX and FLUOREX endoprostheses with a carboxymethylcellulose layer, the tensile elongation was 62% and 79%, respectively. The minimum value was noted in the complex with the Symbotex prosthesis along the hinge column – only 56.8%.

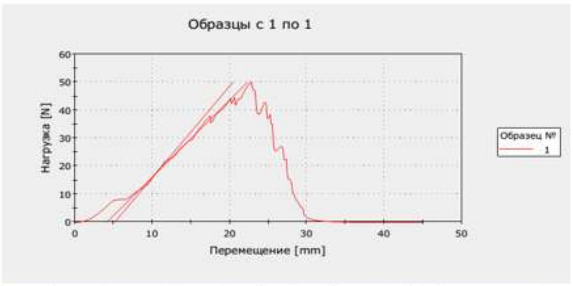
The breaking load during the integration of endoprostheses into tissues increased when compared with the indicator for the prosthesis alone. For the complex with the FLUOREX endoprosthesis, it increased by 93.8%; with the FLUOREX endoprosthesis with an additional anti–adhesive layer – by 146.9%; with

the Symbotex endoprosthesis – by 67.9% along the loop row, by 9.2% along the loop column; with the Ventralight ST endoprosthesis – by 66.7% along the loop row, by 107.7% along the loop column; with a Reperen endoprosthesis – by 120.8%. The parameters for the xenomaterial were not compared.

	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,80000	12,10738	14,24357	2,97033
2	25,00000	10,00000	0,08000	238,04075	14,48974	83,17155

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	23,76263	7,65211	17,10000	
2	66,53725	11,16320	17,40000	

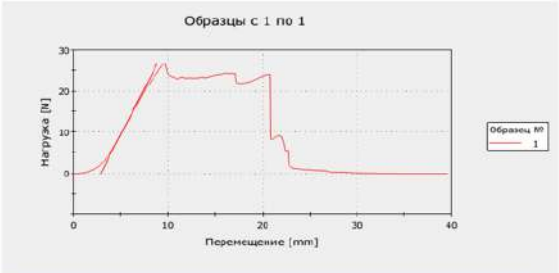
a



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,70000	9,81630	22,82587	7,14589

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	50,02126	17,63339	27,40000	

b

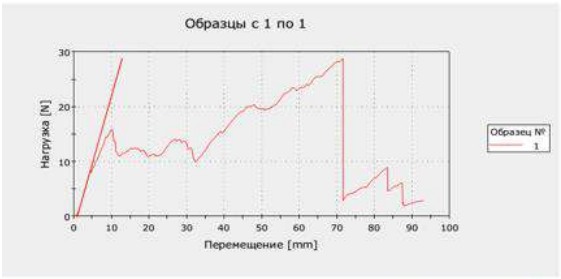


	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,75000	14,82459	9,65693	3,54889

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	26,61665	6,78349	11,60000	

c

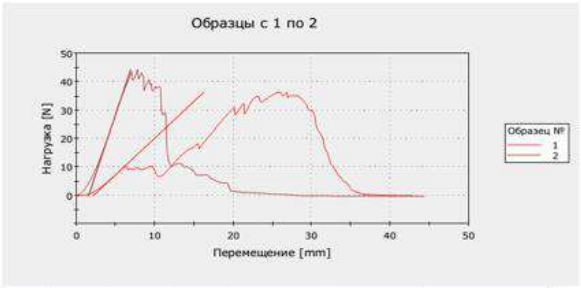
Figure 3.2.1.5.1 – Indicators of breaking load and stretching of the prosthesis-tissue complex for FLUOREX endoprosthesis samples along the loop column. *a – animal 1; b – animal 2; c – animal 3.*



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,45000	4,14915	71,57523	1,98931

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	28,84497	70,57310	85,90000	

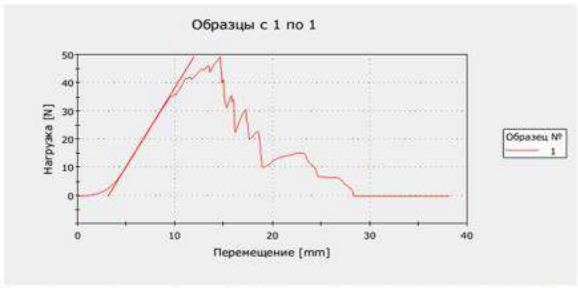
a



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,80000	8,08638	25,82383	4,54615
2	25,00000	10,00000	0,35000	58,73116	7,82303	12,66760

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	36,36923	23,64059	31,00000	
2	44,33661	6,21272	9,40000	

b

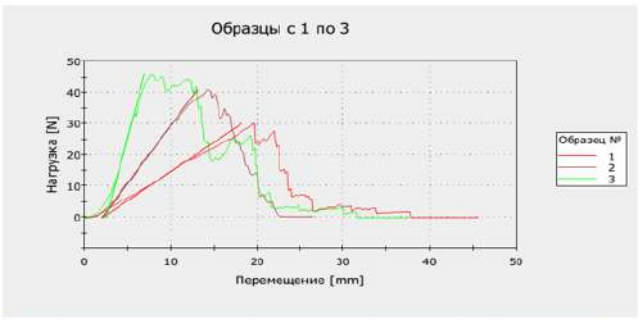


	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,62000	22,62708	14,65830	7,94137

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	49,23648	11,50161	17,60000	

c

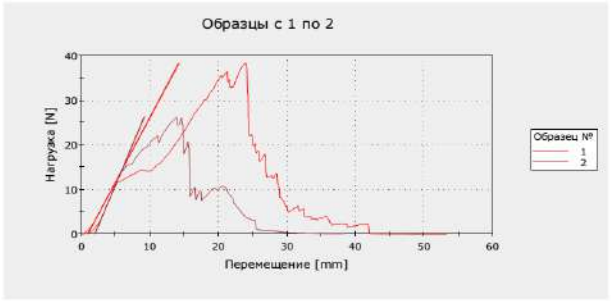
Figure 3.2.1.5.2 – Indicators of the breaking load and stretching of the prosthesis-tissue complex for FLUOREX endoprosthesis samples with an additional layer of carboxymethylcellulose along the loop column. *a – animal 1; b – animal 2; c – animal 3.*



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,65000	7,18996	19,65686	4,62886
2	25,00000	10,00000	0,70000	13,39334	14,32374	5,83511
3	25,00000	10,00000	0,79000	37,14574	7,90631	6,56604

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	30,08759	17,52180	23,60000	
2	40,84579	12,22402	17,20000	
3	45,92029	5,32142	9,50000	

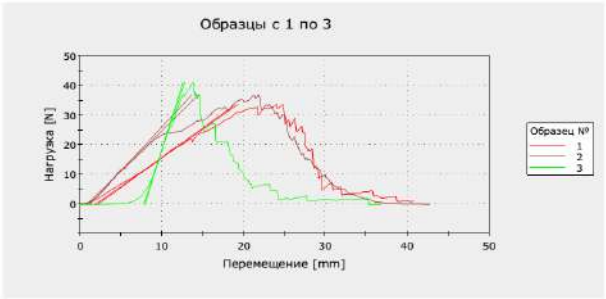
a



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,75000	9,66670	24,07365	5,09477
2	25,00000	10,00000	0,60000	15,03713	13,91229	4,37849

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	38,21079	23,13305	28,90000	
2	26,27097	11,90179	16,70000	

b



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,66000	7,59894	23,99190	5,09674
2	25,00000	10,00000	0,66000	10,26176	21,74062	5,58201
3	25,00000	10,00000	0,66000	33,42641	13,82395	6,21173

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	33,63851	22,08649	28,80000	
2	36,84124	20,55001	26,10000	
3	40,99745	6,03159	16,60000	

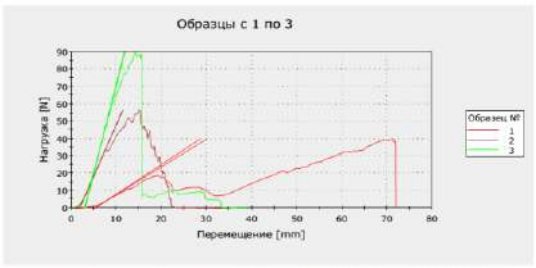
c

Figure 3.2.1.5.3 – Indicators of breaking load and stretching of the prosthesis-tissue complex for Symbotex endoprosthesis samples. *a – animal 1 (sample 1 along the loop row, samples 2 and 3 along the loop column); b – animal 2 (sample 1 along the loop row, sample 2 along the loop column); c – animal 3 (sample 1 along the loop row, samples 2 and 3 along the loop column).*

	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,70000	12,42772	27,91274	9,91867

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	69,43066	22,62008	33,50000	

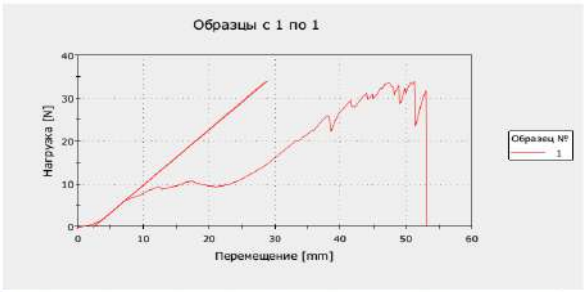
a



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,50000	8,54560	71,07503	7,98337
2	25,00000	10,00000	0,55000	27,06506	15,15690	10,28199
3	25,00000	10,00000	0,55000	47,09201	10,24061	16,32037

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	39,91683	65,98639	85,30000	
2	59,55094	13,27003	18,20000	
3	69,76203	11,27040	17,10000	

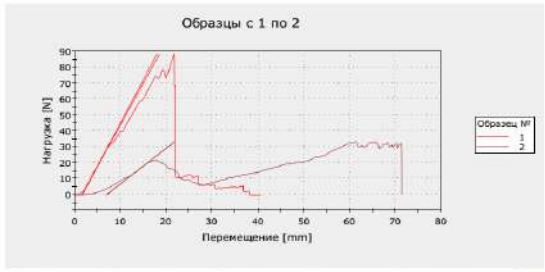
b



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,67000	4,84341	51,15713	5,08437

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	34,06531	48,73872	61,40000	

c



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,62000	21,91244	21,82337	14,25523
2	25,00000	10,00000	0,65000	8,72891	61,32395	5,11830

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	86,38240	20,20395	26,20000	
2	33,26894	54,34911	73,60000	

d

Figure 3.2.1.5.4 – Indicators of breaking load and stretching of the prosthesis-tissue complex for Ventralight ST endoprosthesis samples. *a – animal 1 (sample 1 along the loop column); b – animal 2 (sample 1 along the loop row, samples 2 and 3 along the loop column); c – animal 3, endoprosthesis 1 (sample 1 along the loop column); d – animal 3, endoprosthesis 2 (sample 1 along the loop row, sample 2 along the looped column).*

	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,45000	4,14915	71,57523	1,98931

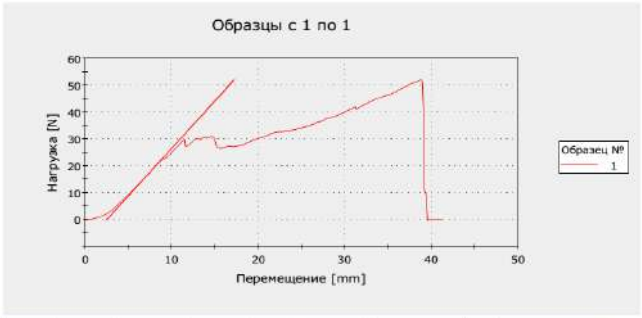
	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	28,84497	70,57310	85,90000	

a

	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,50000	7,83339	48,65594	3,14896

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	47,23446	46,99957	58,40000	

b

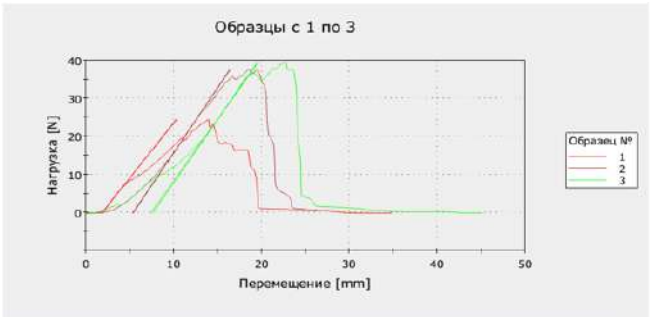


	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,50000	5,92572	38,82321	3,47222

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	52,08328	36,40535	46,60000	

c

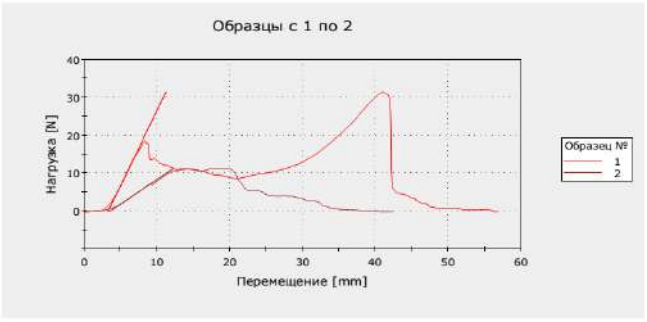
Figure 3.2.1.5.5 – Indicators of the breaking load and stretching of the prosthesis-tissue complex for endoprosthesis samples Reperen 16. *a – animal 1; b – animal 2; c – animal 3.*



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениепримаксимумНагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,30000	5,53653	13,99125	1,89022
2	25,00000	10,00000	1,20000	7,15891	18,57261	3,13688
3	25,00000	10,00000	1,20000	6,93831	22,65695	3,29963

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	24,57288	12,16337	16,80000	
2	37,64252	13,23967	22,30000	
3	39,59555	15,28531	27,20000	

a

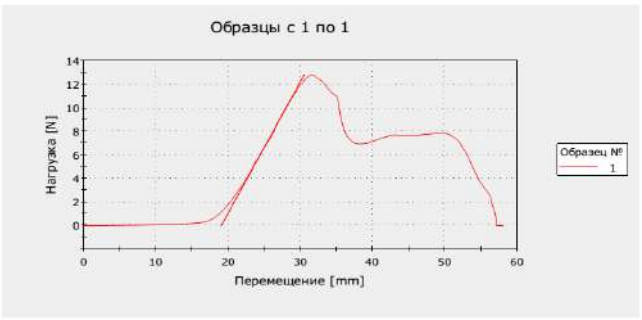


	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	1,10000	9,02328	40,99141	2,86590
2	25,00000	10,00000	1,10000	2,96708	19,65803	1,03808

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	31,52494	37,66516	49,20000	
2	11,41892	16,10725	23,60000	

b

Figure 3.2.1.5.6 – Indicators of breaking load and stretching of the prosthesis-tissue complex for endoprosthesis samples from decellularized porcine peritoneum (xenomaterial). *a – animal 1; b – animal 2.*



	Длина [mm]	Ширина [mm]	Толщина [mm]	Модуль (Автоматический Юнга) [MPa]	ПеремещениеприМаксимум Нагрузка [mm]	Напряжение при растяженииприМаксимум Нагрузка [MPa]
1	25,00000	10,00000	0,15000	18,61808	31,65699	8,54321

	Максимум Нагрузка [N]	Перемещение при растяженииприМаксимум Нагрузка [mm]	ВремяприМаксимум Нагрузка [s]	Примечание по образцу
1	12,81482	12,63178	38,00000	

Figure 3.2.1.5.7 – Indicators of breaking load and stretching for samples from native porcine peritoneum

Table 3.2.1.5.1 – Physical properties and biomechanical strength of the prosthesis-tissue complex under uniaxial tension

Sample number	An endo-prosthesis variant	Base	Coating or anti-adhesive layer	Surface den-sity declared by the manu-facturer, g/m^2	Number of samples	Parameters				
						Thickness, mm	Along the loop row		Along the looped column	
							Breaking load, N	Breaking elonga-tion, %	Breaking load, N	Breaking elonga-tion, %
1	FLUOREX	PE	SKF-26	36 – 42	4	0,7	-	-	42,0	62
2	ФТОРЭКС с АС	PE	SKF-26 and CMC	36 – 42	4	0,7	-	-	39,5	79
3	Symbotex	PE	Collagen	66	8	0,7	33,6	89	37,7	56,8
4	Ventralight ST	PP	GC-CMC	No more than 213	7	0,7	64,2	180	65,2	135
5	Reperen	PP	Reperen	No data available	3	1,5	42,7*	212*	-	-
6	Pork perito-neum (xen-omaterial)	Perito neum	-	-	5	1,2	28,6*	89*	-	-
7	Pork peritoneum (native)	Perito neum	-	-	3	0,15	12,8*	126*	-	-

The width of the sample strip is 10 mm, the clamping length is 25 mm, the speed is 50 m/min

PE – polyester; PP – polypropylene; CMC – carbox-ymethylcellulose; GC-CMC – hyaluronic acid and carboxymethylcelllose; AC – anti-adhesive layer – the tests were carried out for one direction (the structure is homogeneous in two directions)*

3.2.1.6. Histological changes in the area of implantation of endoprostheses

Endoprosthesis with fluoropolymer coating FLUOREX

FLUOREX endoprostheses, which are basically knitted meshes made of complex filaments consisting of elementary filaments connected by a small twist, were evenly positioned on the surface of the parietal peritoneum without the formation of coarse folds. Relatively uniform enveloping connective tissue structures with clear contours, without signs of integration into the structures of the underlying peritoneum, were determined in the projection of the fibers of the thread. The connective tissue was mainly overgrown with the threads of the mesh, the spaces between the fibers of the threads were minimally involved in this process (Fig. 3.2.1.6.1).

The height of the entire thickness of the mesh-peritoneum complex was 0.90 mm, the mesh overgrown with connective tissue was 0.55 mm, only the mesh was 0.33 mm, the underlying peritoneum was 0.35 mm (Table 3.2.1.6.1). The ratio of the area of the FLUOREX endoprosthesis and the area of the formed fibrous tissue was 14.5%. The area of the mesh threads by 10 mm was 1.22 mm^2, while there was a localized arrangement of the volume of the thread elements at a sufficient distance from each other, which allowed the basic peritoneum matrix to be preserved in this location. The area of the newly formed fibrous tissue in the 10 mm section of the installed mesh was 7.47 mm^2.

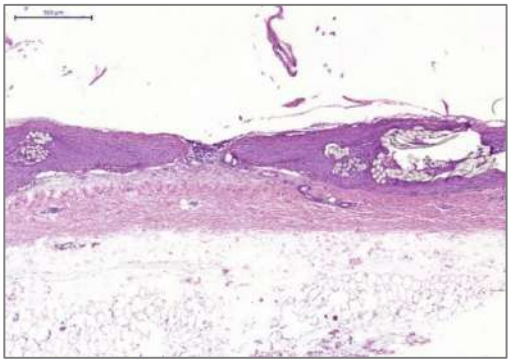


Figure 3.2.1.6.1 – Micrography of the thickness of the newly formed tissue complex around the filaments of the FLUOREX endoprosthesis. *Staining with hematoxylin and eosin. ×30.*

Table 3.2.1.6.1 – Morphometric parameters of integration of mesh endoprostheses and decellularized porcine peritoneum

Endoprosthesis	Parameter (M)							
	h of the entire tissue complex, mm	h of the grid, mm	h of newly formed fibrous tissue around the endoprosthesis, mm	h of the peritoneum's own plate, mm	S mesh/ S fabric (5 mm^2), %	S grid elements per 10 mm^2	S of fibrous tissue per 10 mm^2	S mesh / 10 mm fibrous fabric
FLUOREX	0,90	0,33	0,55	0,35	14,50	1,22	7,47	16,28
FLUOREX with AC	0,85	0,29	0,53	0,30	16,17	1,28	6,49	19,84
Ventralight ST	0,75	0,34	0,50	0,27	21,73	1,63	7,83	21,14
Symbotex	0,82	0,35	0,49	0,21	11,27	0,93	7,56	12,04
Reperen 16	1,34	0,26	0,74	0,44	6,40	0,78	9,77	8,29
Pork peritoneum*	1,40	-	-	0,39	-	-	-	-

*AC – anti–adhesive layer; h - thickness; S – area; * – measurement of parameters when using pork peritoneum was not carried out due to the fundamentally different composition of the product compared with mesh endoprostheses.*

There was mild inflammation around the filaments of the fluoropolymer-coated endoprosthesis, represented by the presence of macrophages, multinucleated cells and proliferating fibroblasts. There were minimal connective tissue growths in the areas between the fibers of the threads, these gaps were covered with the parietal peritoneum, vascular growth was noted in the thickness, the peritoneum was rebuilt and formed a neoperitoneum creeping onto the grid structures.

In general, inflammation around the filamentous fibers was characterized by a sluggish granulomatous reaction with a predominance of macrophages and a small number of giant multinucleated cells of the type of foreign bodies, weakly expressed general activity with minor infiltration by lymphocytes. Minimal changes were noted in

the peritoneum's own plate in the form of some thickening of the collagen layers. With minor vascular rearrangement, fibroblasts and inflammatory infiltration cells were absent. Intensive expression of pan-cytokeratins by mesothelial cells was noted during the IHC study (Fig. 3.2.1.6.2).

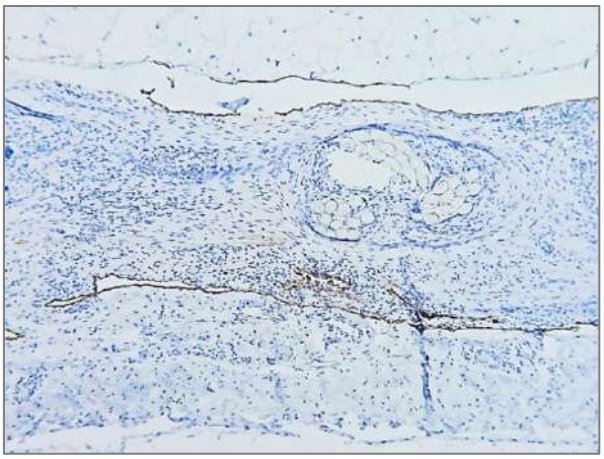


Figure 3.2.1.6.2 – Micrography of the thickness of the newly formed tissue complex around the filaments of the FLUOREX endoprosthesis. *Mesothelial cells have a positive cytoplasmic staining in a golden brown color. Mesothelium growth is noted both on the surface of the endoprosthesis (neoperitoneum) and under it (basic peritoneum). IHC reaction with PCK marker AE1/AE3. ×200.*

FLUOREX endoprosthesis with an additional anti-adhesive layer of carboxymethylcellulose

The results obtained in the study of the integration of this endoprosthesis turned out to be similar to the results of the study of the FLUOREX implant, which does not have an additional layer of carboxymethylcellulose, except that the distances between the thread elements and the spaces between the threads turned out to be larger. This significantly reduced the amount of fibrous tissue formed and preserved the structures of the underlying peritoneum as much as possible (Fig. 3.2.1.6.3, Fig. 3.2.1.6.4).

Morphometric parameters (height of the mesh-peritoneum complex, mesh thickness, and a number of others) also practically did not differ from those obtained using the FLUOREX endoprosthesis without additional coating (Table 3.2.1.6.1).

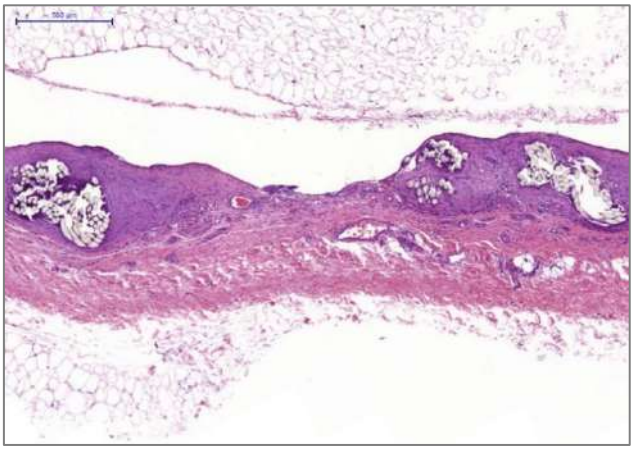


Figure 3.2.1.6.3 – Micrograph of the thickness of the newly formed tissue complex around the filaments of the FLUOREX endoprosthesis with an additional layer of carboxymethylcellulose. *Staining with hematoxylin and eosin.* ×30.

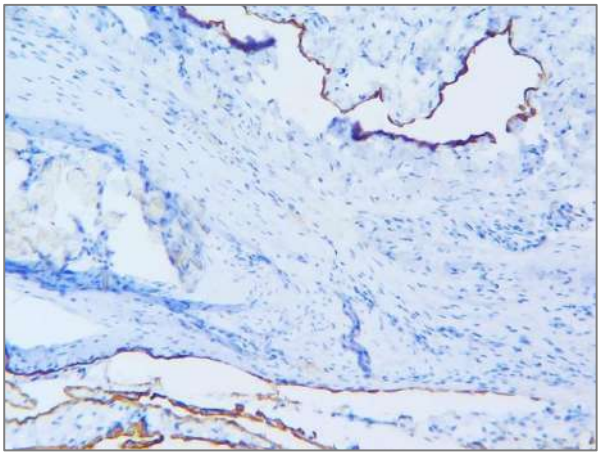


Figure 3.2.1.6.4 – Micrograph of the thickness of the newly formed tissue complex around the filaments of the FLUOREX endoprosthesis with an additional layer of carboxymethylcellulose. *Mesothelium growth is noted both on the surface of the endoprosthesis (neoperitoneum) and under it (basic peritoneum). IHC reaction with PCK marker AE1/AE3. ×200.*

Ventralight ST Endoprosthesis

Ventralight ST endoprostheses, represented by bundles of thick homogeneous intertwined fibers with equidistant interval weaving of mesh structures, lay on the parietal peritoneum without forming coarse folds. Diffuse continuous connective tissue structures were formed in the projection of the fibers of the thread, tightly soldered to the structures of the underlying peritoneum (Fig. 3.2.1.6.5). The filaments of the mesh and the spaces

between the fibers themselves were uniformly and monolithically overgrown with connective tissue. The filaments were located superficially to the abdominal cavity in places. Mild inflammation was noted around the filaments, represented by an abundance of blood vessels, macrophages, multinucleated cells and delimiting fibrocytes forming an uneven framework of mature collagen fibers.

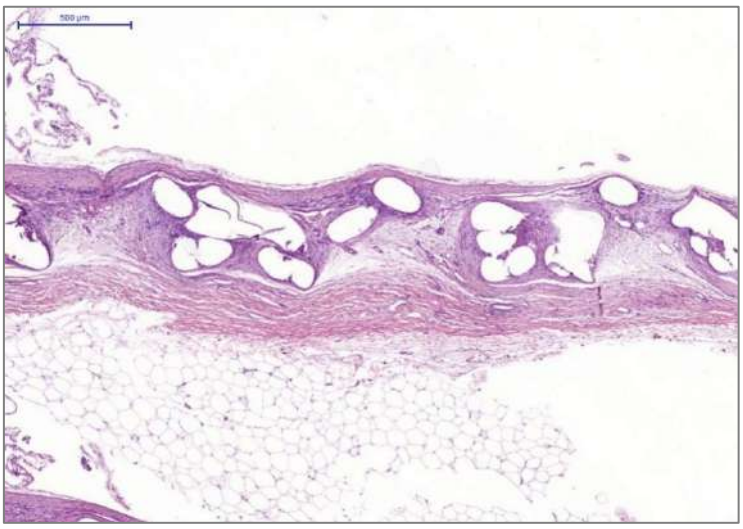


Figure 3.2.1.6.5 – Micrography of the thickness of the newly formed tissue complex around the threads of the Ventralight ST endoprosthesis. *Staining with hematoxylin and eosin. ×30.*

The morphometric parameters of this endoprosthesis and the fluoropolymer-coated endoprosthesis differed slightly (Table 3.2.1.6.1). Thus, the area of the mesh threads per 10 mm for this endoprosthesis was 1.63 mm^2, which turned out to be higher than that of FLUOREX endoprostheses. At the same time, a uniform solid arrangement of the thread elements was noted, which did not allow the basic matrix of the peritoneum to be preserved.

In general, inflammation around the fibers of the mesh filaments was characterized by a sluggish granulomatous reaction with a predominance of macrophages and a small number of giant multinucleated cells of the type of foreign body cells, and weakly expressed general activity with minor infiltration by lymphocytes. Lymphocytes were located diffusely, forming small-cell perivascular clusters. The tissues surrounding the filaments of the mesh were dominated by connective tissue stroma cells, mainly fibrocytes, and formed collagen fibers, which indicated a mature sclerotic process. There

was a pronounced vascular component, represented by mature, stagnantly full-blooded, medium-caliber and capillary-type vessels, an abundance of lymphatic vessels.

In the peritoneal lamina itself, minor changes were noted in the form of thickening of collagen layers, moderate vascular restructuring, the presence of fibroblasts and inflammatory infiltration cells, the presence of thickened collagen fibers with disorganization phenomena, which indirectly indicated a subcompensated course of inflammation.

The basic peritoneum was mostly absent, the mesh elements were covered with neoperitoneum (Fig. 3.2.1.6.6). The proliferation and migration of mesothelial cells were facilitated by adhesions of varying degrees of maturity, detected in sufficient quantities.

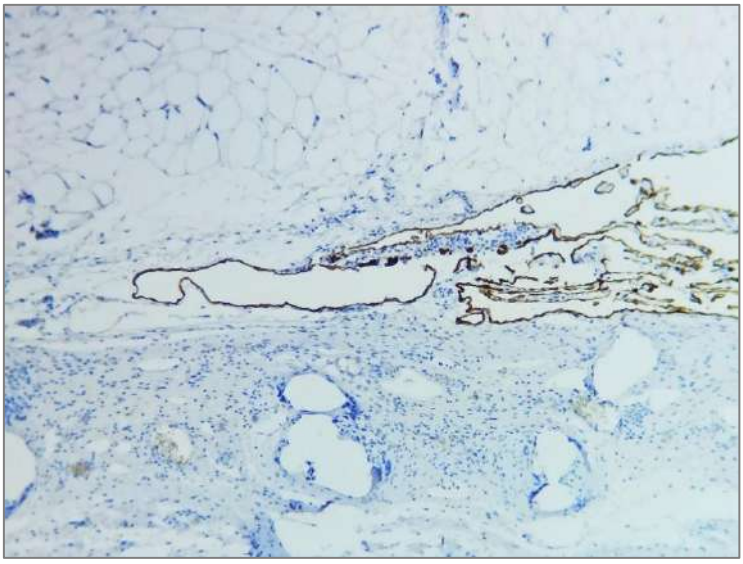


Figure 3.2.1.6.6 – Micrography of the thickness of the newly formed tissue complex around the threads of the Ventralight ST endoprosthesis. *Against the background of a well-formed neoperitoneum, the basic peritoneum is absent. IHC reaction with PCK marker AE1/AE3. ×200.*

Endoprosthesis Symbotex

These prostheses, like the previous ones, were evenly positioned on the surface of the peritoneum without the formation of rough folds. Diffuse continuous connective tissue structures formed in the projection of the fibers of the mesh threads, in places tightly, in places loosely soldered to the structures of the underlying peritoneum, with the

phenomena of edema and hypervascularization. The threads of the mesh and the spaces between the fibers themselves were unevenly, but over the entire area, overgrown with connective tissue. In places, the filaments were located superficially to the abdominal cavity with a tendency to break beyond the fibrous capsule. Mild inflammation around the filaments was represented by macrophages, multinucleated cells and delimiting fibrocytes, mature collagen fibers forming a loose uneven framework (Fig. 3.2.1.6.7).

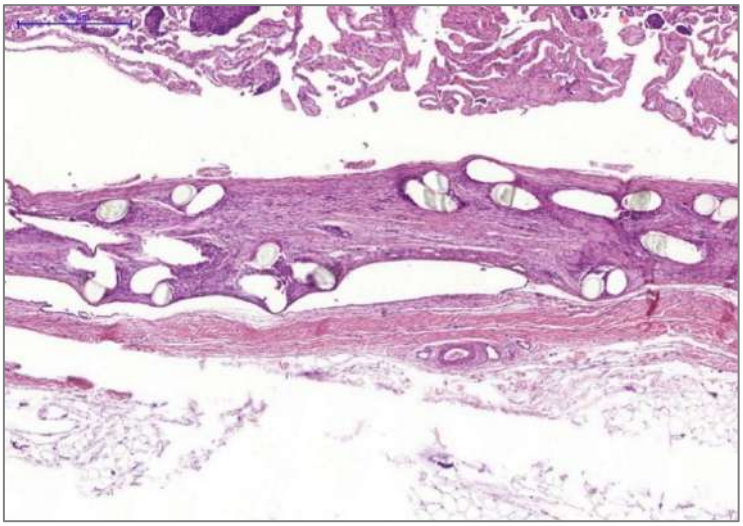


Figure 3.2.1.6.7 – Micrography of the thickness of the newly formed tissue complex around the threads of the Symbotex endoprosthesis. *Staining with hematoxylin and eosin. ×30.*

Morphometric parameters of Symbotex endoprostheses differed from the endoprostheses discussed above in a number of indicators, for example, in the ratio of the area of the endoprosthesis to the area of the formed tissue. They were closer to the parameters of fluoropolymer-coated implants than to endoprostheses with hyaluronic acid and carboxymethylcellulose (Table 3.2.1.6.1).

Inflammation around the fibers of the mesh filaments was characterized by a sluggish granulomatous reaction with a predominance of macrophages and a small number of giant multinucleated cells of the type of foreign body cells and weakly expressed general activity with minor infiltration by lymphocytes. Lymphocytes were located diffusely, forming small-cell perivascular clusters. There was a mature sclerotic process and a pronounced vascular component.

The basic peritoneum was mostly absent, the mesh elements were covered with neoperitoneum (Fig. 3.2.1.6.8). The adhesions of various maturity detected in sufficient numbers contributed to the proliferation and migration of mesothelial cells.

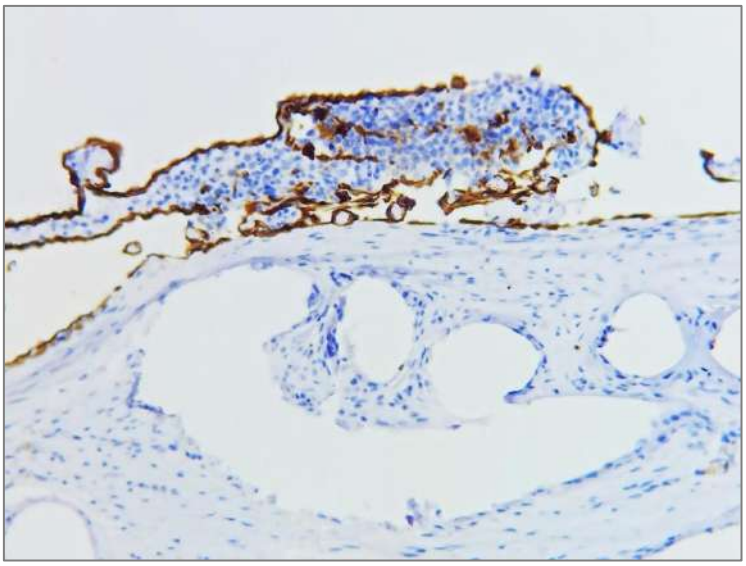


Figure 3.2.1.6.8 – Micrography of the thickness of the newly formed tissue complex around the threads of the Symbotex endoprosthesis. *Against the background of a well-formed neoperitoneum, the basic peritoneum is absent. IHC reaction with PCK marker AE1/AE3. ×200.*

Endoprosthesis Reperen 16

Reperen 16 endoprostheses made of a spatially crosslinked polymer based on methacrylic oligomers using a mesh layer of polypropylene deformed the parietal peritoneum and were partially covered with a newly formed peritoneum, while the presence of edema of surrounding tissues, an abundance of mature thickened adhesions were noted.

Diffuse continuous connective tissue structures were formed in the projection of the mesh fibers, tightly soldered to the structures of the underlying peritoneum, with the phenomena of edema and hypervascularization. The threads of the mesh and the spaces between the fibers themselves were overgrown with connective tissue over the entire area. In some places, the filaments were located superficially with respect to the abdominal cavity with a tendency to break through the fibrous capsule, in some places they were

deeply sealed with a fibrous layer and pressed against the peritoneum. Inflammation was noted around the filaments, represented by macrophages, multinucleated cells, fibrocytes and mature collagen fibers with dystrophy phenomena (Fig. 3.2.1.6.9).

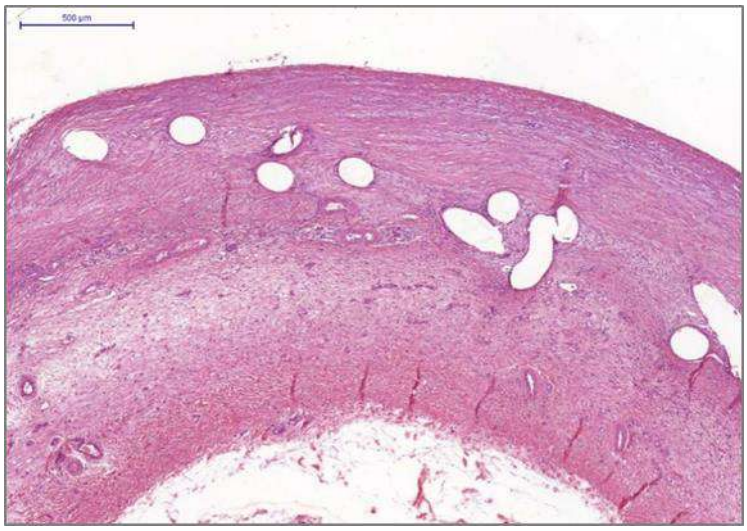


Figure 3.2.1.6.9 – Micrography of the thickness of the newly formed tissue complex around the filaments of the Reperen endoprosthesis 16. *Staining with hematoxylin and eosin. ×30.*

The morphometric parameters of the Reperen 16 endoprostheses differed significantly from the parameters of other implants (Table 3.2.1.6.1). Inflammation around the fibers of the mesh filaments was characterized by a weakly expressed granulomatous reaction with a small number of macrophages and giant multinucleated cells of the type of foreign body cells, weakly expressed general activity with insignificant infiltration by lymphocytes. An uneven fibroplastic reaction, significantly pronounced relative to other materials, attracted attention. Fibrous elements of the connective tissue stroma, collagen fibers with dystrophic changes, and fibrocytes predominated in the thickness of the tissue surrounding the filaments. The unexpressed vascular component was represented by a meager number of capillary-type vessels and an abundance of lymphatic vessels. Thickened adhesions of a mature type with large vessels were formed with pronounced infiltration by lymphocytes, active growth of capillary vessels, and proliferation of mesothelium.

Thickening of collagen layers, moderate vascular restructuring were noted in the peritoneal lamina proper, fibroblasts and inflammatory infiltration cells were present, thickened collagen fibers with disorganization phenomena, there was an abundance of lymphatic vessels, which indicated a decompensated course of inflammation. Areas of purulent aseptic inflammation were detected on the surface of the peritoneum, under a layer of mesh.

There was no underlying peritoneum. The mesh surface was mostly not covered with neoperitoneum (Fig. 3.2.1.6.10). Adhesions of various maturity were detected in sufficient numbers, which contributed to the proliferation and migration of mesothelial cells, but they were not enough to overgrow the elements of the film.

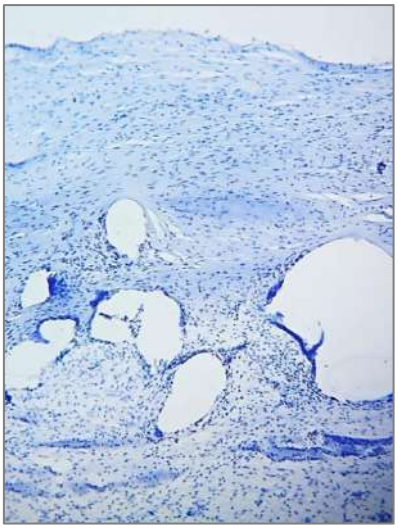


Figure 3.2.1.6.10 – Micrography of the thickness of the newly formed tissue complex around the filaments of the Reperen endoprosthesis 16. *The neoperitoneum is insufficiently formed, and the basic peritoneum is absent. IHC reaction with PCK marker AE1/AE3. ×200.*

Decellularized pork peritoneum

The plate of the pork peritoneum was loosely soldered to the underlying tissues. The height of the entire thickness of the implant-peritoneum complex was 1.40 mm, the thickness of the underlying peritoneum was 0.39 mm (Table 3.2.1.6.1). The thickness of the implanted material was represented by disorganized collagen fibers with uneven

vascularization and pronounced granulomatous reaction at the interface of joints with the peritoneum and on the surface in granulation growth areas (Fig. 3.2.1.6.11).

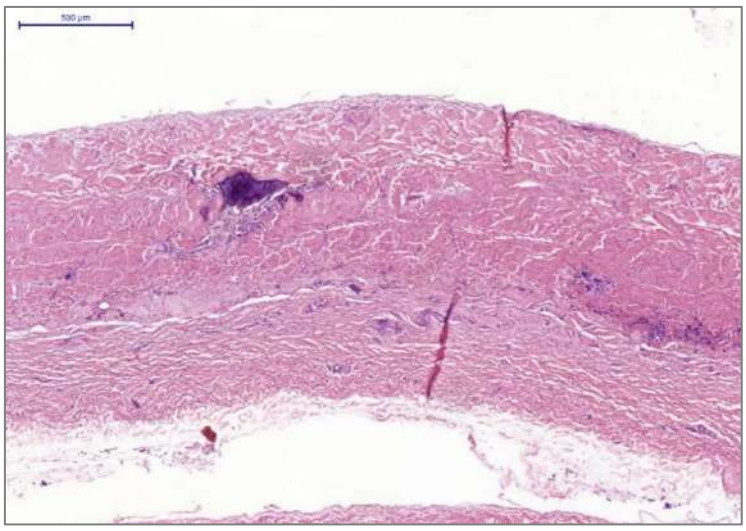


Figure 3.2.1.6.11 – Micrography of the thickness of the newly formed tissue complex around the xenomaterial from the decellularized porcine peritoneum. *Staining with hematoxylin and eosin. ×30.*

In the thickness of the decellularized peritoneum, there was a pronounced fibroplastic reaction with dystrophic changes in connective tissue fibers, hyalinosis, weak vascular germination, and massive involvement of the recipient's peritoneal tissues in the fibroplastic process. The unexpressed inflammatory response to the material was represented by a mosaic secondary nonspecific granulomatous inflammation with an abundance of giant multinucleated cells of the type of foreign body cells. There were areas of disorganization and fibrinoid necrosis, islands of cartilage metaplasia. Lymphocytes were located diffusely, forming small-cell perivascular clusters. The vascular component was represented by a meager number of capillary-type vessels and an abundance of lymphatic vessels.

Thickening of collagen layers, moderate vascular restructuring were detected in the recipient's own peritoneal plate, fibroblasts and inflammatory infiltration cells were present, collagen fibers were thickened, had signs of disorganization, an abundance of lymphatic vessels was noted, indicating a decompensated course of inflammation.

There was no underlying peritoneum. The surface was mostly not covered with neoperitoneum (Fig. 3.2.1.6.12). Adhesions of various maturity detected in significant numbers contributed to the proliferation and migration of mesothelial cells, but they were not enough to fouling the implant elements.

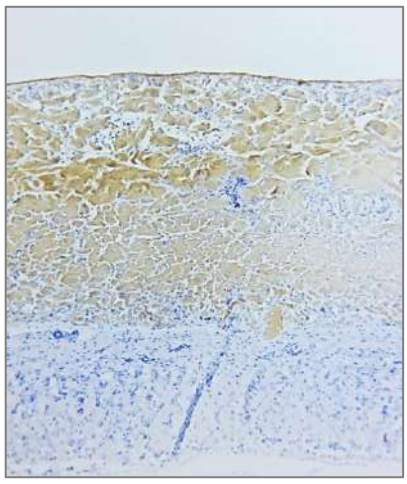


Figure 3.2.1.6.12 – Micrography of the thickness of the newly formed tissue complex around the xenomaterial from decellularized porcine peritoneum. *The neoperitoneum is insufficiently formed, and the basic peritoneum is absent. IHC reaction with PCK marker AE1/AE3. ×200.*

3.2.2. Evaluation of the effectiveness and safety of the use of full-size fluoropolymer-coated implants and various methods of their fixation in the conditions of modeling a hernial defect of the abdominal wall (2nd series of the experiment)

The main task of the 2nd series of experiments was to evaluate the possibility of safe use of large-sized mesh endoprostheses made of polyester with fluoropolymer coating FLUOREX in the conditions of modeling and elimination of hernial defect in IPOM hernioplasty. For this purpose, 1 endoprosthesis of various sizes was installed in 3 animals – from 10 by 15 cm to 20 by 20 cm. Another task of this stage was to determine the optimal method of fixation of these implants. The choice was made between the traditionally used non-absorbable, absorbable and adhesive fixation. No comparative studies have been conducted in this series.

3.2.2.1. Installation of endoprostheses and performance characteristics

The total duration of the operation in the 1st animal was 31 minutes, while modeling and suturing a hernial defect was 21 minutes, and installing an endoprosthesis measuring 15 by 20 cm (300 cm^2) was 10 minutes. The prosthesis was not fixed with transfascial sutures. 27 non-absorbable ProTack titanium coils (Medtronic, USA) were used (Fig. 3.2.2.1.1). The area of the implant per 1 retainer was 11.1 cm^2.

There were no technical difficulties during the operation. During fixation, 4 spirals passed through the cells of the endoprosthesis, causing minor damage to the mesh structure (Fig. 3.2.2.1.2). The ease of use was assessed by two surgeons on a 5-point scale as good.

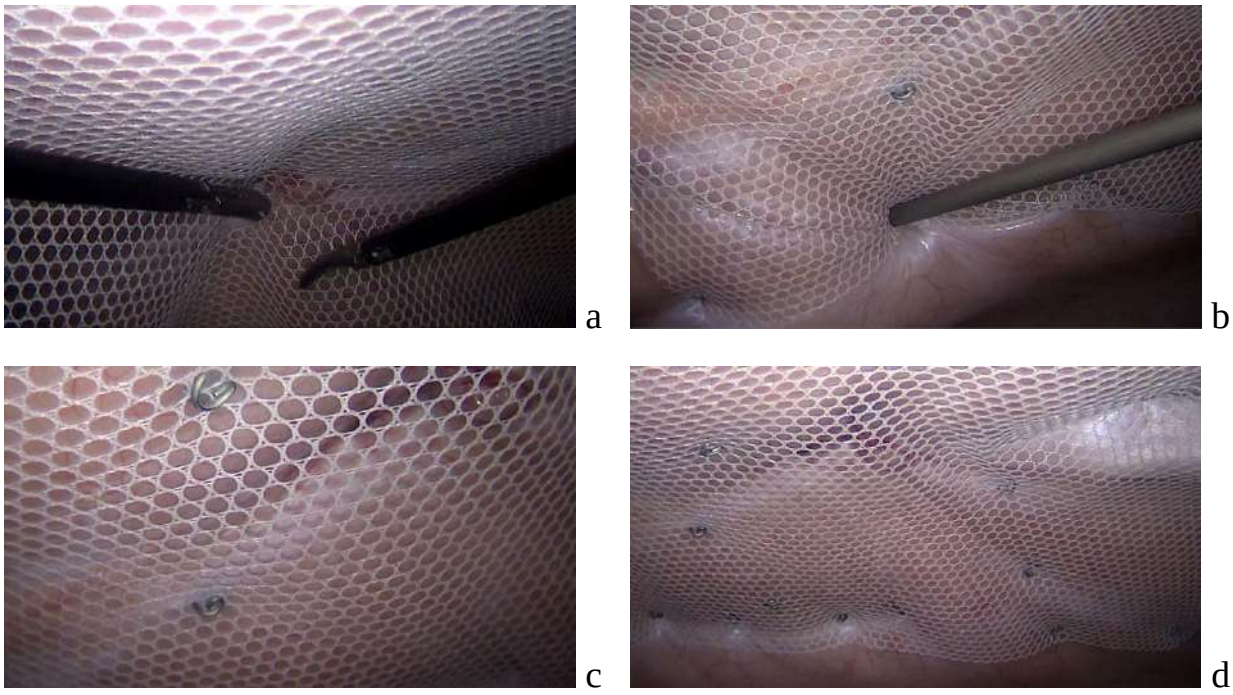


Figure 3.2.2.1.1 – Stages of endoprosthesis fixation with the use of ProTack titanium coils (intraoperative photographs)

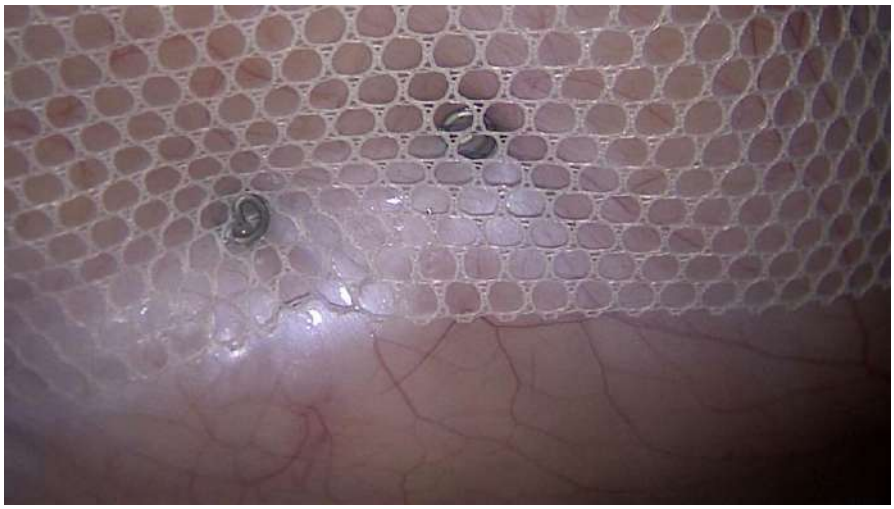
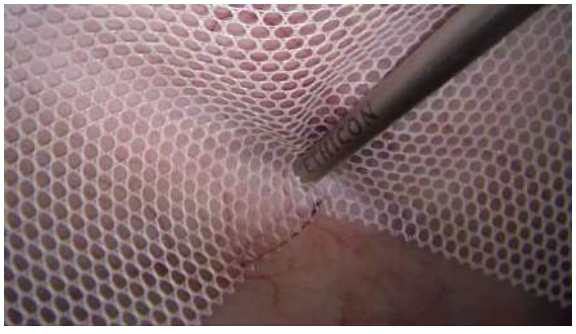


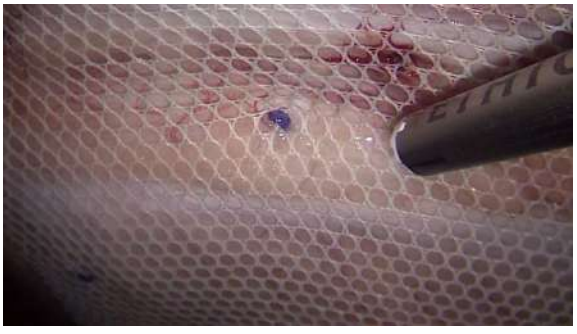
Figure 3.2.2.1.2 – Passage of one of the ProTack titanium fixators through the mesh cells without fixing it (intraoperative photo)

The duration of the operation in the 2nd animal was 59 minutes, while modeling and suturing a hernial defect was 29 minutes, and installing an endoprosthesis measuring 20 by 20 cm (400 cm^2) was 30 minutes. Previously, the prosthesis was fixed with 4 transfascial polypropylene sutures, one of which was later removed. 20 absorbable harpoon-type fixators were used from a mixture of polydioxanone and a copolymer of L-lactide and SecureStrap glycolide (Ethicon, USA) (Fig. 3.2.2.1.3). The area of the implant per 1 retainer was 20.0 cm^2.

There were no technical difficulties during the operation. 2 fixators did not fully enter the fabric (Fig. 3.2.2.1.4), 3 more slightly damaged the mesh structure. From two places in the fixation area, minor bleeding was noted, which spontaneously stopped by the end of the operation (Fig. 3.2.2.1.5). The ease of use was assessed by two surgeons on a 5-point scale as good.



a



b

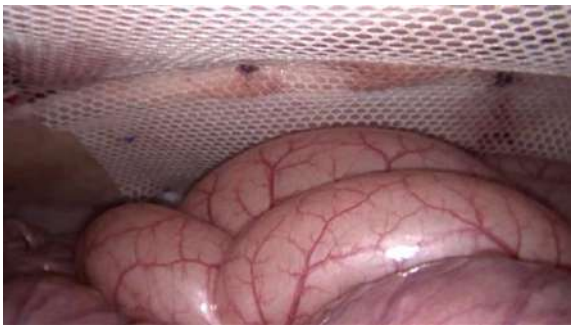

c

d

Figure 3.2.2.1.3 – Stages of endoprosthesis fixation with the use of absorbable harpoon-type SecureStrap fixators (intraoperative photographs)

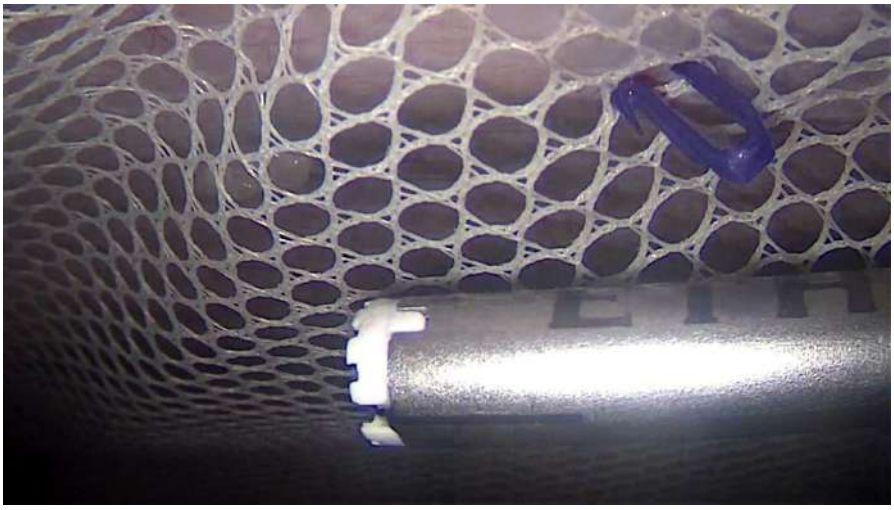


Figure 3.2.2.1.4 – The harpoon-type retainer did not fully enter the abdominal wall tissue (intraoperative photograph)

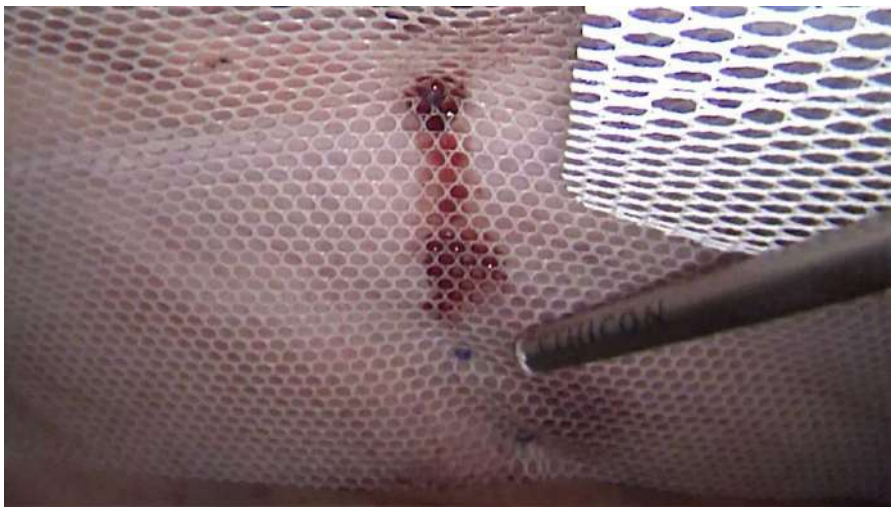


Figure 3.2.2.1.5 – Non-intensive spontaneous stopped bleeding from the installation site of the harpoon-type retainer (intraoperative photograph)

The duration of the operation in the 3rd animal was 67 minutes, while modeling and suturing a hernial defect was 29 minutes, and installing an endoprosthesis measuring 10 by 15 cm (150 cm^2) was 38 minutes. At the first stage, the prosthesis was fixed with 4 transfascial polypropylene sutures. Next, 50 drops of butyl-2-cyanoacrylate surgical glue Glubran 2 (GEM, Italy) were used through a Glutack pistol-type glue delivery device (GEM, Italy) (Fig. 3.2.2.1.6). The implant area per 1 drop of glue was 3.0 cm^2.

There were no technical difficulties during the operation. Attention was drawn to the fact that the adhesive, due to surface tension, spreads quite well over the mesh and the surrounding peritoneum. There was no gluing of the end part of the delivery device to the prosthesis. In some cases, when applying an excessive amount of glue to the endoprosthesis, which is higher relative to the working laparoscopic ports, leakage was noted along the delivery device. The ease of use was assessed by two surgeons on a 5-point scale as good.

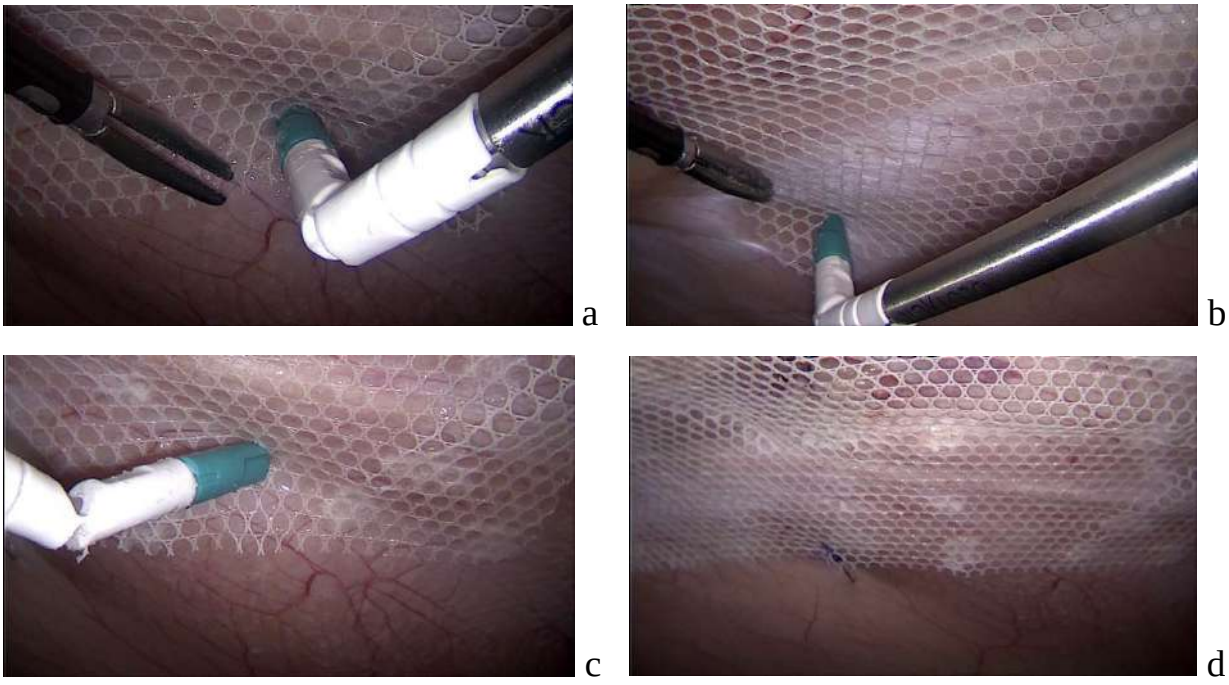


Figure 3.2.2.1.6 – Stages of endoprosthesis fixation with the use of Glubran 2 surgical glue and Glutack delivery device (intraoperative photos)

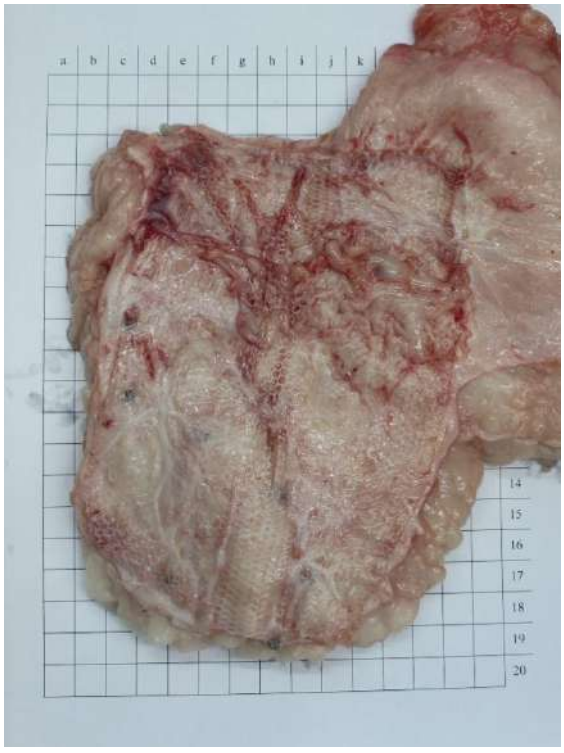
3.2.2.2. Inflammation, deformity and retraction

After 90 days, all the animals involved in the experiment survived. They actively gained weight in accordance with their growth rate. No early or late reactions or postoperative complications were observed. No adhesive splices were found in the area of installation of trocar ports.

There were no visual signs of inflammation in the implant placement area and their deformation. Visual signs of retraction during laparoscopy were present in all endoprostheses. During autopsy, the size of the endoprosthesis in 1 animal decreased by 36% (from 300 cm^2 to 192 cm^2), in 2 – by 14.5% (from 400 cm^2 to 342 cm^2), in 3 – by 52.3% (from 150 cm^2 to 71.5 cm^2) (Fig. 3.2.2.2.1).

When using the Protack herniostepler, migration of fixators was noted in 1 animal. Of the 27 titanium coils in the area of the mesh endoprosthesis, only 15 were found. Some of them were fixed to the loops of the intestine (Fig. 3.2.2.2.2). All harpoon-type clamps used in 2 animals retained their structure. No migration was observed.

The strength of fixation of the endoprosthesis to the underlying tissues in all cases is noted as good. A sharp incision was required for separation.


a


b

Figure 3.2.2.2.1 – Retraction of the endoprostheses revealed after an autopsy. *a* is animal 1; *b* is animal 3.

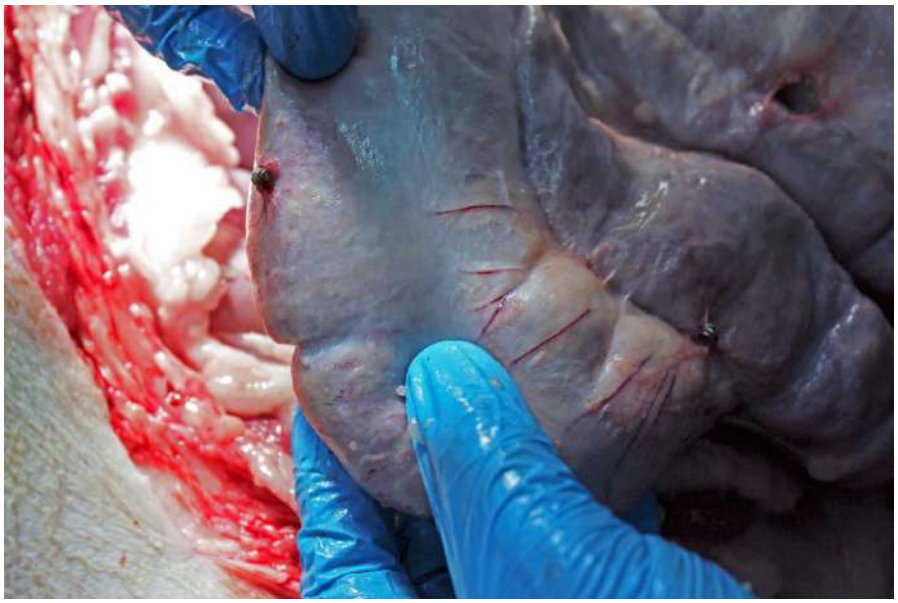
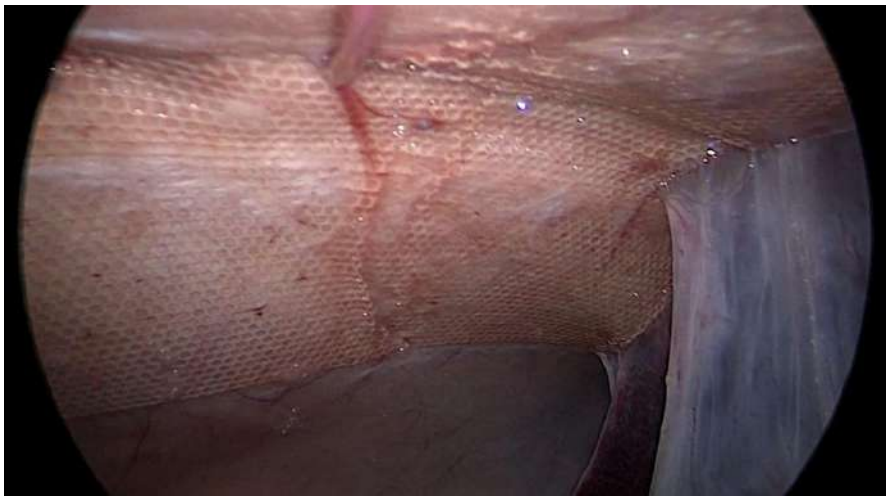


Figure 3.2.2.2.2 – Migrated titanium coils found after autopsy. *Two fixators are visible, fixed to the peritoneum of the intestine.*

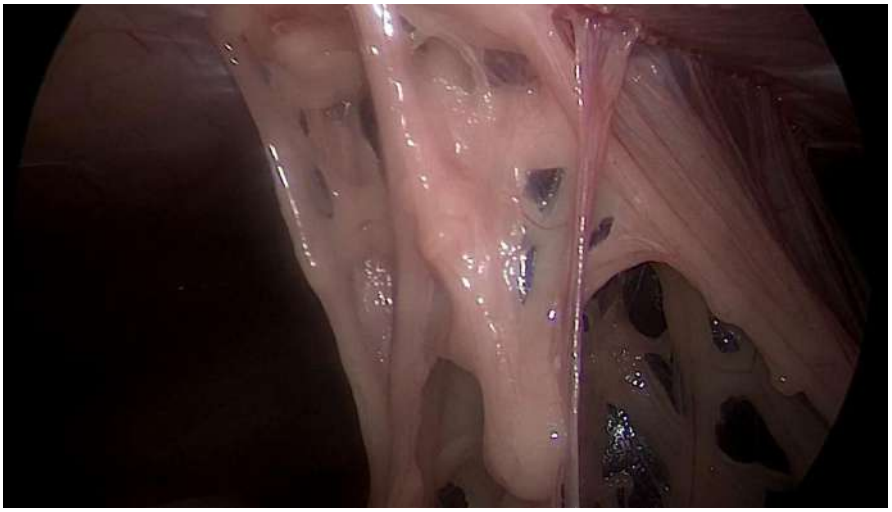
3.2.2.3. Spike formation

During the observation period, no clinical manifestations and behavioral reactions indicating the effect of adhesions on the condition of animals were noted. After 90 days, during laparoscopy, adhesion phenomena, expressed to varying degrees, were revealed in all animals, but only in the areas of implant placement (Fig. 3.2.2.3.1). There were no adhesions found in other parts of the abdominal cavity.

a



b



c

Figure 3.2.2.3.1 – Adhesive joints in the area of endoprosthesis installation (intraoperative photographs). *a – animal 1; b – animal 2; c – animal 3.*

When using surgical glue, 3 animals had adhesive joints both at the edges and in the center of the endoprosthesis. When using titanium spirals in 1 animal and absorbable harpoon-type fixators in 2 animals, adhesions were found only along the upper edge of the implant at the points of contact with parenchymal organs (Fig. 3.2.2.3.2).

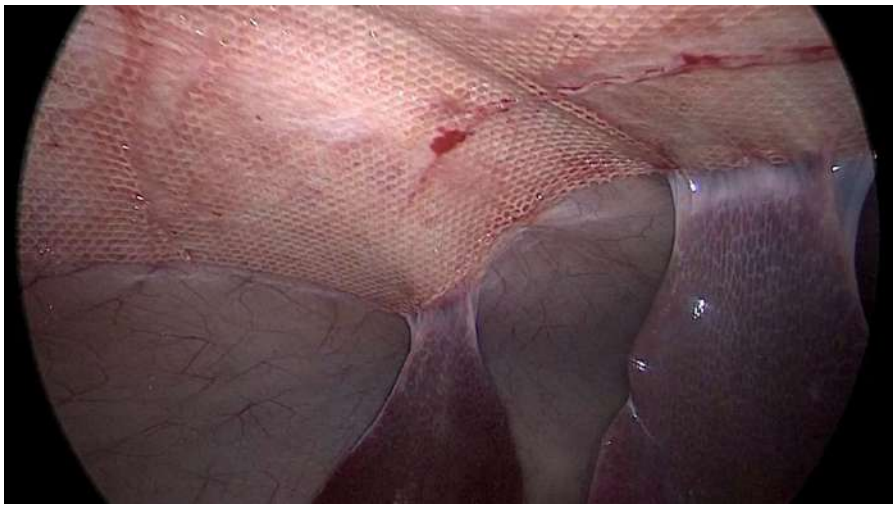


Figure 3.2.2.3.2 – Adhesions with the liver and spleen along the edge of the endoprosthesis in 2 animals (intraoperative photographs)

The area of adhesions calculated by the method of P.A. Lucas et al., in 1 and 2 animals was 1 point (up to 25% of the surface), in 3 animals – 4 points (from 75 to 100% of the surface). Assessment of the appearance of adhesions according to the method of M.D. Muller et al. all endoprostheses had 1 point, and the adhesive strength, estimated by H.V. Zühlke et al., 2 points. In the integral assessment of spike formation carried out by M.P. Diamond, the best result (4 points) was found in 2 animals using harpoon-type fixators. In 1 animal, when using titanium coils, the result was 6 points. The worst result was obtained when using surgical glue in 3 animals – 7 points. In 1 animal, the omentum and spleen were involved in adhesions, in 2 – the liver and spleen, in 3 – the liver, spleen, omentum and colon.

3.2.3. Comparative assessment of biomechanical properties and biocompatibility of endoprostheses with fluoropolymer coating and composite endoprostheses with anti-adhesive collagen layer, as well as fixing filaments with fluoropolymer coating (3rd series of experiment)

The main objective of the 3rd series of the experiment was to confirm the effectiveness and safety of using mesh endoprostheses made of polyester with fluoropolymer coating FLUOREX. The comparison was carried out with the polyester

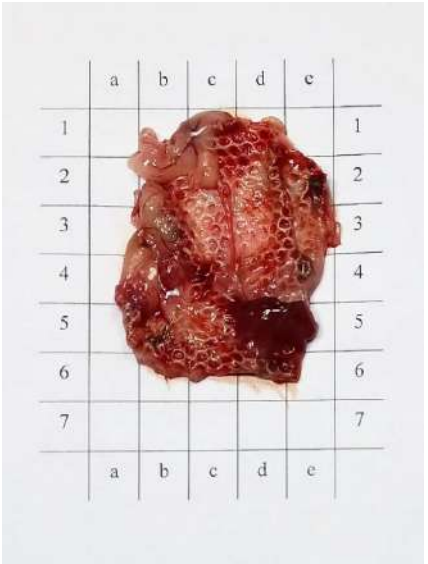
endoprosthesis with an anti-adhesive layer of Symbotex collagen, which is most often used in IPOM operations. Another task was to evaluate the possibility of safe use for intraperitoneal implant fixation of polyester threads with fluoropolymer coating FLUOREX. The results obtained using the thread are compared with the results that were noted when fixing the endoprosthesis with resorbable SecureStrap fixators, which proved themselves best in previous series. The experiment was performed on 2 animals, in which 12 endoprostheses were installed.

3.2.3.1. Results of using FLUOREX and Symbotex mesh endoprostheses

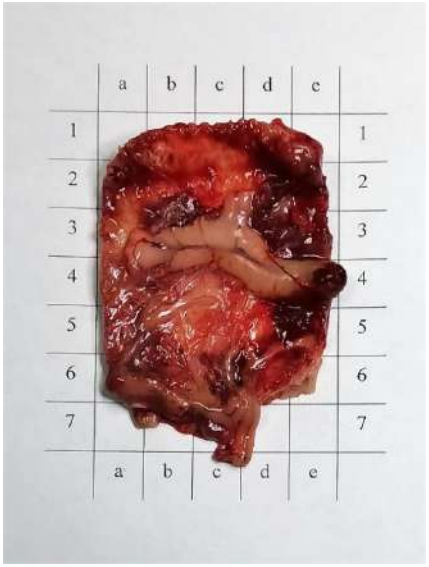
The average time of positioning and fixation of one endoprosthesis did not have significant differences ($p = 0.663$). For the FLUOREX prosthesis, it was 14.5 (1.0–16.5) minutes, for the Symbotex prosthesis – 16.0 (10.8 – 18.0) minutes.

All the animals involved in the experiment survived. They were actively gaining weight in accordance with the growth rate. Early and late reactions and postoperative complications were not observed. Adhesive joints were not detected in the installation area of the trocar ports.

No visual signs of inflammation were observed during autopsy by 45 days in the area of implant localization. There was also no migration of fixators. Such indicators as the number of implants with deformation and retraction did not have significant differences, while there were more deformed FLUOREX prostheses (Fig. 3.2.3.1.1) (Table 3.2.3.1.1).



a



b

Figure 3.2.3.1.1 – Signs of deformation and retraction associated with adhesion formation in FLUOREX (a) and Symbotex (b) endoprostheses after excision and flattening on the plane by 45 days of the experiment. *The price of dividing the grid on paper is 1.0 cm.*

Table 3.2.3.1.1 – Deformation and retraction indices when using FLUOREX and Symbotex mesh endoprostheses by 45 days of the experiment

Parameter	Endoprosthesis		Reliability (p)	Odds ratio (OR) (95% CI)
	FLUOREX (n = 8)	Symbotex (n = 4)		
Deformation, abs. (%)	2 (25,0)	0 (0,0)	0,515	0,289 (0,011 – 7,568)
Retraction, abs. (%)	4 (50,0)	2 (50,0)	1,000	1,0 (0,091 – 11,028)
The area of the prosthesis in the animal's body, cm2, M ± SD (95% CI)	26,8 ± 3,3 (24,0 – 29,5)	29,5 ± 4,2 (22,8 – 36,2)	0,242	-
The area of the prosthesis after excision, cm2, M ± SD (95% CI)	26,1 ± 3,6 (23,1 – 29,1)	30,5 ± 3,1 (25,6 – 35,4)	0,064	-
The size of the prosthesis compared to the original one in the animal's body, %, M ± SD (95% CI)	79,6 ± 9,9 (71,4 – 87,9)	87,8 ± 12,5 (67,9 – 107,7)	0,242	-
The size of the prosthesis compared to the original one after excision, %, M ± SD (95% CI)	77,8 ± 10,6 (68,9 – 86,6)	90,8 ± 9,3 (76,0 – 105,5)	0,064	-

Despite the fact that at the time of the autopsy, the area of Symbotex endoprostheses both in the animal's body and after excision turned out to be larger in absolute and relative figures, no significant difference in indicators was revealed. It was also noted that after excision, the area of the FLUOREX endoprosthesis decreased slightly (from 79.6% to 77.8%), and the area of the Symbotex prostheses, on the contrary, increased (from 87.8% to 90.8%) (Fig. 3.2.3.1.2).

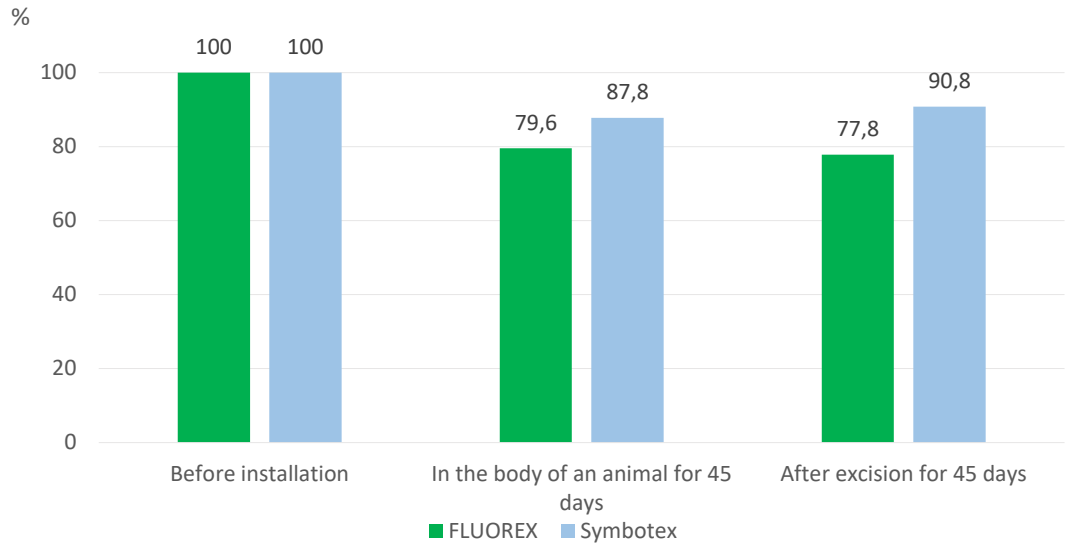


Figure 3.2.3.1.2 – The area of the FLUOREX and Symbotex mesh endoprostheses compared to the initial one before and after excision of the prosthesis-tissue complex

Adhesions were observed when using all types of implants (Fig. 3.2.3.1.3). Despite the fact that Symbotex endoprostheses had an advantage in a number of parameters for assessing adhesion formation, no significant differences were found (Table 3.2.3.1.2).

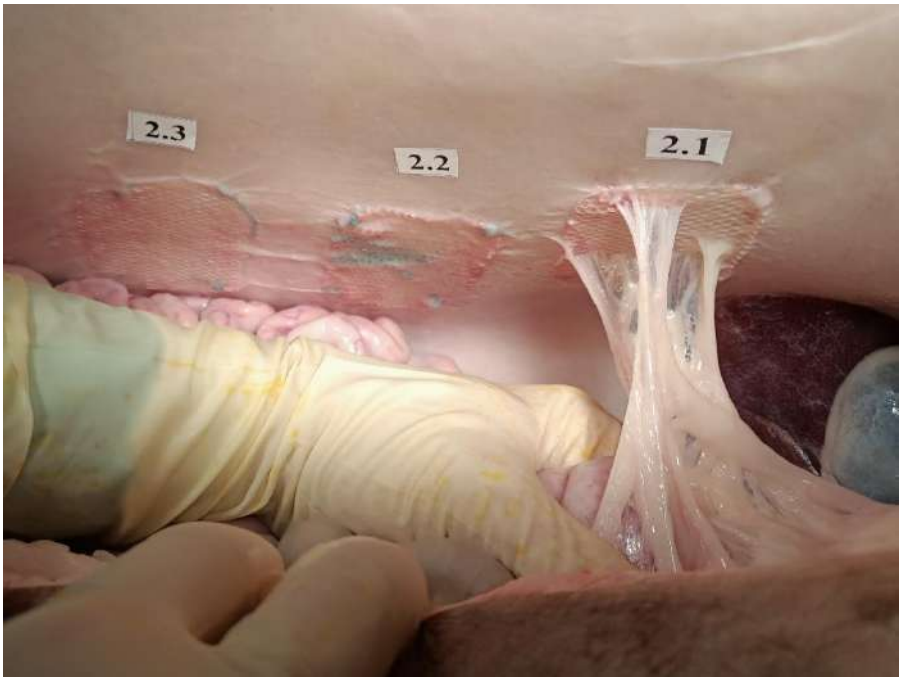


Figure 3.2.3.1.3 – Adhesions on the surface of the FLUOREX endoprosthesis located in the upper floor of the abdominal cavity, near the liver, during autopsy on the 45th day of the experiment *(Notation in the photo: 2.1 FLUOREX endoprosthesis, 2.2 Symbotex, 2.3. FLUOREX)*

Table 3.2.3.1.2 – Parameters of adhesion formation when using FLUOREX and Symbotex mesh endoprostheses by 45 days of the experiment

Parameter		Endoprosthesis		Reliability (p)	Odds ratio (OR) (95% CI)
		FLUOREX (n = 8)	Symbotex (n = 4)		
Dentures with adhesions, abs. (%)		6 (75,0)	2 (50,0)	0,547	0,333 (0,027 – 4,186)
Coverage of the surface of the prosthesis with adhesions, abs. (%)	Mooring	2 (33,3)	0 (0,0)	0,155	-
	Edges	0 (0,0)	1 (50,0)		
	Edges and center	4 (66,7)	1 (50,0)		
The area of the implant involved in adhesions (P.A. Lucas et al.), points, Me (Q1 – Q3)		1,0 (0,8 – 1,0)	0,5 (0,0 – 1,5)	0,781	-
Type of adhesions (M.D. Muller et al.), points, Me (Q1 – Q3)		1,5 (0,8 – 2,0)	0,5 (0,0 – 1,2)	0,366	-
Adhesive strength (H.V. Zühlke et al.), points, Me (Q1 – Q3)		2,0 (1,5 – 2,0)	1,0 (0,0 – 2,0)	0,407	-
Involvement of parenchymal and hollow organs in the adhesive process, abs. (%)		3 (37,5)	1 (25,0)	1,000	0,556 (0,038 – 8,085)
Involvement of abdominal organs in the adhesive process, abs. (%)	Oil seal	2 (40,0)	1 (50,0)	0,292	-
	The spleen	0 (0,0)	1 (50,0)		
	The large intestine	2 (40,0)	0 (0,0)		
	Omentum and colon	1 (20,0)	0 (0,0)		
Integral assessment of spike formation (M.P. Diamond), points, Me (Q1 – Q3)		4,0 (3,0 – 5,0)	2,0 (0,0 – 4,8)	0,659	-

The thickness of the resulting prosthesis-tissue complex had significant differences. For FLUOREX, it was 0.8±0.2 mm, for Symbotex – 1.2±0.2 mm (p=0.009) (Table 3.2.3.1.3). When estimating the average breaking load, which was 34.0±10.7 N for the FLUOREX endoprosthesis and 41.4±8.0 N for the Symbotex endoprosthesis, no significant difference was found. At the same time, the average tensile elongation was significantly higher for the Sympatex implant. It was 94.7 (89.2–107.5) mm versus 69.2 (63.9–70.7) mm for the FLUOREX implant (p = 0.007) (Fig. 3.2.3.1.4).

Table 3.2.3.1.3 – Physical properties and biomechanical strength of the prosthesis-tissue complex when using FLUOREX and Symbotex mesh endoprostheses by 45 days of the experiment

Parameter	Endoprosthesis		Reliability (p)	Odds ratio (OR) (95% CI)
	FLUOREX (n = 8)	Symbotex (n = 4)		
The thickness of the complex, mm, M ± SD (95% CI)	0,8 ± 0,2 (0,7 – 1,0)	1,2 ± 0,2 (0,9 – 1,4)	0,009*	-
Mechanical fixation strength of the prosthesis, points, Me (Q1 – Q3)	4,0 (4,0 – 4,0)	4,0 (4,0 – 4,0)	0,480	-
Average breaking load, N, M ± SD (95% CI)	34,0 ± 10,7 (25,1 – 43,0)	41,4 ± 8,0 (28,6 – 54,2)	0,253	-
Breaking load along the loop row, N, M ± SD (95% CI)	-	37,7 ± 3,7 (28,4 – 47,0)	-	-
Breaking load along the loop column, N, Me (Q1 – Q3)	35,1 (24,3 – 39,2)	43,0 (38,2 – 47,8)	0,602	-
Average breaking elongation, mm, Me (Q1 – Q3)	69,2 (63,9 – 70,7)	94,7 (89,2 – 107,5)	0,007*	-
Breaking elongation along the loop row, mm, M ± SD (95% CI)	-	93,8 ± 3,4 (85,3 – 102,2)	-	-
Breaking elongation along the loop column, mm, Me (Q1 – Q3)	69,2 (63,9 – 70,7)	104,3 (88,0 – 120,6)	0,068	-

* – statistically significant differences

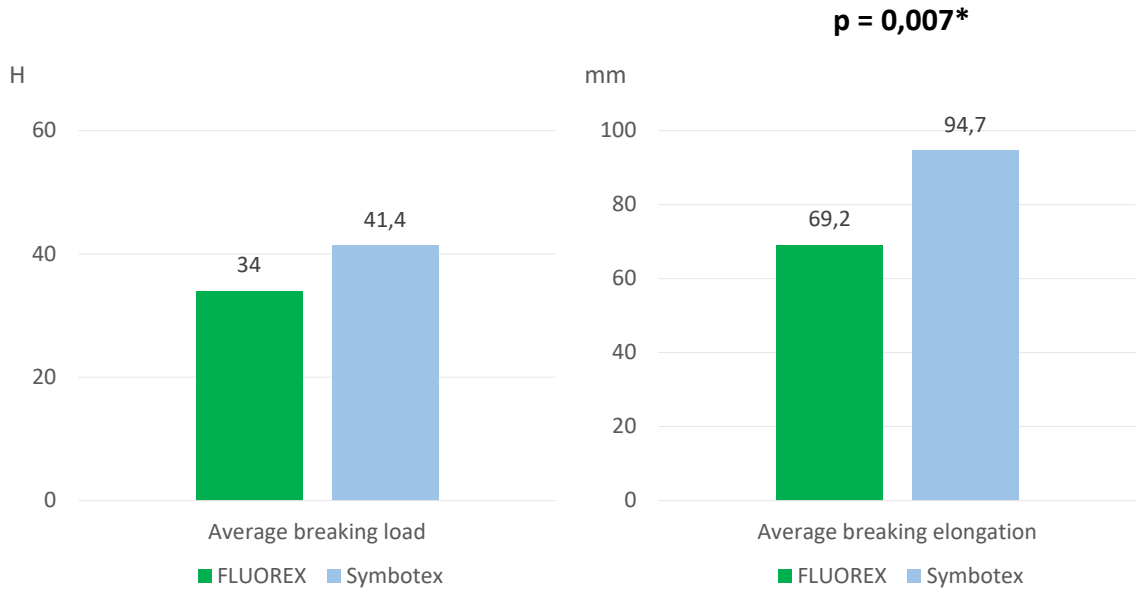


Figure 3.2.3.1.4 – Average breaking load and average breaking elongation of the prosthesis-tissue complex when using FLUOREX and Symbotex mesh endoprostheses. * – statistically significant differences.

3.2.3.2. Results of fixation of endoprostheses with a fluoropolymer coated FLUOREX thread

The average time of positioning and fixation of one endoprosthesis was significantly less when using stapler fixation. When using the SecureStrap herniator, it was 1.0 ± 0.0 minutes, when suturing – 16.6 ± 2.3 minutes (p <0.001) (Fig. 3.2.3.2.1).

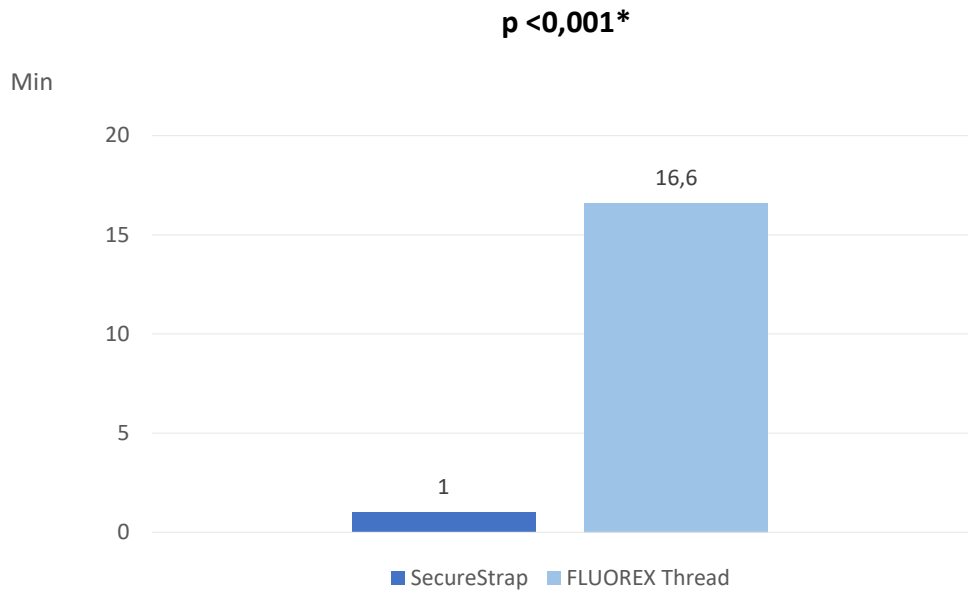


Figure 3.2.3.2.1 – Positioning time of one endoprosthesis when using stapler and suture fixation. * – statistically significant differences.

By day 45, all absorbable stapler clamps were in their installation zones, and all suture ligatures were consistent. Such indicators as the number of implants with deformation and retraction did not have significant differences, while there were fewer prostheses with retraction when using FLUOREX thread (37.5% vs. 75% when using a stapler) (Table 3.2.3.2.1). The chances of retraction when using FLUOREX thread, compared with SecureStrap, were lower by 5.0 times (OR = 0.200; 95% CI: 0.014–2.911).

All absolute and relative indicators of the area of the endoprosthesis both in the animal's body and after excision were slightly higher when fixed with a FLUOREX thread, however, no significant differences were noted (Table 3.2.3.2.1, Fig. 3.2.3.2.2).

Table 3.2.3.2.1 – Indicators of deformation and retraction when using various options for fixing mesh endoprostheses by 45 days of the experiment

Parameter	The retainer		Reliability (p)	Odds ratio (OR) (95% CI)
	SecureStrap (n = 4)	FLUOREX Thread (n = 8)		
Deformation, abs. (%)	1 (25,0)	1 (12,5)	1,000	0,429

				(0,020 – 9,364)
Retraction, abs. (%)	3 (75,0)	3 (37,5)	0,545	0,200 (0,014 – 2,911)
The area of the prosthesis in the animal's body, cm^2, Me (Q1 – Q3)	26,0 (25,0 – 27,0)	29,0 (26,8 – 30,5)	0,172	-
The area of the prosthesis after excision, cm^2, M ± SD (95% CI)	26,0 ± 2,2 (22,6 – 29,4)	28,4 ± 4,5 (24,6 – 32,1)	0,346	-
The size of the prosthesis compared to the original one in the animal's body, %, Me (Q1 – Q3)	77,4 (74,4 – 80,4)	86,3 (79,6 – 90,8)	0,172	-
The size of the prosthesis compared to the original one after excision, %, M ± SD (95% CI)	77,4 ± 6,4 (67,1 – 87,6)	84,5 ± 13,3 (73,3 – 95,6)	0,345	-

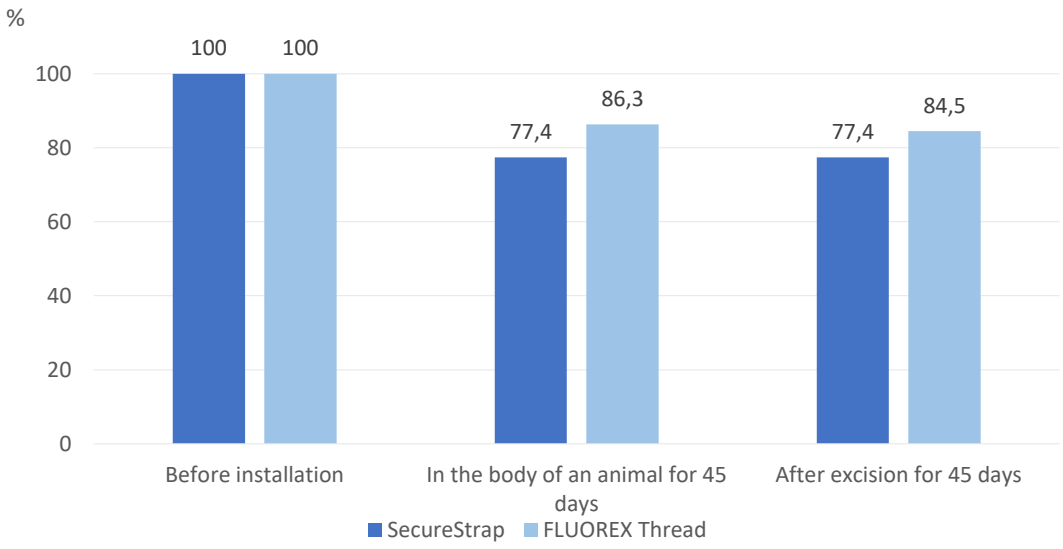


Figure 3.2.3.2.2 – The area of mesh endoprostheses compared to the initial one when using various fixation options

All the indicators of adhesion formation in the area of localization of the prosthesis when using the SecureStrap herniospler and FLUOREX filaments did not have significant differences (Table 3.2.3.2.2). The most pronounced adhesive process was noted when using a Symbotex implant and absorbable SecureStrap stapler clamps (Fig. 3.2.3.2.3).

Table 3.2.3.2.2 – Parameters of adhesion formation in the area of the endoprosthesis when using various fixation options by the 45th day of the experiment

Parameter		The retainer		Reliability (p)	Odds ratio (OR) (95% CI)
		SecureStrap (n = 4)	FLUOREX Thread (n = 8)		
Dentures with spikes, abs. (%)		3 (75,0)	5 (62,5)	1,000	0,556 (0,038 – 8,085)
Coverage of the surface of the prosthesis with adhesions, abs. (%)	Mooring	1 (33,3)	1 (20,0)	0,688	-
	Edges	0 (0,0)	1 (20,0)		
	Edges and center	2 (66,7)	3 (60,0)		
The area of the implant involved in adhesions (P.A. Lucas et al.), points, M ± SD (95% CI)		1,2 ± 1,3 (0,8 – 3,3)	0,8 ± 0,7 (0,2 – 1,3)	0,390	-
Type of adhesions (M.D. Muller et al.), points, Me (Q1 – Q3)		1,0 (0,8 – 1,2)	1,5 (0,0 – 2,0)	0,786	-
Adhesive strength (H.V. Zühlke et al.), points, Me (Q1 – Q3)		2,0 (1,5 – 2,0)	2,0 (0,0 – 2,0)	0,678	-
Involvement of parenchymal and hollow organs in the adhesive process, abs. (%)		1 (25,0)	3 (37,5)	1,000	-
Involvement of abdominal organs in the adhesive process, abs. (%)	Oil seal	2 (66,7)	1 (25,0)	0,525	-
	The spleen	0 (0,0)	1 (25,0)		
	The large intestine	1 (33,3)	1 (25,0)		
	Omentum and colon	0 (0,0)	1 (25,0)		
Integral assessment of spike formation (M.P. Diamond), points, Me (Q1 – Q3)		4,0 (3,0 – 4,8)	4,0 (0,0 – 5,0)	0,791	-

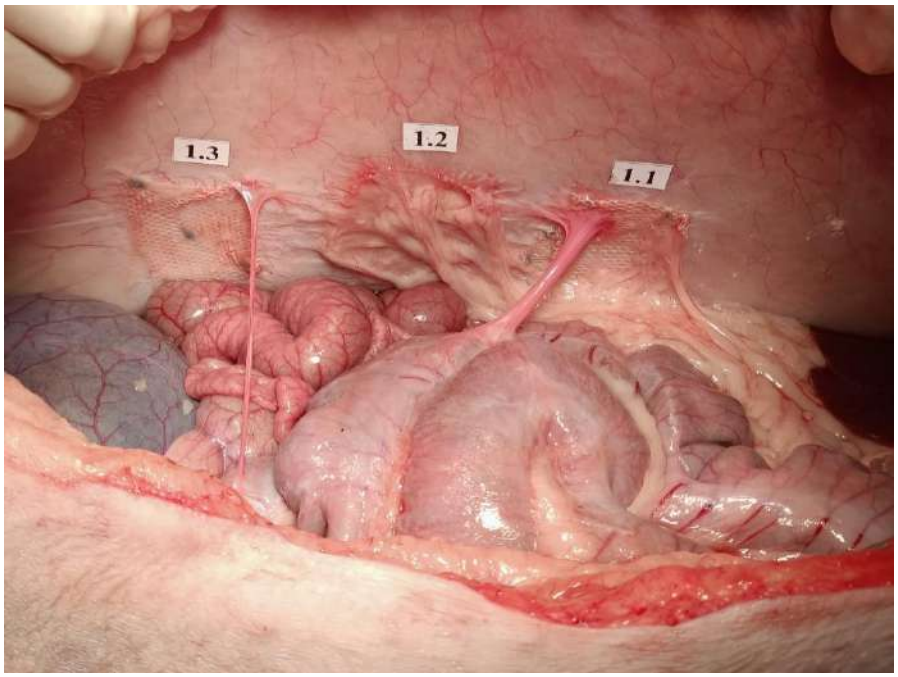


Figure 3.2.3.2.3 – A common adhesive process on the surface of the Sympatex prosthesis fixed by the SecureStrap herniator. *Sample 1.2 is Symbotex.*

Fixation did not affect the thickness of the resulting prosthesis-tissue complex. The average breaking load of the complex turned out to be higher when using FLUOREX filament (37.3 ± 8.3 N versus 34.9 ± 14.6 N for SecureStrap), and the average breaking elongation, on the contrary, turned out to be less (75.9 ± 14.0 mm versus 83.0 ± 36.8 mm for SecureStrap). At the same time, no significant differences were found (Table 3.2.3).

Table 3.2.3.2.3 – Physical properties and biomechanical strength of the prosthesis-tissue complex when using various options for fixing mesh endoprostheses by 45 days of the experiment

Parameter	The retainer		Reliability (p)	Odds ratio (OR) (95% CI)
	SecureStrap (n = 4)	FLUOREX Thread (n = 8)		
The thickness of the complex, mm, M ± SD (95% CI)	0,9 ± 0,3 (0,5 – 1,4)	0,9 ± 0,2 (0,8 – 1,1)	0,900	-
Mechanical fixation strength of the prosthesis, points, Me (Q1 – Q3)	4,0 (4,0 – 4,0)	4,0 (4,0 – 4,0)	0,480	-

Average breaking load, N, M ± SD (95% CI)	34,9 ± 14,6 (11,7 – 58,2)	37,3 ± 8,3 (30,3 – 44,2)	0,728	-
Breaking load along the loop row, N, M ± SD (95% CI)	-	37,7 ± 3,7 (28,4 – 47,0)	-	-
Breaking load along the loop column, N, M ± SD (95% CI)	34,9 ± 14,6 (11,7 – 58,2)	36,4 ± 9,7 (26,3 – 46,5)	0,852	-
Average breaking elongation, mm, M ± SD (95% CI)	83,0 ± 36,8 (24,4 – 141,6)	75,9 ± 14,0 (64,2 – 87,6)	0,629	-
Breaking elongation along the loop row, mm, M ± SD (95% CI)	-	93,8 ± 3,4 (85,3 – 102,2)	-	-
Breaking elongation along the loop column, mm, M ± SD (95% CI)	83,0 ± 36,8 (24,4 – 141,6)	67,9 ± 7,0 (60,5 – 75,3)	0,344	-

CHAPTER 4. THE RESULTS OF THE STUDY OF THE CLINICAL EFFICACY AND SAFETY OF COMPOSITE ENDOPROSTHESES AND FIXATION METHODS USED IN IPOM HERNIOPLASTY: A MULTICENTER RETROSPECTIVE STUDY

4.1. Results of the use of composite endoprostheses with different anti-adhesive coating in intraperitoneal hernioplasty IPOM in patients with primary and postoperative ventral hernias

The first task of the retrospective clinical study was to assess the effect of the anti-adhesive coating of the mesh endoprosthesis on a number of the most significant indicators characterizing the results of treatment of patients after intraperitoneal hernioplasty [71,72]. For this purpose, depending on the anti-adhesive coating option, 3 study groups were formed. Collagen–coated endoprostheses were previously installed in 1 patient, hyaluronic acid and carboxymethylcellulose in 2, and Reperen in 3.

The largest number of patients turned out to be in group 1, which was due to the most frequent use of such implants in clinical practice. Also in this group, the largest number of different endoprostheses were presented: Parietene Composite with a polypropylene base, Parietex Composite and Symbotex – with a polyester base. In group 3, several variants of endoprostheses were also used: Reperen-16-1 and Reperen-16-2. Both variants had a similar design and differed only in the presence of filaments for positioning the second implant. In group 2, only one variant of the Ventralight ST endoprosthesis was used.

The average age of patients in the groups was 57.9 ± 13.3 years. Women made up 65.7% (90 people), men – 34.3% (47 people). According to these indicators, there were no significant differences in the groups (Table 4.1.1). The follow–up period was 84.0 (16.0-108.0) months. If in the groups where prostheses coated with collagen and hyaluronic acid and carboxymethylcellulose were used, the follow–up period practically did not differ and amounted to more than 90 months, then in the group with Reperen implants it turned out to be significantly less and amounted to only 13.0 (12.0-14.0) months ($p = 0.003$) (Fig. 4.1.1).

Table 4.1.1 – Demographic and statistical indicators in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
Age, years, M ± SD	57,9 ± 13,3	58,4 ± 13,7	53,3 ± 13,3	58,4 ± 10,6	0,631
Gender (men), abs. (%)	47 (34,3)	26 (34,2)	11 (29,7)	10 (41,7)	0,851
Gender (women), abs. (%)	90 (65,7)	50 (65,8)	26 (70,3)	14 (58,3)	
Observation period, months, Me (Q1 – Q3)	84,0 (16,0 – 108,0)	91,0 (24,0 – 108,0)	90,0 (49,5 – 95,5)	13,0 (12,0 – 14,0)	0,003*

GC-CMC – hyaluronic acid and carboxymethylcellulose

* – statistically significant differences

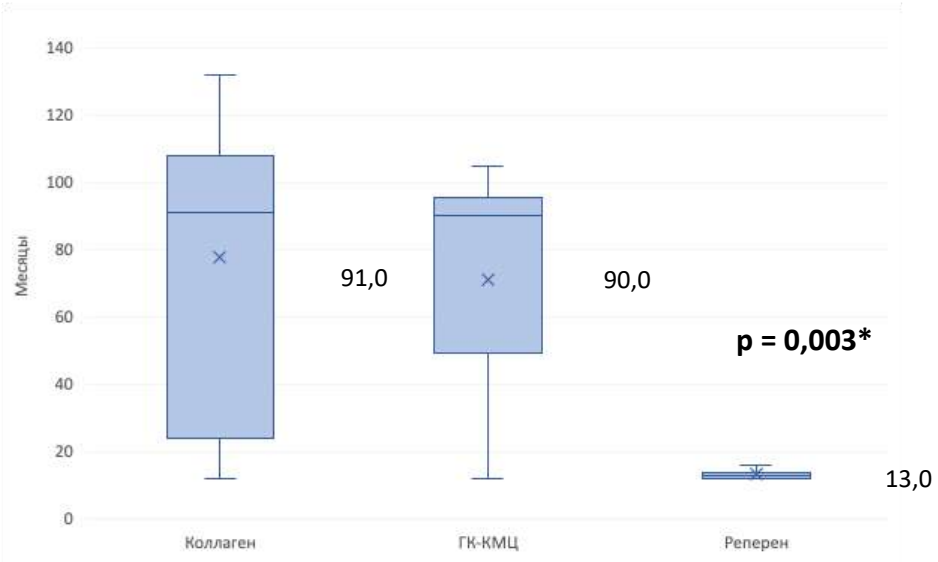


Figure 4.1.1 – Average follow-up periods in groups divided by type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

According to health indicators, patients in the groups had no significant differences (Table 4.1.2), but had certain risk factors for hernia (sedentary lifestyle, physical activity, sports, smoking, etc.). 35.0% had 1 factor, 53.3% had 2 factors, and 11.7% had 3 or more risk factors. Concomitant diseases were present in 94 patients (68.6%). There were slightly more than half of those with varying degrees of obesity, while the average BMI was 30.5 ± 4.9 kg/m^2. 73 patients (53.3%) had previously undergone surgery on the abdominal cavity or abdominal wall.

Table 4.1.2 – Health indicators in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
BMI, kg/m^2, M ± SD	30,5 ± 4,9	30,5 ± 5,1	30,2 ± 3,4	30,2 ± 4,4	0,977
Normal weight (<30 kg/m2), abs. (%)	66 (48,2)	35 (46,1)	21 (56,8)	10 (41,7)	0,834
Obesity (≥30 kg/m2), abs. (%)	71 (51,8)	41 (53,9)	16 (43,2)	14 (58,3)	
1 risk factor, abs. (%)	48 (35,0)	30 (39,5)	11 (29,7)	7 (29,2)	0,761
2 risk factors, abs. (%)	73 (53,3)	37 (48,7)	21 (56,8)	15 (62,5)	
3 or more risk factors, abs. (%)	16 (11,7)	9 (11,8)	5 (13,5)	2 (8,3)	
The presence of concomitant diseases, abs. (%)	94 (68,6)	56 (73,7)	21 (56,8)	17 (70,8)	0,650

The presence of operations on abdominal organs, abs. (%)	73 (53,3)	47 (61,8)	16 (43,2)	10 (41,7)	0,412

GC-CMC – hyaluronic acid and carboxymethylcellulose

Primary hernias were present in 79 patients (57.7%), postoperative in 58 (42.3%) (Table 4.1.3). Median hernias accounted for 83.2% of cases, and lateral hernias accounted for 16.8%. 31 patients (22.6%) had diastasis of the rectus abdominis muscles. The median duration of herniation was 3.0 (2.0 – 5.0) years.

The area of the hernial gate was the largest in the group where collagen–coated implants were used – 24.0 (4.0 – 48.5) cm^2, the smallest in the group with a coating of a prosthesis made of hyaluronic acid and carboxymethylcellulose – 4.0 (3.2 – 8.9) cm^2. The indicators in the Reference group showed an intermediate value of 12.6 (2.4 – 37.3) cm^2 (Fig. 4.1.2).

Table 4.1.3 – Parameters related to the presence of hernia in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
Primary hernias, abs. (%)	79 (57,7)	40 (52,6)	25 (67,6)	14 (58,3)	0,055
Postoperative hernias, abs. (%)	58 (42,3)	36 (47,4)	12 (32,4)	10 (41,7)	
Median hernias, abs. (%)	114 (83,2)	63 (82,9)	33 (89,2)	18 (75,0)	0,278
Lateral hernias, abs. (%)	23 (16,8)	13 (17,1)	4 (10,8)	6 (25,0)	
Duration of herniation, years, Me (Q1 – Q3)	3,0 (2,0 – 5,0)	3,0 (2,0 – 5,0)	5,0 (3,5 – 10,0)	2,0 (2,0 – 11,5)	0,525

Hernial gate area, cm^2, Me (Q1 – Q3)	19,6 (3,1 – 44,0)	24,0 (4,0 – 48,5)	4,0 (3,2 – 8,9)	12,6 (2,4 – 37,3)	0,096
Diastasis, abs. (%)	31 (22,6)	14 (18,4)	11 (29,7)	6 (25,0)	0,135

GC-CMC – hyaluronic acid and carboxymethylcellulose

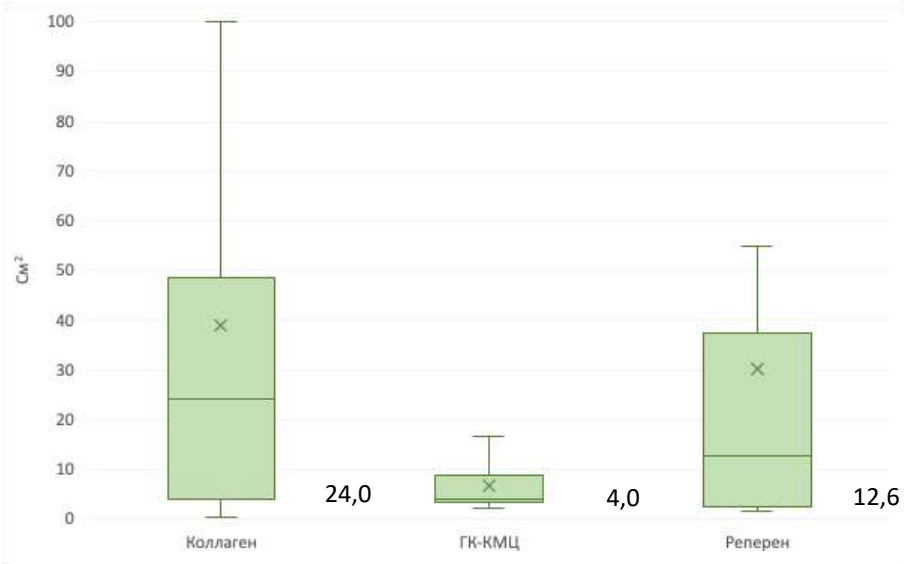


Figure 4.1.2 – The area of the hernial gates in groups divided by the type of anti-adhesive coating of the endoprosthesis
GC-CMC – hyaluronic acid and carboxymethylcellulose

During the operation, 53 patients (38.7%) used local anesthetics of prolonged action (Table 4.1.4). Hernial gate suturing was performed more often when using a Reperen–coated endoprosthesis - in 87.5% of cases (Fig. 4.1.3). In the other groups, suturing was performed significantly less frequently.

The endoprosthesis areas ranged from 63.6 to 640.0 cm^2, with a median of 294.5 (117.9 – 300.0) cm^2. In the group with collagen coating of the prosthesis, the median was the largest – 300.0 (150.0 – 300.0) cm^2, in the group with a coating of Reperene the smallest – 117.9 (117.9 – 176.8) cm^2 (Fig. 4.1.4). The highest ratio of the implant area and the area of the hernial gate was noted when using prostheses coated with hyaluronic

acid and carboxymethylcellulose – 28.3 (19.7 – 105.8), the lowest – when using prostheses coated with Reperene – 9.4 (5.7 – 56.5) (Fig. 4.1.5).

Damage to the visceral layer was more often observed in groups 1 and 2, where the prostheses had a biodegradable layer (Table 4.1.4). In most cases, this occurred when the implant was inserted into the abdominal cavity through a 10 mm laparoscopic port. One case of damage to a prosthesis with a non-absorbable protective layer of Reperen was caused by mechanical action of a spiral titanium retainer.

Of the clinical and economic indicators, there was a significant difference in the groups only when comparing the cost of an endoprosthesis (Table 4.1.4). It ranged from 19239 to 66741 rubles with a median value of 35219.0 (25429.5 – 45784.0) rubles. In the group where the implant was coated with collagen, this indicator was 35219.0 (26260.0 – 45784.0) rubles, from hyaluronic acid and carboxymethylcellulose – 30990.0 (26990.0 – 48980.0) rubles, from Reperen – 20900.0 (20900.0 – 26950.0) rubles (p = 0.016) (Fig. 4.1.6). The median time of the operation was 100.0 (70.0 – 130.0) minutes, and the time spent in the hospital was 3.0 (2.0 – 4.0) days.

Table 4.1.4 – Operational and clinical and economic indicators in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
The use of prolonged local anesthetics, abs. (%)	53 (38,7)	36 (47,4)	14 (37,8)	3 (12,5)	0,473
Hernia gate suturing, abs. (%)	51 (37,2)	19 (25,0)	11 (29,7)	21 (87,5)	0,004*
Endoprosthesis area, cm^2, Me (Q1 – Q3)	294,5 (117,9 – 300,0)	300,0 (150,0 – 300,0)	235,6 (115,5 – 294,5)	117,9 (117,9 – 176,8)	0,077
The ratio of the area of the prosthesis to the area	12,5 (6,4 – 36,5)	12,0 (6,3 – 27,9)	28,3 (19,7	9,4 (5,7 – 56,5)	0,096

of the hernial gate, Me (Q1 – Q3)			– 105,8)		
Damage to the visceral layer of the prosthesis, abs. (%)	37 (27,0)	26 (34,2)	10 (27,0)	1 (4,2)	0,238
Operation time, min., Me (Q1 – Q3)	100,0 (70,0 – 130,0)	105,0 (70,0 – 135,0)	110,0 (62,5 – 122,5)	90,0 (67,5 – 110,0)	0,768
Hospital stay time, days, Me (Q1 – Q3)	3,0 (2,0 – 4,0)	3,0 (2,0 – 4,0)	3,0 (2,5 – 3,0)	3,0 (2,5 – 4,5)	0,602
The cost of the endoprosthesis, rub., Me (Q1 – Q3)	35219,0 (25429,5 – 45784,0)	35219,0 (26260,0 – 45784,0)	30990,0 (26990,0 – 48980,0)	20900,0 (20900,0 – 26950,0)	0,016*

GC-CMC – hyaluronic acid and carboxymethylcellulose

* – statistically significant differences

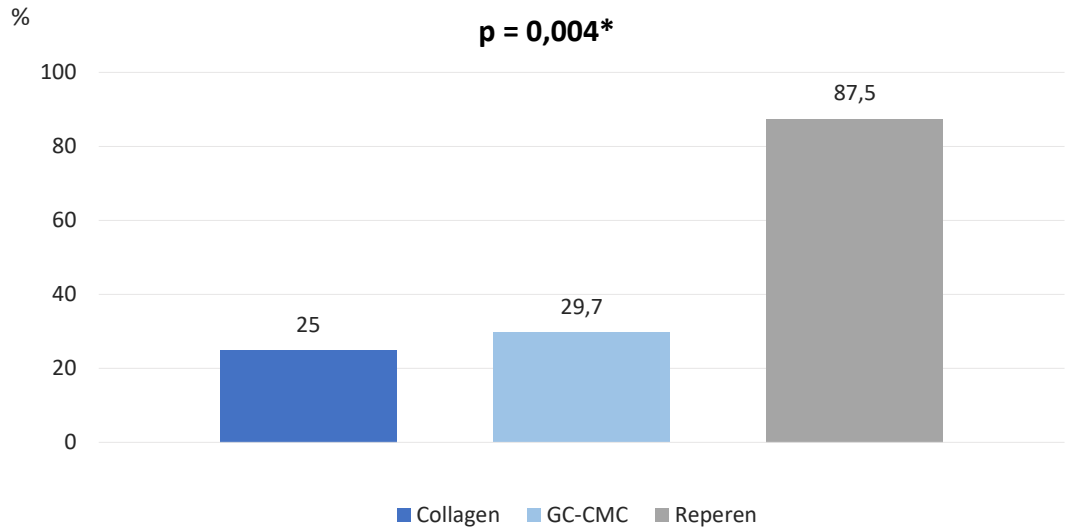


Figure 4.1.3 – The frequency of hernial gate suturing in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

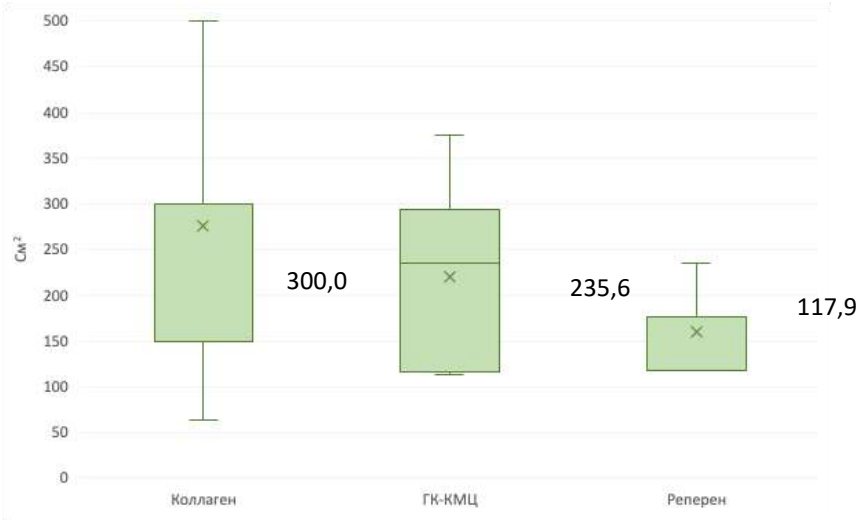


Figure 4.1.4 – The area of the implant in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

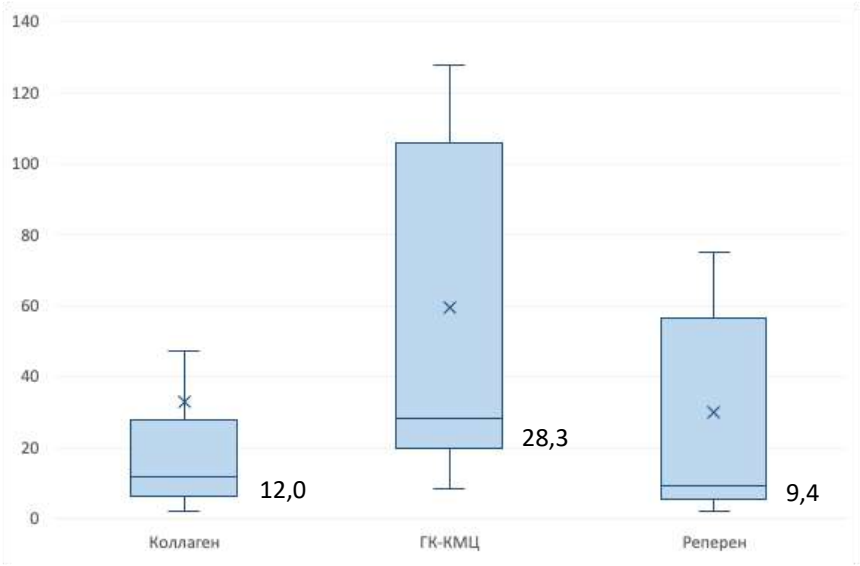
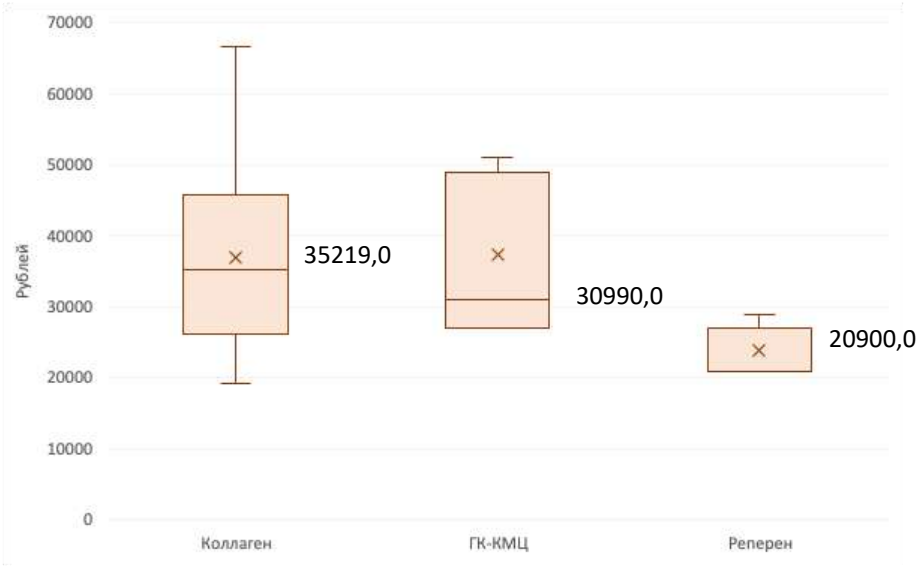


Figure 4.1.5 – The ratio of the implant area to the area of the hernial gate in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose



p = 0,016*

Figure 4.1.6 – Cost of implants in groups divided by type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

When performing IPOM hernioplasty, only 2 intraoperative complications were documented, which amounted to 1.5% (Table 4.1.5). In both cases, it was bleeding from the main trunk or branches of the inferior epigastric artery, which occurred when transfascial ligature devices and stapler fixators were damaged (Table 4.1.6).

Early postoperative complications were observed in 26 patients, which was 19.0% (Table 4.1.5). In the group with a collagen coating, their number was 15.8%, with a coating of hyaluronic acid and carboxymethylcellulose – 13.5%, with a coating of Reperene – 37.5% (Fig. 4.1.7). All complications were classified in classes I and II according to the Clavien-Dindo Classification. Half of the cases of all complications were seromas (Table 4.1.6). Hematomas in the tissues surrounding the area of hernial protrusion or trocar wounds, wound suppuration, dermatitis, and severe pain syndrome were less common. It should be noted that persistent pain syndrome in one case was observed not in the area of localization of the endoprosthesis, but in the place of the sutured trocar wound. When using implants with a coating of Reperenes, in 2 cases, such

a specific complication as intestinal paresis was noted. The complications were eliminated by conservative methods. Repeated surgical interventions were not required.

Late postoperative complications were detected in 27 patients, which amounted to 19.7% (Table 4.1.5). There were significant differences in their number in the compared groups. In the group with a collagen coating, their number was 13.2%, with a coating of hyaluronic acid and carboxymethylcellulose – 16.2%, with a coating of Reperene – 45.8% ($p = 0.025$) (Fig. 4.1.8). As in the group of early complications, seromas accounted for more than half of the cases – in 14 patients (51.9%) (Table 4.1.6). Most of the complications belonged to classes I and II according to the Clavien-Dindo Classification. In 2 cases, trocar hernias occurred, requiring repeated surgical intervention (Class III according to Clavien-Dindo Classification).

A clinical example

Patient M., 68 years old, was admitted for surgical treatment to the Department of General Surgery of the A.S. Loginov Moscow Medical Center on April 6, 2022 with the diagnosis: Postoperative ventral hernia M2-3W2. CHD. Hypertension 2 st. Diabetes mellitus, type 2, compensated. Nodular goiter. Gout. Earlier, in 2013, laparoscopic cholecystectomy was performed for gallstone disease, chronic calculous cholecystitis. Under general anesthesia, the patient underwent laparoscopic prosthetic hernioplasty IPOM Plus. A Parietex Composite endoprosthesis measuring 15 by 20 cm was installed, fixation was performed using non-absorbable stainless steel staples coated with polyester etheric ketone CapSure. The postoperative period was uneventful. After 3 months, a hernial protrusion appeared in the localization zone of the 10 mm port in the left lumbar region. The patient was re-operated on November 14, 2022 (7 months after the first operation) with the diagnosis: Postoperative trocar hernia L2W2 on the left. Combined plastic surgery from traditional access was performed under general anesthesia. The 10 by 15 cm SoftMesh implant was located partly in the Sublay position, partly between the fibers of the oblique abdominal muscles. The postoperative period was uneventful. With a follow-up period of 12 months, no recurrence of hernias was noted.

Table 4.1.5 – Complications in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
Intraoperative	2 (1,5)	1 (1,3)	0 (0,0)	1 (4,2)	0,890
Early postoperative (up to 30 days)	26 (19,0)	12 (15,8)	5 (13,5)	9 (37,5)	0,124
Late postoperative	27 (19,7)	10 (13,2)	6 (16,2)	11 (45,8)	0,025*

GC-CMC – hyaluronic acid and carboxymethylcellulose

* – statistically significant differences

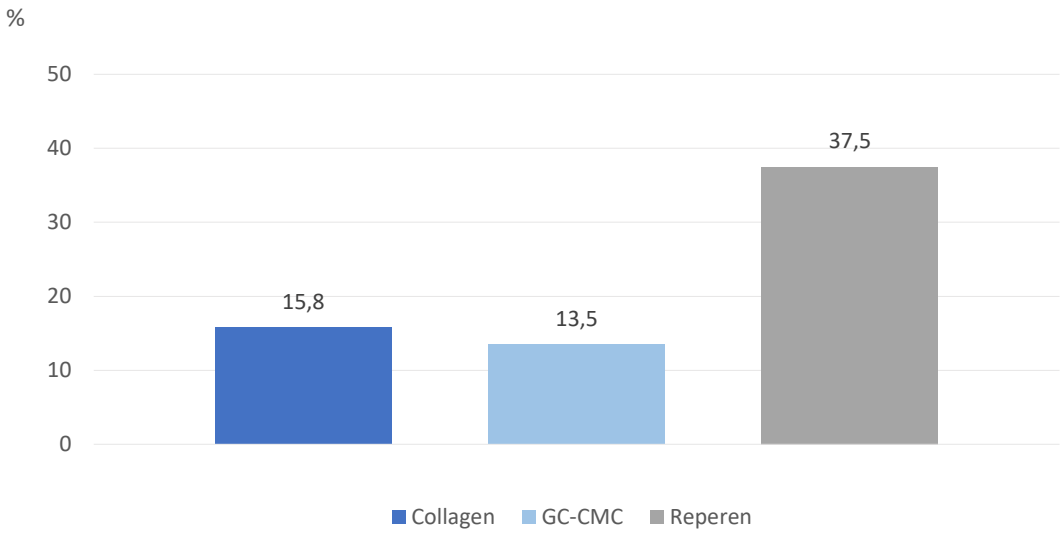


Figure 4.1.7 – Frequency of early (up to 30 days) postoperative complications in groups divided by type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

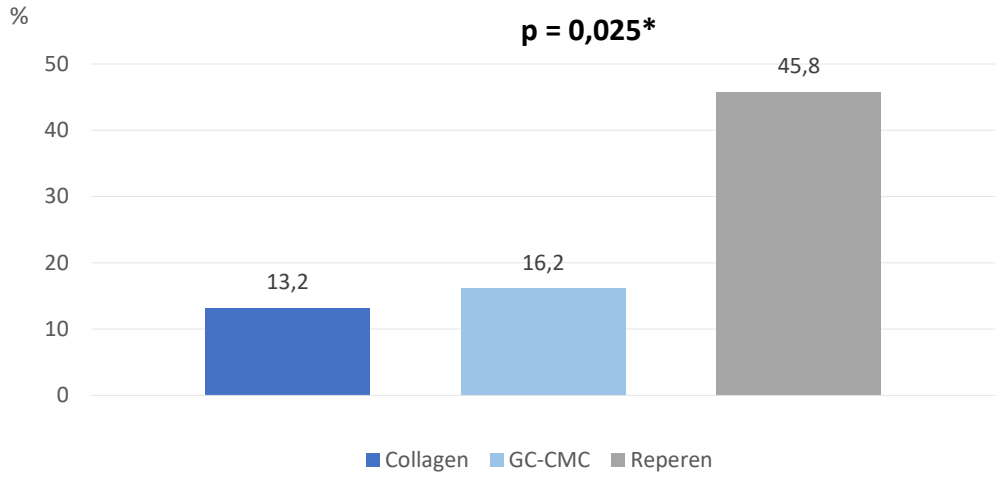


Figure 4.1.8 – The frequency of late postoperative complications in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

Table 4.1.6 – Nosology of complications in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Anti-adhesive coating		
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)
Intraoperative				
Bleeding	2 (100,0)	1 (100,0)	0 (0,0)	1 (100,0)
Early postoperative (up to 30 days)				
Hematoma	4 (15,4)	2 (16,7)	1 (20,0)	1 (11,1)
Seroma	13 (50,0)	6 (50,0)	2 (40,0)	5 (55,6)
Suppuration	4 (15,4)	2 (16,7)	1 (20,0)	1 (11,1)
Dermatitis	1 (3,8)	0 (0,0)	1 (20,0)	0 (0,0)
Intestinal paresis	2 (7,7)	0 (0,0)	0 (0,0)	2 (22,2)
Pain syndrome	2 (7,7)	2 (16,7)	0 (0,0)	0 (0,0)
Late postoperative				
Chronic seroma	14 (51,9)	6 (60,0)	2 (33,3)	6 (54,5)
Infiltration	3 (11,1)	2 (20,0)	0 (0,0)	1 (9,1)
Suppuration	2 (7,4)	0 (0,0)	1 (16,7)	1 (9,1)
Dermatitis	2 (7,4)	0 (0,0)	1 (16,7)	1 (9,1)
Dysuria	2 (7,4)	1 (10,0)	0 (0,0)	1 (9,1)
Chronic pain	2 (7,4)	0 (0,0)	1 (16,7)	1 (9,1)
Trocar hernia	2 (7,4)	1 (10,0)	1 (16,7)	0 (0,0)

GC-CMC – hyaluronic acid and carboxymethylcellulose

A separate assessment of recurrent hernia and diastasis, as well as adhesions in the area of localization of the endoprosthesis, did not reveal significant differences in the groups (Table 4.1.7). Relapses were noted in 4 patients (2.9%), of which 2 were in the group with a collagen coating and one each in the groups with a coating of hyaluronic acid and carboxymethylcellulose, and Reperene. All patients have been operated on again.

Of the 31 patients who underwent additional elimination of rectus muscle diastasis at the stage of IPOM hernioplasty, its recurrence was noted in 25.8% of cases. Diastasis recurrence was more often observed in the group with a coating of an endoprosthesis made of hyaluronic acid and carboxymethylcellulose (44.4%), less often with a coating of collagen (16.7%) (Fig. 4.1.9).

The assessment of adhesion formation using ultrasound also did not reveal significant differences in the groups (Table 4.1.7). Large figures were obtained in the group where a Reperen–coated implant was used – 50.0%, smaller ones – in the group with a coating of hyaluronic acid and carboxymethylcellulose - 24.3% (Fig. 4.1.10).

Table 4.1.7 – Recurrence of hernia, diastasis of rectus muscles and adhesions in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
Recurrence of hernia	4 (2,9)	2 (2,6)	1 (2,7)	1 (4,2)	0,790
Recurrence of diastasis	8 of 31 (25,8)	3 of 18 (16,7)	4 of 9 (44,4)	1 of 4 (25,0)	0,190
Adhesions in the area of localization of the endoprosthesis	48 (35,0)	27 (35,5)	9 (24,3)	12 (50,0)	0,173

GC-CMC – hyaluronic acid and carboxymethylcellulose

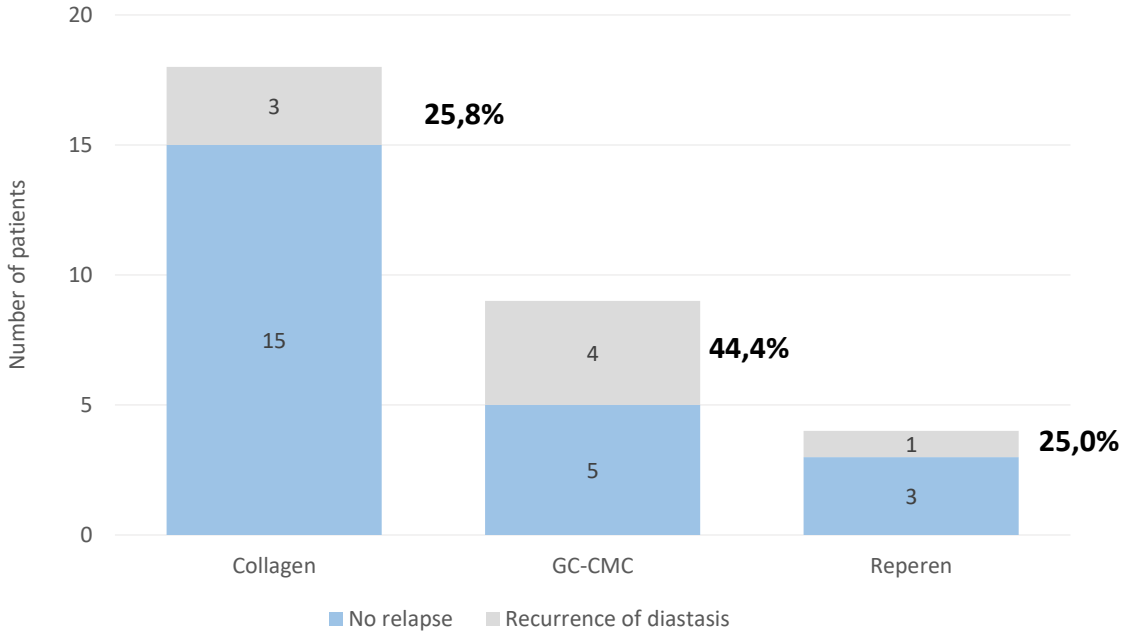


Figure 4.1.9 – Frequency of recurrence of diastasis in groups divided by type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

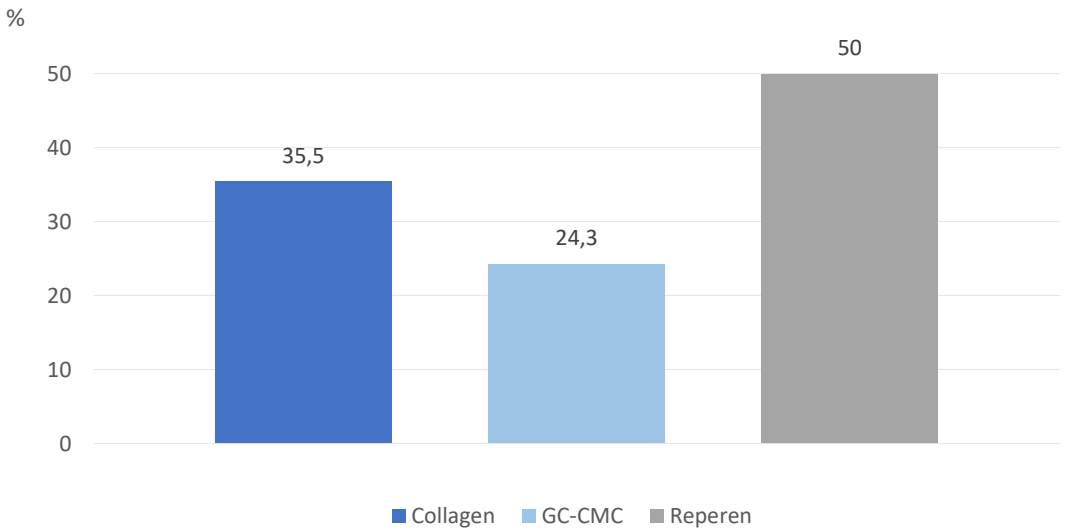


Figure 4.1.10 – Frequency of detection of adhesions in the hernioplasty area in groups divided by type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

The assessment of the quality of life in the groups did not show significant differences (Table 4.1.8). Overall dissatisfaction with the quality of life was the lowest

when using implants coated with hyaluronic acid and carboxymethylcellulose – 5.0 (0.0 – 12.0) points, the highest when using prostheses coated with Reperene – 20.0 (11.0 – 22.5) points (Fig. 4.1.11). Such figures were obtained mainly due to the difference in such a parameter as restriction of physical activity (p = 0.065) (Fig. 4.1.12). In terms of pain and cosmetic dissatisfaction, the difference was insignificant.

Table 4.1.8 – Quality of life parameters in groups of patients divided by type of anti-adhesive coating of the endoprosthesis with primary and postoperative ventral hernias

Parameters, Points, Me (Q1 – Q3)	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Collagen (n = 76)	GC-CMC (n = 37)	Reperen (n = 24)	
General dissatisfaction with the quality of life	12,0 (2,5 – 22,0)	12,0 (3,0 – 22,0)	5,0 (0,0 – 12,0)	20,0 (11,0 – 22,5)	0,271
Pain	0,0 (0,0 – 1,5)	0,0 (0,0 – 2,0)	0,0 (0,0 – 0,0)	0,0 (0,0 – 0,0)	0,309
Activity restriction	5,0 (0,0 – 20,0)	8,0 (0,0 – 20,0)	0,0 (0,0 – 0,0)	20,0 (9,0 – 20,0)	0,065
Cosmetic dissatisfaction	1,0 (0,0 – 4,5)	2,0 (0,0 – 4,0)	0,0 (0,0 – 8,5)	0,0 (0,0 – 1,0)	0,367

GC-CMC – hyaluronic acid and carboxymethylcellulose

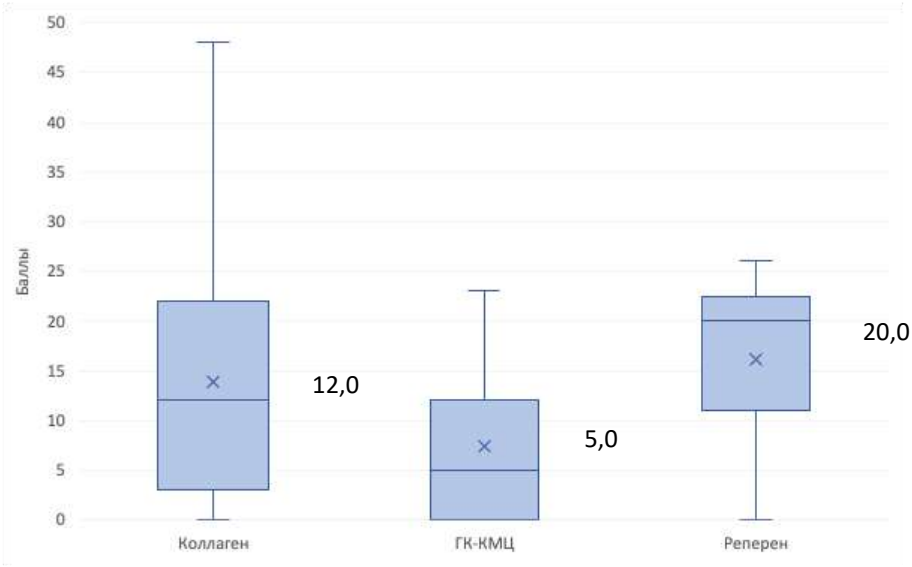


Figure 4.1.11 – General dissatisfaction with the quality of life in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

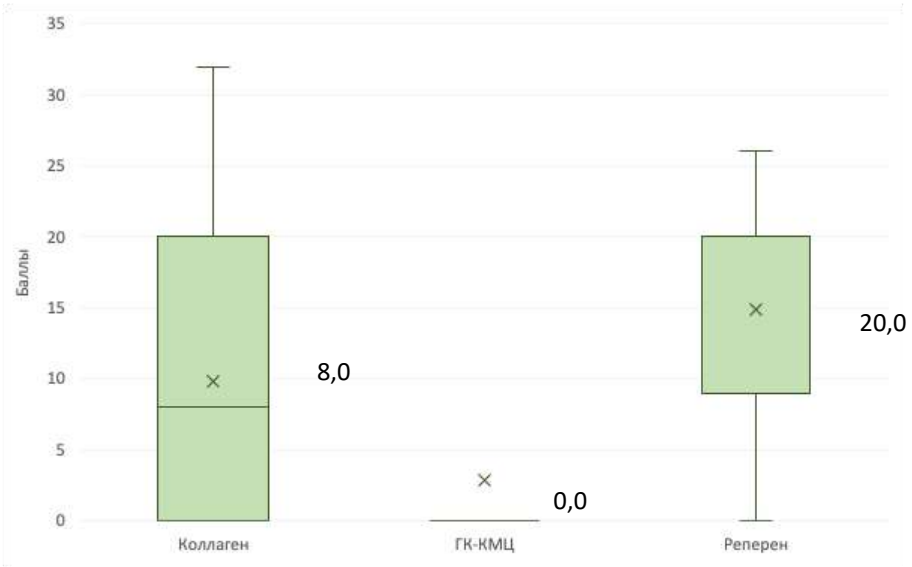


Figure 4.1.12 – Restriction of physical activity in groups divided by the type of anti-adhesive coating of the endoprosthesis

GC-CMC – hyaluronic acid and carboxymethylcellulose

4.2. Results of the use of absorbable, non-absorbable and adhesive fixation of the endoprosthesis in intraperitoneal hernioplasty IPOM in patients with primary and postoperative ventral hernias

The second important task of the retrospective clinical study was to assess the effect of the type of fixation of the endoprosthesis to the abdominal wall on the results of treatment. The patients were divided into 3 groups. In the 1st, non-absorbable stapler fixators were used, in the 2nd - absorbable fixators, in the 3rd – fixation was carried out using surgical cyanoacrylate glue.

The largest number of patients entered the 1st group. During the operation, both spiral titanium ProTack and L-0196 fixators and steel fixators coated with polyester etheric ketone CapSure were used. Bioresorbable fixators AbsorbaTack, ReliaTack and SecureStrap were used in the 2nd group. In group 3, Glubran 2 butyl-2-cyanoacrylate surgical adhesive was used, which was delivered to the fixation zone using a Glutack atraumatic laparoscopic mesh fixation device.

The average age of patients in the groups was 57.9 ± 13.3 years. Women made up 65.7% (90 people), men – 34.3% (47 people). According to these indicators, no significant differences were found in the groups (Table 4.2.1). The median follow–up period was 84.0 (16.0 - 108.0) months. The follow–up periods in the groups with non–absorbable and absorbable fixation were practically the same (91.0 (19.2 – 108.5) versus 85.0 (30.0 - 102.0) months), while in the group where adhesive fixation was used, they were significantly less (13.0 (12.0 - 13.0) months, p = 0.017) (Fig. 4.2.1).

Table 4.2.1 – Demographic and statistical indicators in groups of patients with primary and postoperative ventral hernias, divided by type of fixation of the endoprosthesis

Parameters	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
Age, years, M ± SD	57,9 ± 13,3	58,8 ± 13,6	52,8 ± 13,5	62,8 ± 5,4	0,227

Gender (men), abs (%)	47 (34,3)	35 (38,9)	9 (28,1)	3 (20,0)	0,637
Gender (women), abs (%)	90 (65,7)	55 (61,1)	23 (71,9)	12 (80,0)	
Observation period, months, Me (Q1 – Q3)	84,0 (16,0 – 108,0)	91,0 (19,2 – 108,5)	85,0 (30,0 – 102,0)	13,0 (12,0 – 13,0)	0,017*

* – statistically significant differences

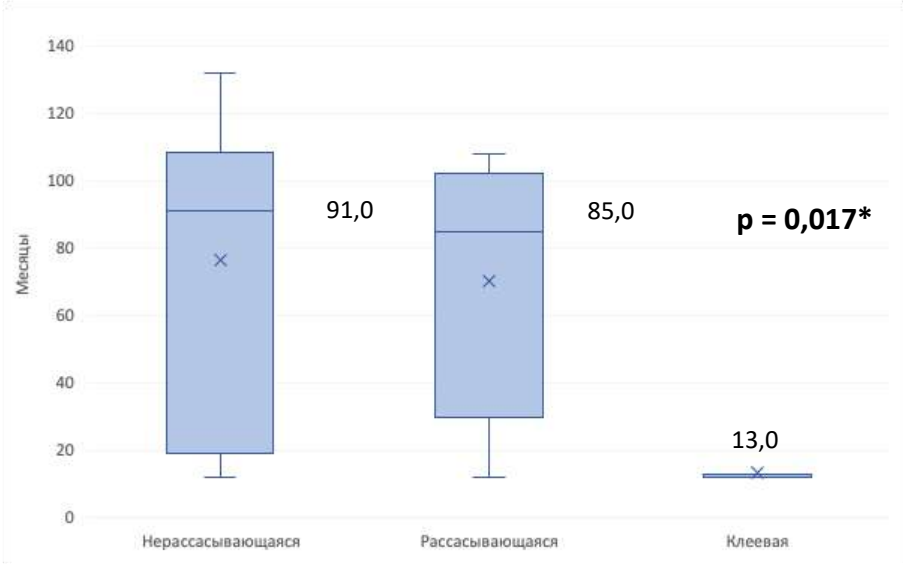


Figure 4.2.1 – Average follow-up periods in groups divided by type of endoprosthesis fixation

There were no significant differences in the number of risk factors (p = 0.518) and BMI (p = 0.062) in the groups (Table 4.2.2). However, when dividing patients into groups based on the presence of obesity, this indicator was significantly lower in the group where absorbable fixation was used (25.0% versus 60.0% in the other two groups, p = 0.030). In the group where absorbable fixation was used, patients had fewer concomitant diseases (43.8% versus 76.6% in the group with non-absorbable fixation and 73.3% in the group with adhesive fixation, p = 0.014). There were also fewer patients in this group who had previously undergone abdominal surgery (28.1% versus 64.4% in the group with non-absorbable fixation and 40.0% in the group with adhesive fixation, p = 0.019).

Table 4.2.2 – Health indicators in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
BMI, kg/m^2, M ± SD	30,5 ± 4,9	31,1 ± 5,1	27,7 ± 2,9	30,8 ± 5,1	0,062
Normal weight (<30 kg/m^2), abs. (%)	66 (48,2)	36 (40,0)	24 (75,0)	6 (40,0)	0,030*
Obesity (≥30 kg/m^2), abs. (%)	71 (51,8)	54 (60,0)	8 (25,0)	9 (60,0)	
1 risk factor, abs. (%)	48 (35,0)	29 (32,2)	16 (50,0)	3 (20,0)	0,518
2 risk factors, abs. (%)	73 (53,3)	50 (55,6)	11 (34,4)	12 (80,0)	
3 or more risk factors, abs. (%)	16 (11,7)	11 (12,2)	5 (15,6)	0 (0,0)	
The presence of concomitant diseases, abs. (%)	94 (68,6)	69 (76,7)	14 (43,8)	11 (73,3)	0,014*
The presence of operations on abdominal organs, abs. (%)	73 (53,3)	58 (64,4)	9 (28,1)	6 (40,0)	0,019*

* – statistically significant differences

When evaluating the parameters associated with the presence of hernia, no differences were found in the groups in terms of such indicators as the duration of herniation and the presence of diastasis of the rectus abdominis muscles (Table 4.2.3). Absorbable fixation was used significantly more often in patients with primary hernias (90.6% versus 45.6% in the group with non-absorbable fixation and 60.0% in the group with adhesive fixation, p = 0.001) (Fig. 4.2.2). Also, absorbable fixators were not used in any patients with lateral hernias. Significant differences were also revealed in such a parameter as the area of the hernial gate. In the group where non–absorbable fixators were used, it was 25.0 (6.8 - 55.8) cm^2, absorbable – 3.0 (2.1 – 4.7) cm^2, surgical glue – 12.6 (1.6 – 19.6) cm^2 (p <0.001) (Fig. 4.2.3).

Table 4.2.3 – Parameters related to the presence of hernia in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
Primary hernias, abs. (%)	79 (57,7)	41 (45,6)	29 (90,6)	9 (60,0)	0,001*
Postoperative hernias, abs. (%)	58 (42,3)	49 (54,4)	3 (9,4)	6 (40,0)	
Median hernias, abs. (%)	114 (83,2)	71 (78,9)	32 (100,0)	11 (73,3)	0,160
Lateral hernias, abs. (%)	23 (16,8)	19 (21,1)	0 (0,0)	4 (26,7)	
Duration of herniation, years, Me (Q1 – Q3)	3,0 (2,0 – 5,0)	3,0 (2,0 – 5,0)	4,5 (3,0 – 10,2)	2,0 (2,0 – 18,0)	0,522
Hernial gate area, cm^2, Me (Q1 – Q3)	19,6 (3,1 – 44,0)	25,0 (6,8 – 55,8)	3,0 (2,1 – 4,7)	12,6 (1,6 – 19,6)	<0,001*
Diastasis, abs. (%)	31 (22,6)	18 (20,0)	8 (25,0)	5 (33,3)	0,490

* – statistically significant differences

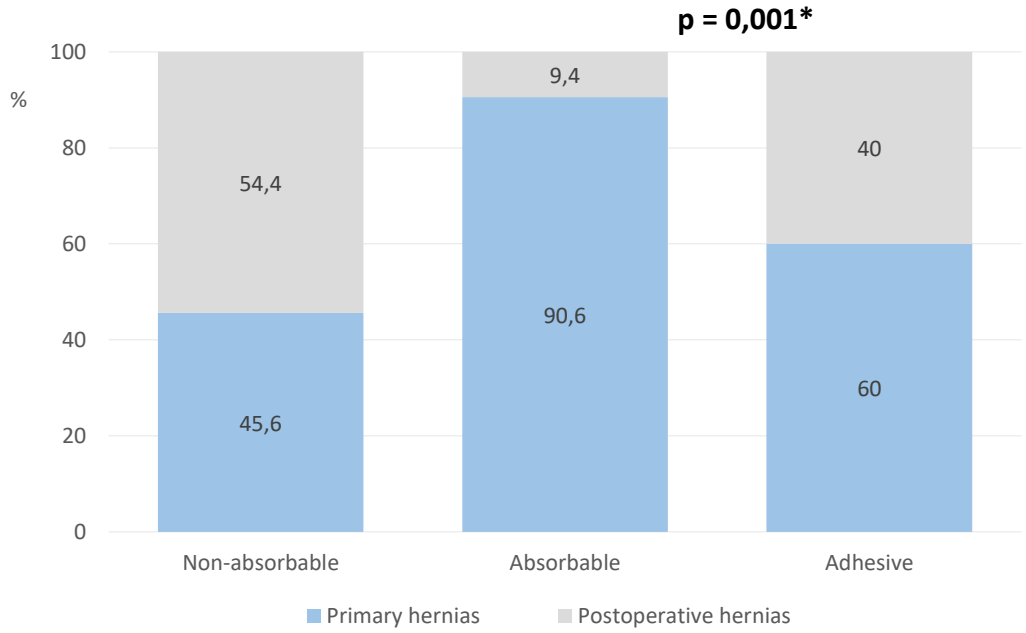


Figure 4.2.2 – The ratio of the number of patients with primary and postoperative hernias in groups divided by the type of fixation of the endoprosthesis

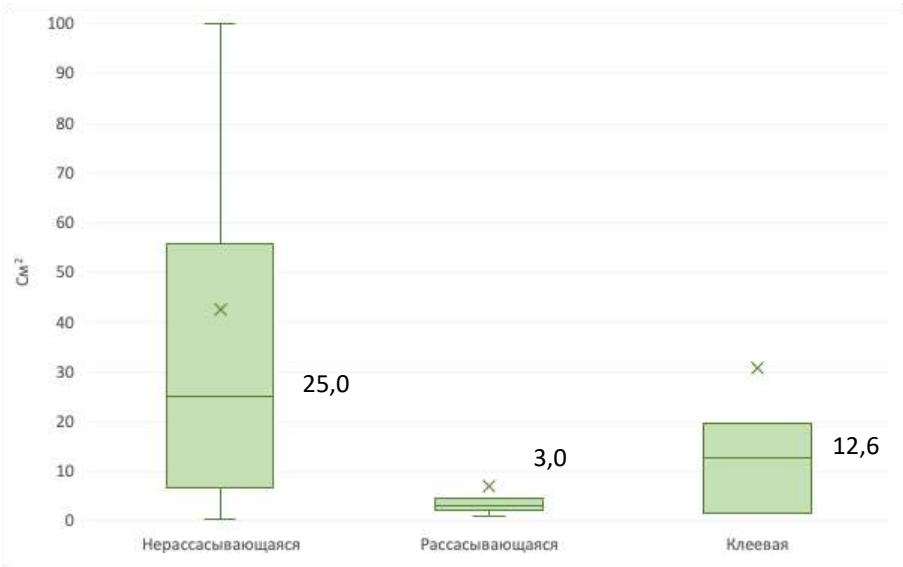


Figure 4.2.3 – The area of the hernial gates in groups divided by the type of fixation of the endoprosthesis

There were no differences in the frequency of use of prolonged local anesthetics and the frequency of damage to the visceral anti-adhesive layer of the implant in the groups (Table 4.2.4). For the rest of the indicators, there was a significant difference, primarily due to the indicators of the group where non-absorbable fixation was used. In this group, hernial gate suturing was performed much less frequently (21.9% of cases), while in the group with adhesive fixation this indicator reached 100.0% of cases ($p < 0.001$) (Fig. 4.2.4).

In the group where non–absorbable fixation was used, the median area of the endoprosthesis was the largest - 300.0 (177.0 – 315.0) cm^2. In the group with absorbable fixation, it was 117.9 (76.2 – 262.5) cm^2, with adhesive – 117.9 (117.9 – 117.9) cm^2 ($p = 0.001$) (Fig. 4.2.5).

The ratio of the area of the endoprosthesis and the area of the hernial gate between the groups with non–absorbable and adhesive fixation practically did not differ, and in

the group with absorbable fixation it turned out to be more than 3 times higher (31.3 (21.3 - 72.2), p = 0.014) (Fig. 4.2.6).

The longest operation time was recorded when using non–absorbable fixators – 120.0 (77.5 – 135.0) minutes, the shortest – when using absorbable fixators – 67.5 (61.2 - 70.0) minutes (p <0.001) (Fig. 4.2.7). Also, in the group with absorbable fixation, the shortest hospital stay was 2.0 (2.0 – 3.0) days versus 3.0 (3.0 – 4.2) days in the group with non–absorbable fixation and 4.0 (3.0 - 5.0) days in the group with adhesive fixation, p = 0.003 (Fig. 4.2.8).

The cost of the fixation device ranged from 6000.0 to 86933.0 rubles with a median value of 23400.0 (23400.0 – 26538.0) rubles. In the group with non–absorbable fixation, this indicator was 23400.0 (23400.0 – 23400.0) rubles, with absorbable – 26538.0 (26538.0 – 30584.2) rubles, with adhesive – 61000.0 (61000.0 - 78400.0) rubles (p <0.001) (Fig. 4.2.9).

Table 4.2.4 – Operational and clinical and economic indicators in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
The use of prolonged local anesthetics, abs. (%)	53 (38,7)	40 (44,4)	10 (31,3)	3 (20,0)	0,232
Hernia gate suturing, abs. (%)	51 (37,2)	29 (32,2)	7 (21,9)	15 (100,0)	<0,001*
Endoprosthesis area, cm^2, Me (Q1 – Q3)	294,5 (117,9 – 300,0)	300,0 (177,0 – 315,0)	117,9 (76,2 – 262,5)	117,9 (117,9 – 117,9)	0,001*
The ratio of the area of the prosthesis to the area of the hernial gate, Me (Q1 – Q3)	12,5 (6,4 – 36,5)	10,0 (5,6 – 24,1)	31,3 (21,3 – 72,2)	9,4 (6,0 – 75,1)	0,014*

Damage to the visceral layer of the prosthesis, abs. (%)	37 (27,0)	32 (35,6)	5 (15,6)	0 (0,0)	0,142
Operation time, min., Me (Q1 – Q3)	100,0 (70,0 – 130,0)	120,0 (77,5 – 135,0)	67,5 (61,2 – 70,0)	90,0 (70,0 – 100,0)	<0,001*
Hospital stay time, days, Me (Q1 – Q3)	3,0 (2,0 – 4,0)	3,0 (3,0 – 4,2)	2,0 (2,0 – 3,0)	4,0 (3,0 – 5,0)	0,003*
The cost of the fixation device, rub., Me (Q1 – Q3))	23400,0 (23400,0 – 26538,0)	23400,0 (23400, 0 – 23400,0)	26538,0 (26538,0 – 30584,2)	61000,0 (61000,0 – 78400,0)	<0,001*

* – statistically significant differences

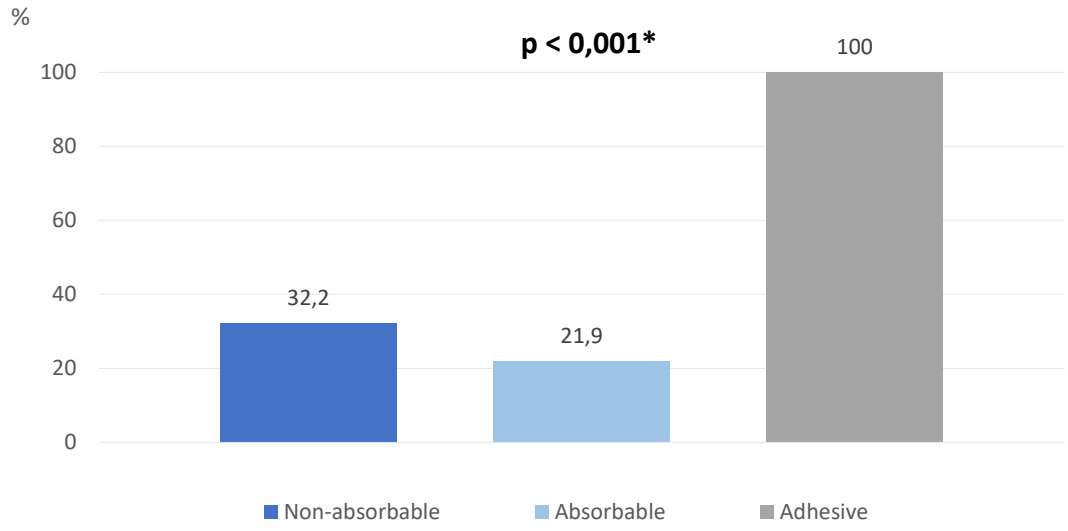


Figure 4.2.4 – The frequency of hernial gate suturing in groups divided by the type of fixation of the endoprosthesis

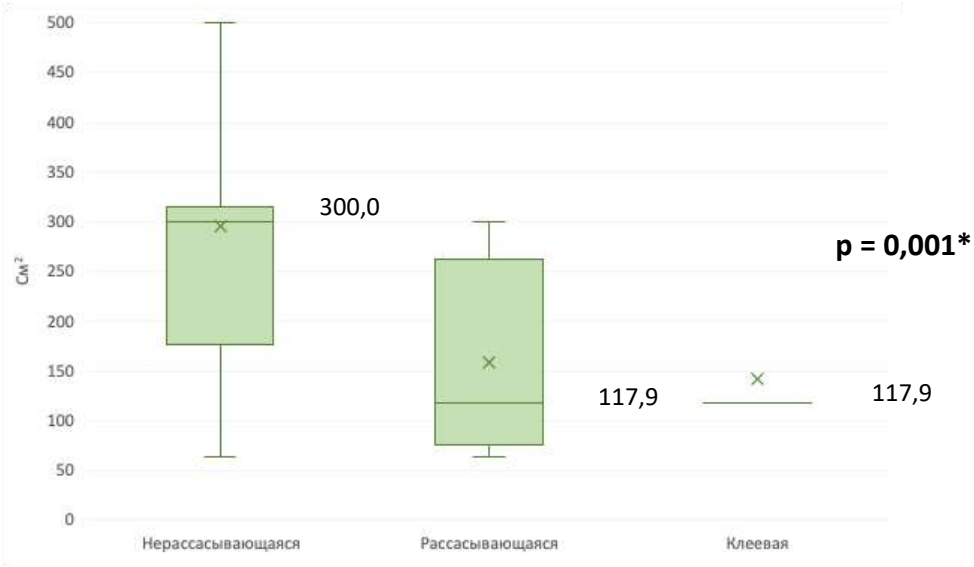


Figure 4.2.5 – The area of the implant in groups divided by the type of fixation of the endoprosthesis

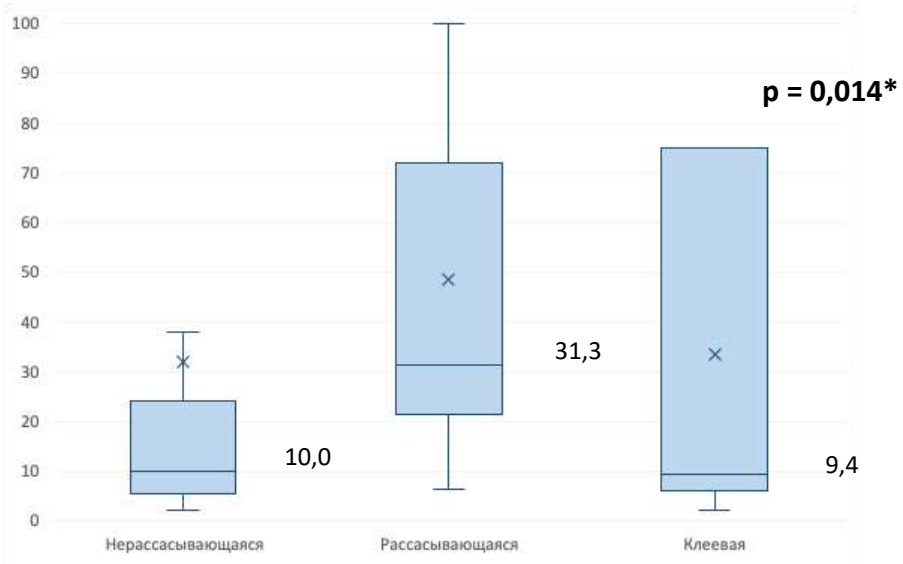


Figure 4.2.6 – The ratio of the implant area to the area of the hernial gate in groups divided by the type of fixation of the endoprosthesis

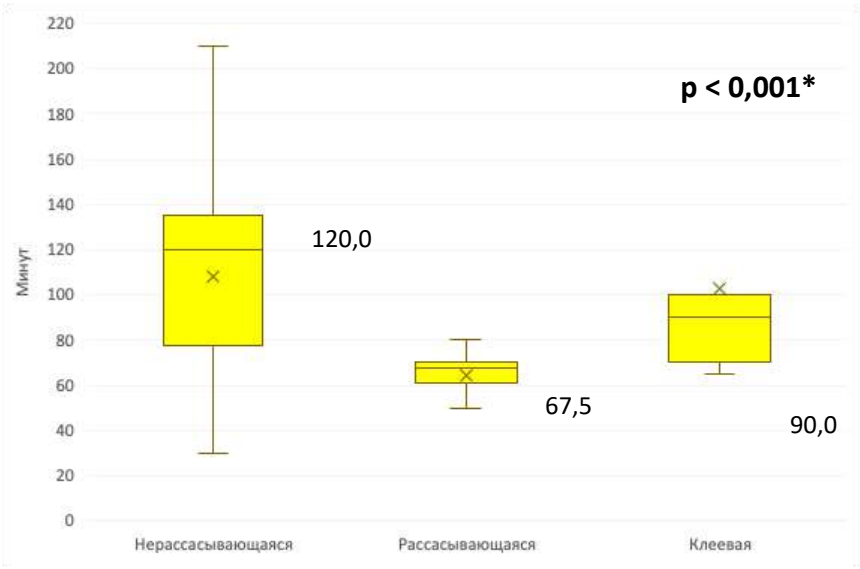


Figure 4.2.7 – The time of the operation in groups divided by the type of fixation of the endoprosthesis

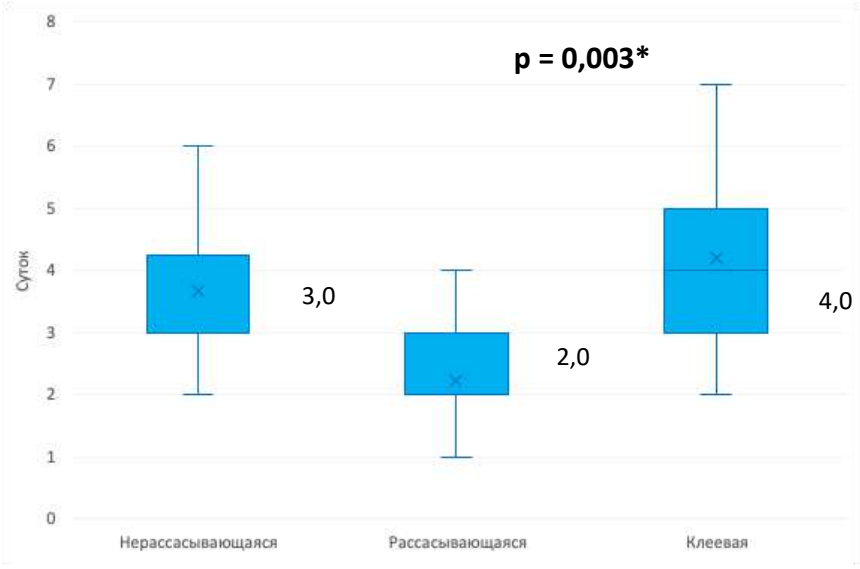


Figure 4.2.8 – The time of the patient's stay in the hospital after surgery in groups divided by the type of fixation of the endoprosthesis

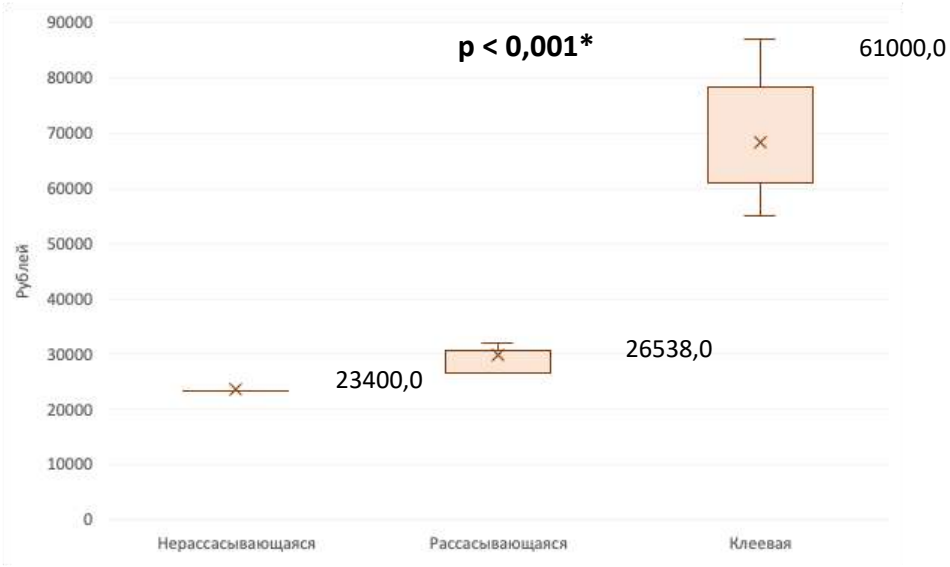


Figure 4.2.9 – Cost of fixation devices in groups divided by the type of fixation of the endoprosthesis

Of the 2 cases of intraoperative complications, one was noted in the group where non–absorbable fixators were used, the second in the group where glue was used (Tables 4.2.5, 4.2.6). In the first case, the damage occurred due to the direct impact of the spiral retainer and was stopped by stitching. In the second case, the vessel was damaged at the time of transfascial ligation. The bleeding was stopped by applying an additional transfascial suture.

Of the 26 cases of early postoperative complications, 14 (15.6%) were detected in the group with non–absorbable fixators, 6 (18.8%) – in the group with absorbable, 6 (40.0%) - in the group with glue (p = 0.041) (Table 4.2.5, Fig. 4.2.10). All complications were classified in classes I and II according to the Clavien-Dindo Classification. Seromas, which accounted for half of all complications, were more common when using absorbable

fixators (Table 4.2.6). In the group where surgical glue was used, 2 cases of intestinal paresis were noted, which resolved against the background of conservative measures.

There were no significant differences in the number of late postoperative complications in the groups (p = 0.076). However, a greater number of them (33.3%) were observed in the group where surgical glue was used (Table 4.2.5, Fig. 4.2.11). As in the group of early complications, seromas accounted for more than half of the cases. They were more common (66.7%) when using absorbable fixators (Table 4.2.6). The majority of complications belonged to classes I and II and according to the Clavien-Dindo Classification, however, there were 2 cases of class IIIB complications (trocar hernias).

Table 4.2.5 – Complications in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
Intraoperative	2 (1,5)	1 (1,1)	0 (0,0)	1 (6,7)	0,642
Early postoperative (up to 30 days)	26 (19,0)	14 (15,6)	6 (18,8)	6 (40,0)	0,041*
Late postoperative	27 (19,7)	16 (17,8)	6 (18,8)	5 (33,3)	0,076

* – statistically significant differences

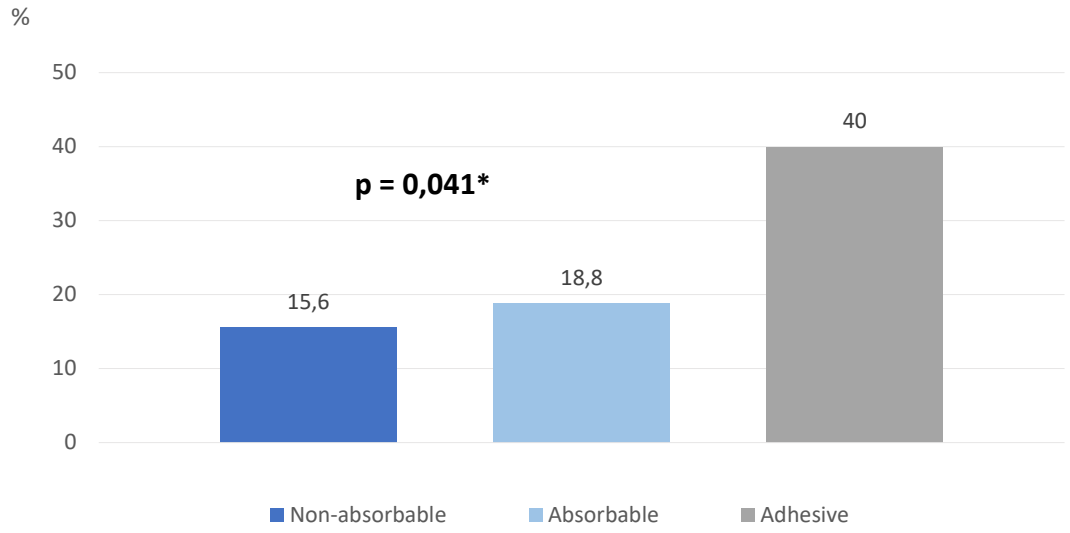


Figure 4.2.10 – Frequency of early (up to 30 days) postoperative complications in groups divided by type of fixation of the endoprosthesis

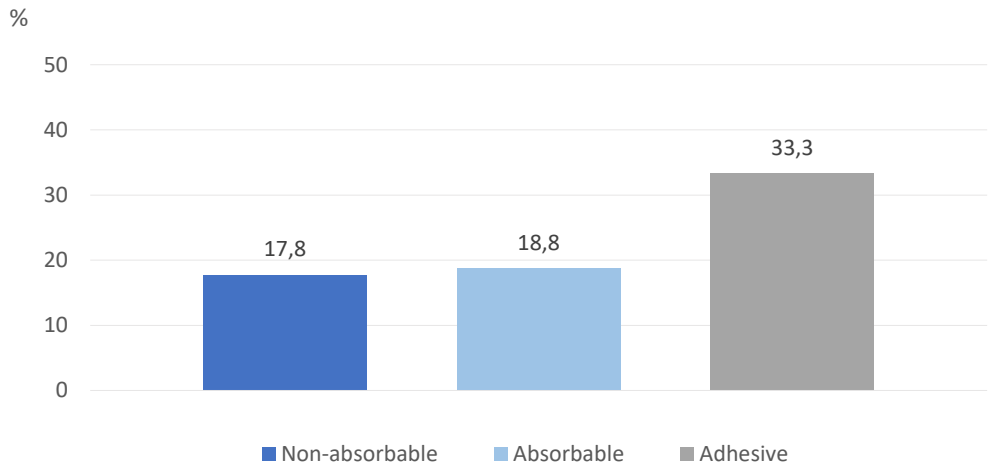


Figure 4.2.11 – The frequency of late postoperative complications in groups divided by the type of fixation of the endoprosthesis

Table 4.2.6 – Nosology of complications in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Type of fixation		
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)
Intraoperative				
Bleeding	2 (100,0)	1 (100,0)	0 (0,0)	1 (100,0)
Early postoperative (up to 30 days)				
Hematoma	4 (15,4)	2 (14,3)	1 (16,7)	1 (16,7)
Seroma	13 (50,0)	7 (50,0)	4 (66,7)	2 (33,3)
Suppuration	4 (15,4)	2 (14,3)	1 (16,7)	1 (16,7)
Dermatitis	1 (3,8)	1 (7,1)	0 (0,0)	0 (0,0)
Intestinal paresis	2 (7,7)	0 (0,0)	0 (0,0)	2 (33,3)
Pain syndrome	2 (7,7)	2 (14,3)	0 (0,0)	0 (0,0)
Late postoperative				
Chronic seroma	14 (51,9)	8 (50,0)	4 (66,7)	2 (40,0)
Infiltration	3 (11,1)	1 (6,3)	2 (33,3)	0 (0,0)
Suppuration	2 (7,4)	1 (6,3)	0 (0,0)	1 (20,0)
Dermatitis	2 (7,4)	2 (12,5)	0 (0,0)	0 (0,0)
Dysuria	2 (7,4)	1 (6,3)	0 (0,0)	1 (20,0)
Chronic pain	2 (7,4)	1 (6,3)	0 (0,0)	1 (20,0)
Trocar hernia	2 (7,4)	2 (12,5)	0 (0,0)	0 (0,0)

There were no significant differences in the groups in terms of such indicators as hernia recurrence, diastasis recurrence and adhesions in the area of localization of the endoprosthesis (Table 4.2.7). Of the 4 recurrences, 3 (3.3%) were detected in the group where non–absorbable fixation was used, 1 (6.7%) - in the group where glue was used. Adhesion formation was higher in the group with adhesive fixation – 46.7%, lower in the group with absorbable fixation – 25.0% (Fig. 4.2.12).

Table 4.2.7 – Recurrence of hernia, diastasis of rectus muscles and adhesions in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters, abs. (%)	All patients (n = 137)	Anti-adhesive coating			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
Recurrence of hernia	4 (2,9)	3 (3,3)	0 (0,0)	1 (6,7)	0,706
Recurrence of diastasis	8 из 31 (25,8)	5 из 18 (27,8)	2 из 8 (25,0)	1 из 5 (20,0)	0,804

Adhesions in the area of localization of the endoprosthesis	48 (35,0)	33 (36,7)	8 (25,0)	7 (46,7)	0,094

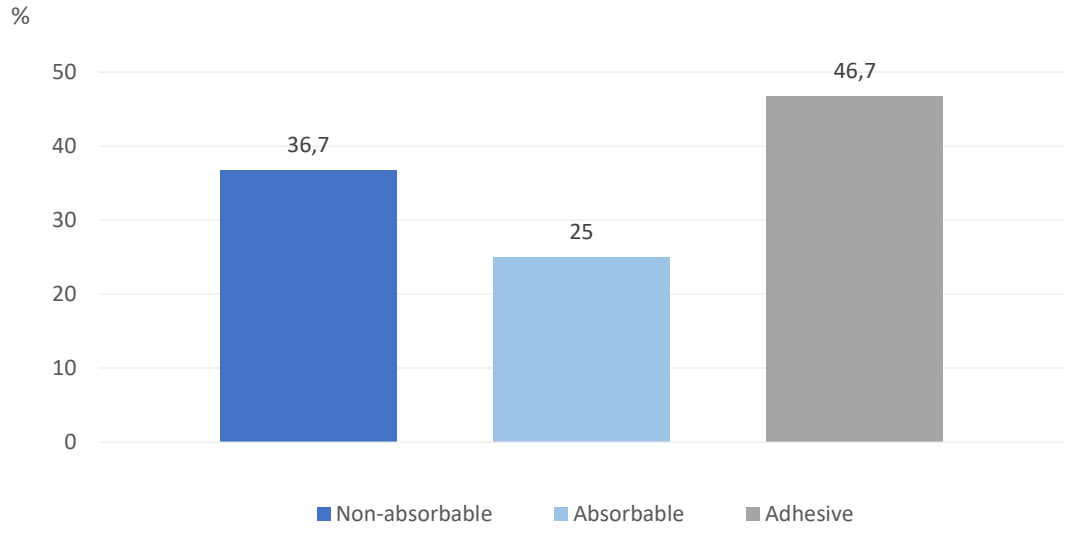


Figure 4.2.12 – The frequency of detection of adhesions in the hernioplasty zone in groups divided by the type of fixation of the endoprosthesis

The assessment of the quality of life in the groups did not show significant differences (Table 4.2.8). Overall dissatisfaction with the quality of life was lower when using absorbable fixators – 7.5 (2.0 – 13.5) points, higher when using surgical glue – 20.0 (20.0 – 22.0) points (Fig. 4.2.13). The overall assessment was formed to a greater extent for the account of the difference in the restriction of physical activity and cosmetic dissatisfaction.

Table 4.2.8 – Parameters of quality of life in groups of patients divided by type of fixation of the endoprosthesis with primary and postoperative ventral hernias

Parameters, Points, Me (Q1 – Q3)	All patients (n = 137)	Type of fixation			Reliability (p)
		Non-absorbable (n = 90)	Absorbable (n = 32)	Adhesive (n = 15)	
General dissatisfaction with the quality of life	12,0 (2,5 – 22,0)	12,0 (3,0 – 23,0)	7,5 (2,0 – 13,5)	20,0 (20,0 – 22,0)	0,217

Pain	0,0 (0,0 – 1,5)	0,0 (0,0 – 2,0)	0,0 (0,0 – 0,8)	0,0 (0,0 – 0,0)	0,581
Activity restriction	5,0 (0,0 – 20,0)	9,5 (0,0 – 20,0)	1,5 (0,0 – 7,2)	20,0 (20,0 – 20,0)	0,111
Cosmetic dissatisfaction	1,0 (0,0 – 4,5)	2,0 (0,0 – 4,2)	0,5 (0,0 – 5,0)	0,0 (0,0 – 0,0)	0,077

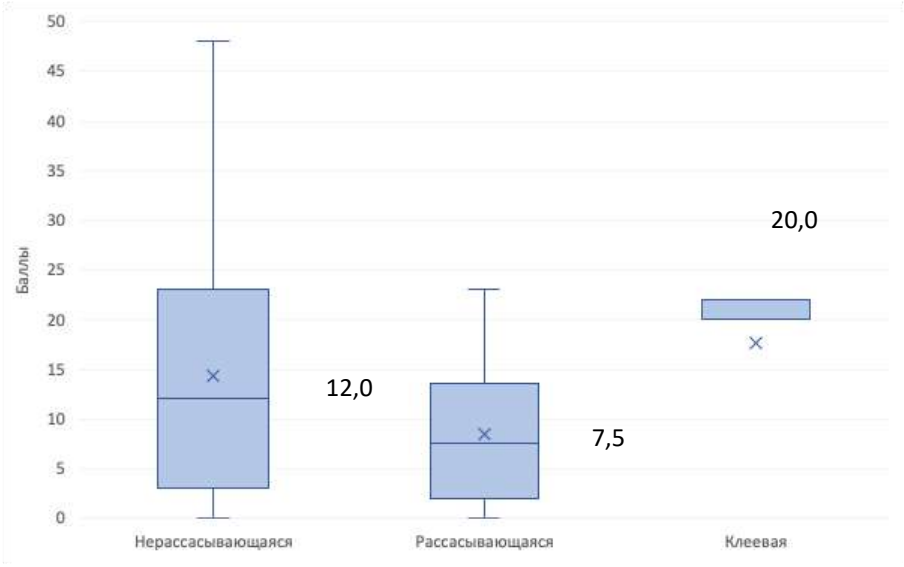


Figure 4.2.13 – General dissatisfaction with the quality of life in groups divided by the type of fixation of the endoprosthesis

CHAPTER 5. EVALUATION OF THE EFFECTIVENESS AND SAFETY OF COMPOSITE ENDOPROSTHESES WITH PHOTOPOLYMER COATING IN INTRA-ABDOMINAL PLASTIC SURGERY (IPOM): A MULTICENTER NON-RANDOMIZED CONTROLLED CLINICAL TRIAL

The main purpose of the multicenter non-randomized controlled clinical trial was to evaluate the results of the use of FLUOROEX fluoropolymer-coated endoprostheses in IPOM. The comparison was carried out with the data obtained using prostheses with an anti-adhesive coating of collagen (Parietene Composite, Parietex Composite and Symbotex), which are most often used in this type of operation. The results were evaluated separately in patients with primary and postoperative hernias [20].

5.1. Results of the use of fluoropolymer-coated endoprostheses in laparoscopic intraperitoneal hernioplasty in patients with primary ventral hernias

There were no significant differences in gender and age in the groups (Table 5.1.1). When using collagen–coated endoprostheses, the median age was 54.0 (43.8 – 65.0) years, and FLUOREX endoprostheses were 49.5 (41.0 – 64.2) years. The observation periods had significant differences. For the group coated with collagen prostheses, they were 87.0 (46.0 – 103.8) months, with a fluoropolymer coating – 12.0 (12.0 – 13.0) months ($p < 0.001$) (Fig. 5.1.1).

Table 5.1.1 – Demographic and statistical indicators in groups of patients with primary ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	

Age, years, Me (Q1 – Q3)	52,5 (42,0 – 65,0)	54,0 (43,8 – 65,0)	49,5 (41,0 – 64,2)	0,381
Gender (men), abs (%)	41 (46,6)	20 (50,0)	21 (43,8)	0,558
Gender (women), abs (%)	47 (53,4)	20 (50,0)	27 (56,2)	
Observation period, months, Me (Q1 – Q3)	13,0 (12,0 – 82,5)	87,0 (46,0 – 103,8)	12,0 (12,0 – 13,0)	<0,001*

* – statistically significant differences

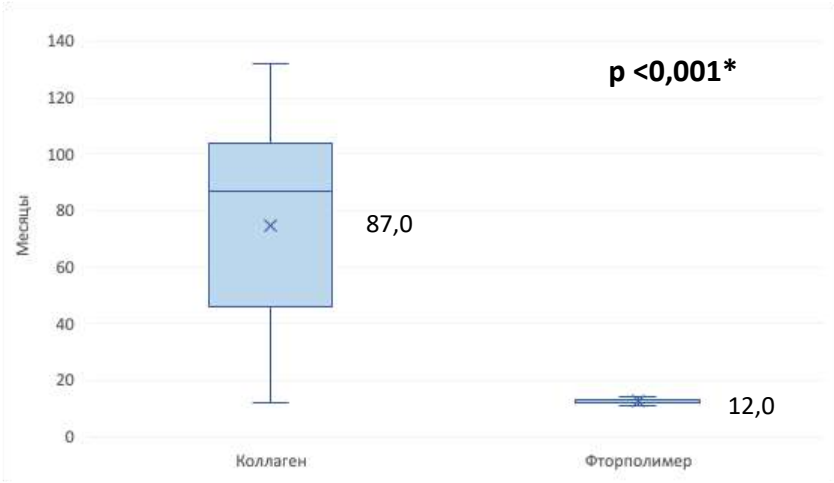


Figure 5.1.1 – Follow-up periods in groups of patients with primary ventral hernias

There were no significant differences in health indicators in the groups where prostheses coated with collagen and fluoropolymer were used (Table 5.1.2). The number of non-obese and obese patients was approximately the same. All patients had certain risk factors for hernia formation.

Table 5.1.2 – Health indicators in groups of patients with primary ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
BMI, kg/m2, Me (Q1 – Q3)	29,9 (27,5 – 34,8)	29,4 (26,8 – 34,1)	30,2 (28,1 – 36,6)	0,111
Normal weight (<30 kg/m^2), abs. (%)	44 (50,0)	21 (52,5)	23 (47,9)	0,669
Obesity (≥30 kg/m^2), abs. (%)	44 (50,0)	19 (47,5)	25 (52,1)	
1 risk factor, abs. (%)	31 (35,2)	14 (35,0)	17 (35,4)	0,878
2 risk factors, abs. (%)	42 (47,7)	20 (50,0)	22 (45,8)	
3 or more risk factors, abs. (%)	15 (17,0)	6 (15,0)	9 (18,8)	
The presence of concomitant diseases, abs. (%)	58 (65,9)	26 (65,0)	32 (66,7)	0,870
The presence of operations on abdominal organs, abs. (%)	21 (23,9)	11 (27,5)	10 (20,8)	0,465

As with the patient's health indicators, there were no differences in the hernia parameters in the groups (Table 5.1.3). Umbilical hernias were more common in the group coated with collagen implants, and a combination of umbilical and epigastric hernias were more common in the group coated with fluoropolymer prostheses. In the group where the FLUOREX endoprosthesis was used, the number of small hernias turned out to be slightly higher (54.2% versus 45.0% in the group with coated collagen implants). As a result, the area of the hernial gate was also smaller (4.3 (2.5 – 19.5) cm^2 versus 3.2 (2.0 – 9.9) cm^2) (Fig. 5.1.2).

Table 5.1.3 – Parameters related to the presence of hernia in groups of patients with primary ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
Duration of herniation, years, Me (Q1 – Q3)	4,0 (2,0 – 8,0)	4,5 (3,0 – 8,0)	4,0 (2,0 – 10,2)	0,455
Umbilical hernia, abs. (%)	50 (56,8)	25 (62,5)	25 (52,1)	0,383
Hernia of the white line of the abdomen, abs. (%)	19 (21,6)	9 (22,5)	10 (20,8)	
Umbilical and epigastric hernia, abs. (%)	19 (21,6)	6 (15,0)	13 (27,1)	
Small hernia, abs. (%)	44 (50,0)	18 (45,0)	26 (54,2)	0,534
Average hernia, abs. (%)	34 (38,6)	16 (40,0)	18 (37,5)	
Large hernia, abs. (%)	10 (11,4)	6 (15,0)	4 (8,3)	
Hernial gate area, cm^2, Me (Q1 – Q3)	4,0 (2,2 – 11,1)	4,3 (2,5 – 19,5)	3,2 (2,0 – 9,9)	0,189
Diastasis, abs. (%)	26 (29,5)	11 (27,5)	15 (31,3)	0,701

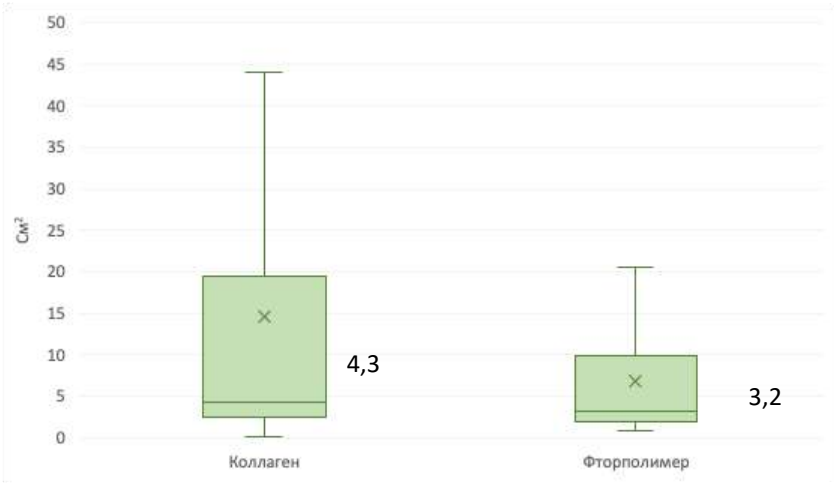


Figure 5.1.2 – Hernial gate area in groups of patients with primary ventral hernias

During the operation, prolonged local anesthetics were more often used in the group where fluoropolymer-coated implants were installed (77.1% vs. 60.0%) (Table 5.1.4). In the same group, hernial gate suturing was performed much more often (100.0% vs. 10.0%, p <0.001) (Fig. 5.1.3).

The sizes of the installed prostheses in the groups did not have a significant difference. However, the ratio of the area of the endoprosthesis and the area of the hernial gate was higher in the group where FLUOROEX fluoropolymer-coated implants were used (41.2 vs. 23.0; p = 0.015) (Fig. 5.1.4).

If no visually visible damage was noted during the installation of FLUOREX prostheses, then when using collagen-coated prostheses, especially Parietene Composite and Parietex Composite, damage to the visceral layer was observed in 30.0% of cases (p <0.001). More often, small damage was noted along the edges, which occurred at the time of the prosthesis through a reusable port with a diameter of 10 mm (Fig. 5.1.5). This was not observed when using Symbotex implants.

Table 5.1.4 – Operational parameters in groups of patients with primary ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
The use of prolonged local anesthetics, abs. (%)	61 (69,3)	24 (60,0)	37 (77,1)	0,084
Hernia gate suturing, abs. (%)	52 (59,1)	4 (10,0)	48 (100,0)	<0,001*
Endoprosthesis area, cm^2, Me (Q1 – Q3)	150,0 (150,0 – 300,0)	150,0 (113,1 – 300,0)	150,0 (150,0 – 300,0)	0,193
The ratio of the area of the prosthesis and the area of the hernial gate, Me (Q1 – Q3)	33,2 (19,2 – 51,2)	23,0 (9,3 – 51,0)	41,2 (29,0 – 51,2)	0,015*
Damage to the visceral layer of the prosthesis, abs. (%)	12 (13,6)	12 (30,0)	0 (0,0)	<0,001*

* – statistically significant differences

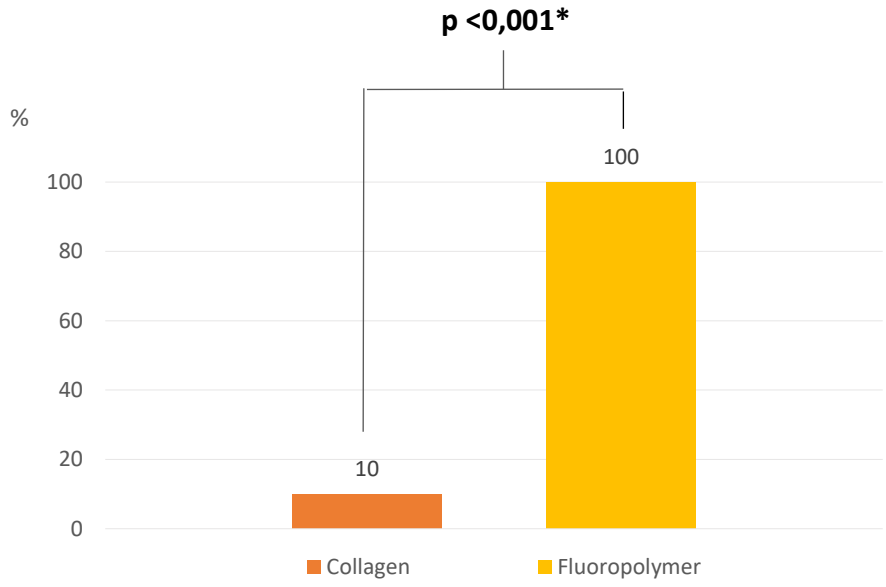


Figure 5.1.3 – The frequency of hernial gate suturing in groups of patients with primary ventral hernias

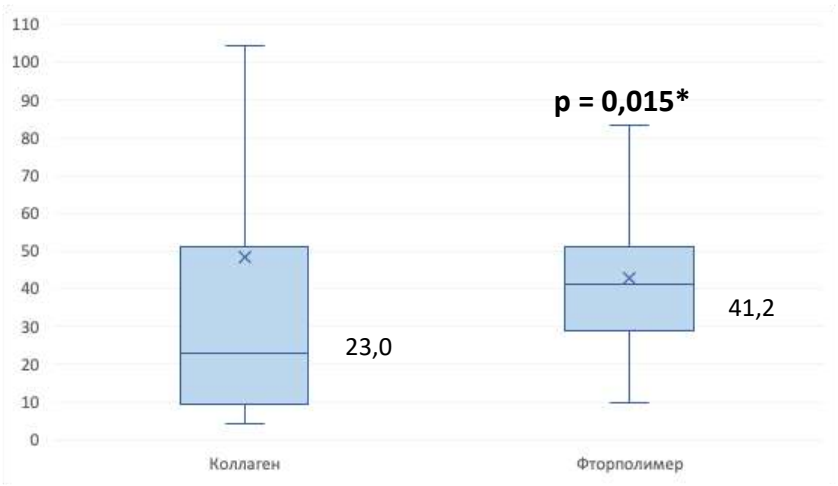


Figure 5.1.4 – The ratio of the area of the endoprosthesis and the area of the hernial gate in groups of patients with primary ventral hernias

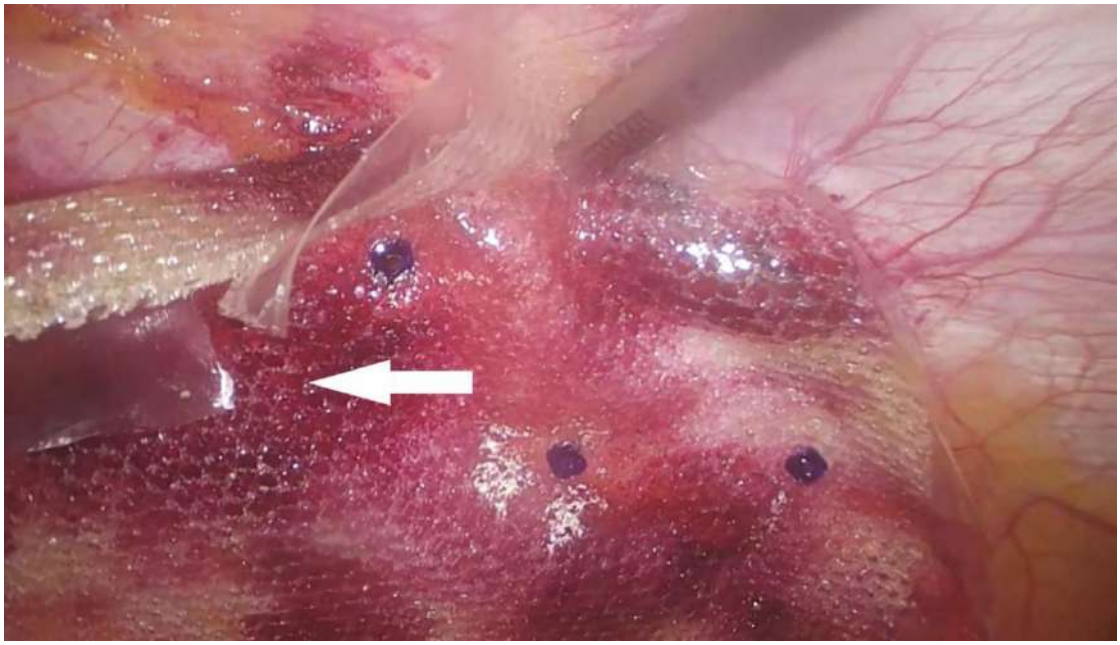


Figure 5.1.5 – Damage to the anti-adhesive layer at the edges of the Parietene Composite implant (indicated by the arrow), which occurred when the latter was inserted into the abdominal cavity through a 10 mm reusable port

There were no significant differences in the time of surgery and the duration of hospitalization after surgery (Table 5.1.5). Simultaneous operations were performed more often in the group of patients who used collagen-coated endoprostheses (17.5% vs. 4.2% in the group of patients with FLUOREX endoprostheses). In the last group, only 2 laparoscopic cholecystectomies were performed.

The cost of surgery turned out to be significantly lower when using endoprostheses with fluoropolymer coating FLUOREX. The ratio of the cost of consumables and the cost of a completed treatment case in the group where collagen–coated prostheses were used was 2.1 (1.7 – 2.5), in the group where fluoropolymer–coated prostheses were used - 5.6 (3.2 - 7.1) ($p < 0.001$) (Fig. 5.1.6).

The reduction in the cost of intervention was achieved both due to the lower price of the prosthesis itself (14500.0 (14500.0 – 19300.0) rubles in the group with fluoropolymer coating of the prosthesis versus 26481.0 (20957.0 – 35219.0) rubles in the group with collagen coating of the prosthesis, $p < 0.001$), and consumables for fixation (3000.0 (3000.0 – 24500.0) rubles in the group with fluoropolymer coating of the prosthesis versus 23400.0 (23400.0 – 26538.0) rubles in the group with collagen coating of the prosthesis, $p < 0.001$) (Fig. 5.1.7).

Table 5.1.5 – Clinical and economic indicators in groups of patients with primary ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
Operation time, min., Me (Q1 – Q3)	70,0 (55,0 – 90,0)	70,0 (58,8 – 92,5)	70,0 (55,0 – 86,2)	0,593

Hospital stay time, days, Me (Q1 – Q3)	2,0 (2,0 – 3,0)	3,0 (2,0 – 3,0)	2,0 (2,0 – 3,0)	0,213
Simultaneous operations, abs. (%)	9 (10,2)	7 (17,5)	2 (4,2)	0,073
The cost of the endoprosthesis, rub., Me (Q1 – Q3)	19300,0 (14500,0 – 26481,0)	26481,0 (20957,0 – 35219,0)	14500,0 (14500,0 – 19300,0)	<0,001*
The cost of the device or consumables for fixing, rub., Me (Q1 – Q3)	23400,0 (3000,0 – 26538,0)	23400,0 (23400,0 – 26538,0)	3000,0 (3000,0 – 24500,0)	<0,001*
The ratio of the cost of a completed treatment case and the cost of consumables, Me (Q1 – Q3)	2,8 (2,1 – 5,6)	2,1 (1,7 – 2,5)	5,6 (3,2 – 7,1)	<0,001*

* – statistically significant differences

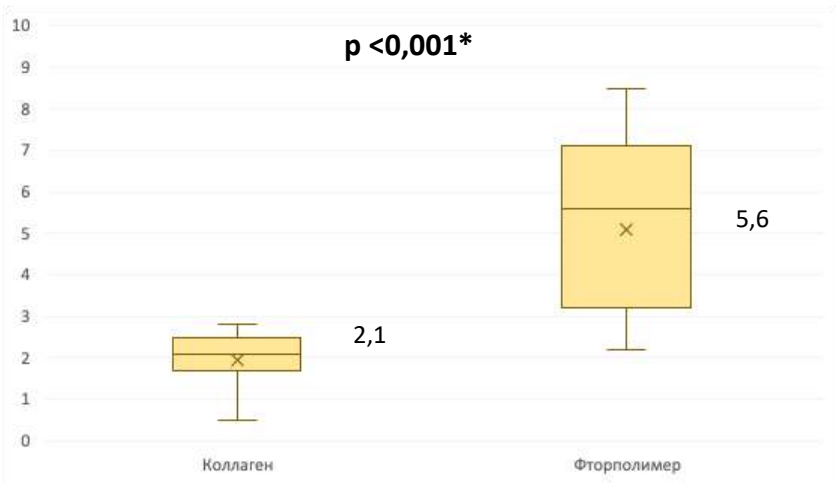


Figure 5.1.6 – The ratio of the cost of a completed treatment case and the cost of consumables in groups of patients with primary ventral hernias

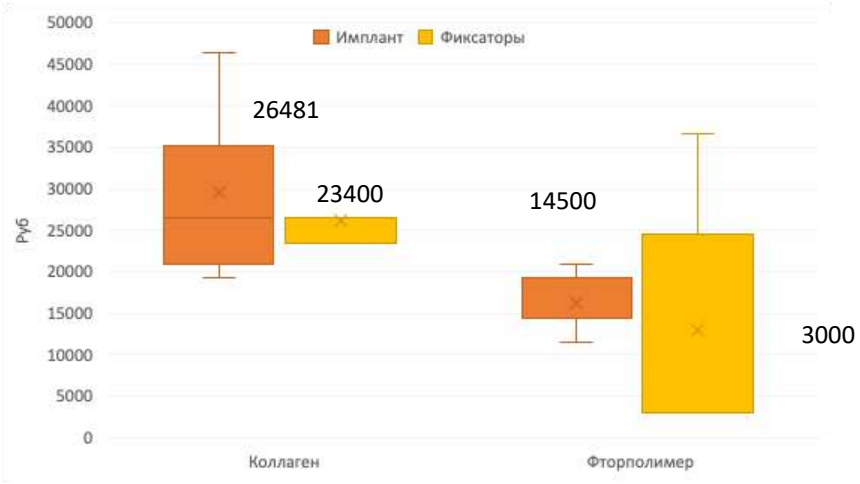


Figure 5.1.7 – Cost of an endoprosthesis and device or consumables for fixation in groups of patients with primary ventral hernias

No intraoperative complications were noted during the study (Table 5.1.6). Despite the fact that the number of early and late postoperative complications in the group where the fluoropolymer-coated endoprosthesis was used was lower, no significant differences were found in the groups. Complications in the groups belonged to Class I or II (Table 5.1.7).

Of the 5 early complications (12.5%) in the group with a collagen implant coating, hematoma was noted in 1 case, seromas in 2 cases, suppuration in 1 case, and pronounced pain syndrome in the trocar wound area in 1 case (more than 5 NRS points within 5 days). Two early complications (4.1%) in the group where fluoropolymer-coated implants were used were gray.

The described complications resolved themselves or were eliminated by conservative measures.

Of the 4 late complications (10.0%) in the group with a collagen implant coating, chronic seromas were noted in 2 cases, infiltration in the area of eliminated hernia intervention in 1 case, dysuria in 1 case. In the latter case, the patient clearly associated the appearance of complaints with the operation. At the control ultrasound after 6 months, the presence of nephroptosis from the installation of trocar ports was noted. In 2 cases of

late complications (4.2%), seromas occurred in the group where fluoropolymer-coated implants were used.

Table 5.1.6 – Group complications in patients with primary ventral hernias operated with various modifications of composite endoprostheses

Parameters, abs. (%)	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
Intraoperative	0 (0,0)	0 (0,0)	0 (0,0)	-
Early postoperative (up to 30 days)	7 (7,9)	5 (12,5)	2 (4,1)	0,460
Late postoperative	6 (6,8)	4 (10,0)	2 (4,2)	0,405

* – statistically significant differences

Table 5.1.7 – Severity of early and late postoperative complications (according to Clavien-Dindo) in patients with primary ventral hernias operated using various modifications of composite endoprostheses

Class, abs. (%)	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses	
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)
I	7	3	4
II	6	6	0
IIIA	0	0	0
IIIB	1	0	1
IVA	0	0	0

IVB	0	0	0
V	0	0	0

There were no hernia recurrences in the patients included in the study (Table.5.1.8). Ultrasonographic assessment of viscero-parietal adhesions in the area of the installed prosthesis did not reveal significant differences. Adhesions were slightly higher in the group where fluoropolymer-coated prostheses were used (35.4% versus 25.0% in the group where collagen-coated prostheses were installed) (Fig. 5.1.8).

Table 5.1.8 – Frequency of hernia recurrence and adhesions in the area of prosthesis localization in patients with primary ventral hernias after surgery using various modifications of composite endoprostheses

Parameters, abs. (%)	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
Recurrence of hernia	0 (0,0)	0 (0,0)	0 (0,0)	-
Adhesion formation in the area of the prosthesis	27 (30,7)	10 (25,0)	17 (35,4)	0,291

* – statistically significant differences

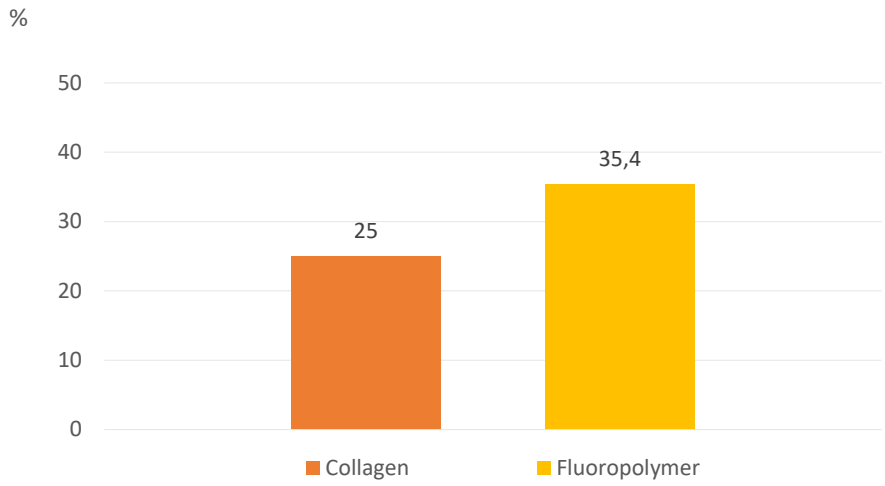


Figure 5.1.8 – Adhesions in the prosthesis area in groups of patients with primary ventral hernias

The quality of life of patients in the study groups did not differ (Table 5.1.9). The differences were minimal both in assessing general dissatisfaction with the quality of life, and the parameters of pain severity, activity restriction and cosmetic dissatisfaction.

Table 5.1.9 – Quality of life parameters in groups of patients with primary ventral hernias after surgery using various modifications of composite endoprostheses

Parameters, Points, Me (Q1 – Q3)	All patients (n = 88)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 40)	Fluoropolymer (FLUOREX) (n = 48)	
General dissatisfaction with the quality of life	6,0 (0,0 – 13,2)	6,0 (0,0 – 12,0)	6,5 (0,8 – 14,2)	0,438
Pain	0,0 (0,0 – 1,0)	0,0 (0,0 – 1,0)	0 (0,0 – 2,0)	0,524

Activity restriction	0,0 (0,0 – 10,0)	0,0 (0,0 – 7,2)	0,0 (0,0 – 10,8)	0,412
Cosmetic dissatisfaction	0,0 (0,0 – 3,0)	0,0 (0,0 – 3,2)	0,0 (0,0 – 3,0)	0,598

* – statistically significant differences

5.2. Results of the use of fluoropolymer-coated endoprostheses in laparoscopic intraperitoneal hernioplasty in patients with postoperative ventral hernias

The groups of patients with postoperative hernias had no differences in terms of gender and age (Table 5.2.1). At the same time, the observation periods differed. When using prostheses with a collagen coating, they amounted to 93.0 (23.8 – 120.0) months, with a fluoropolymer coating – 12.0 (12.0 – 12.0) months (p <0.001) (Fig. 5.2.1). There were also no differences in the groups in terms of patient health (Table 5.2.2).

Table 5.2.1 – Demographic and statistical indicators in groups of patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
Age, years, M ± SD	61,0 ± 12,3	63,4 ± 12,2	58,3 ± 12,0	0,084
Gender (men), abs (%)	16 (23,9)	6 (16,7)	10 (32,3)	0,160
Gender (women), abs (%)	51 (76,1)	30 (83,3)	21 (67,7)	

Observation period, months, Me (Q1 – Q3)	14,0 (12,0 – 94,0)	93,0 (23,8 – 120,0)	12,0 (12,0 – 12,0)	<0,001*

* – statistically significant differences

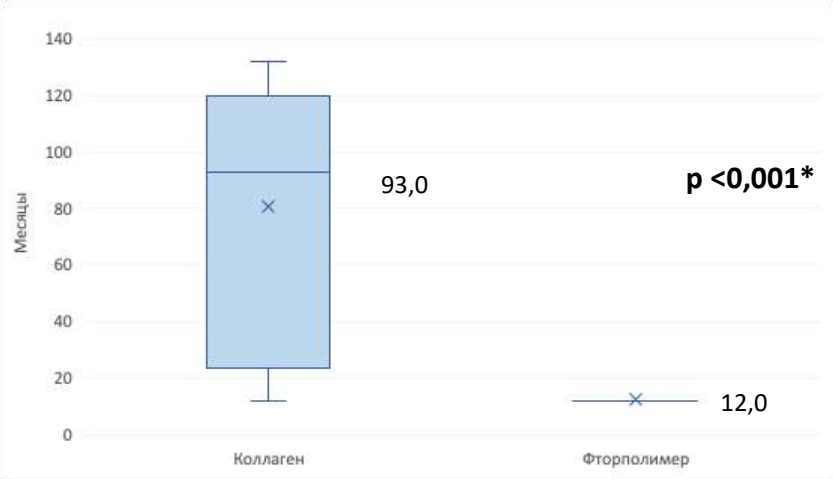


Figure 5.2.1 – Follow-up periods in groups of patients with postoperative ventral hernias

Table 5.2.2 – Health indicators in groups of patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
BMI, kg/m^2, Me (Q1 – Q3)	30,8 ± 4,4	31,2 (28,4 – 32,8)	30,5 (28,8 – 33,2)	0,985
Normal weight (<30 kg/m^2), abs. (%)	28 (41,8)	14 (38,9)	14 (45,2)	0,604
Obesity (≥30 kg/m^2), abs. (%)	39 (58,2)	22 (61,1)	17 (54,8)	

1 risk factor, abs. (%)	23 (34,3)	16 (44,4)	7 (22,6)	0,122
2 risk factors, abs. (%)	35 (52,2)	17 (47,2)	18 (58,1)	
3 or more risk factors, abs. (%)	9 (13,4)	3 (8,3)	6 (19,4)	
The presence of concomitant diseases, abs. (%)	52 (77,6)	30 (83,3)	22 (71,0)	0,254

There were no significant differences between the groups in most of the parameters associated with the presence of hernia (Table 5.2.3). The exception was such an indicator as the localization of a hernia (Fig. 5.2.2). In the group where collagen-coated implants were used, 36.1% of patients had lateral hernias, while in the group where fluoropolymer-coated prostheses were used, only 6.5% of patients had such hernias ($p < 0.001$).

As when comparing the data of patients with primary hernias, in the group where fluoropolymer-coated endoprostheses were used, the number of patients with large postoperative hernias turned out to be slightly lower. This was reflected in the area of the hernia gate. In the group with a collagen implant coating, it was 32.0 (24.0 – 64.0) cm^2, with a fluoropolymer coating – 26.6 (10.5 – 39.0) cm^2.

Table 5.2.3 – Parameters related to the presence of hernia in groups of patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
Duration of herniation, years, Me (Q1 – Q3)	2,0 (2,0 – 3,5)	3,0 (2,0 – 4,0)	2,0 (2,0 – 3,0)	0,178

Median hernia, abs. (%)	52 (77,6)	23 (63,9)	29 (93,5)	0,007*
Lateral hernia, abs. (%)	15 (22,4)	13 (36,1)	2 (6,5)	
Small hernia (W1), abs. (%)	12 (17,9)	3 (8,3)	9 (29,0)	0,073
Average hernia (W2), abs. (%)	40 (59,7)	23 (63,9)	17 (54,8)	
Large hernia (W3), abs. (%)	15 (22,4)	10 (27,8)	5 (16,1)	
Recurrent hernia, abs. (%)	14 (20,9)	10 (27,8)	4 (12,9)	0,228
Hernial gate area, cm^2, Me (Q1 – Q3)	31,4 (20,8 – 58,5)	32,0 (24,0 – 64,0)	26,6 (10,5 – 39,0)	0,064
Diastasis, abs. (%)	9 (13,4)	3 (8,3)	6 (19,4)	0,284

* – statistically significant differences

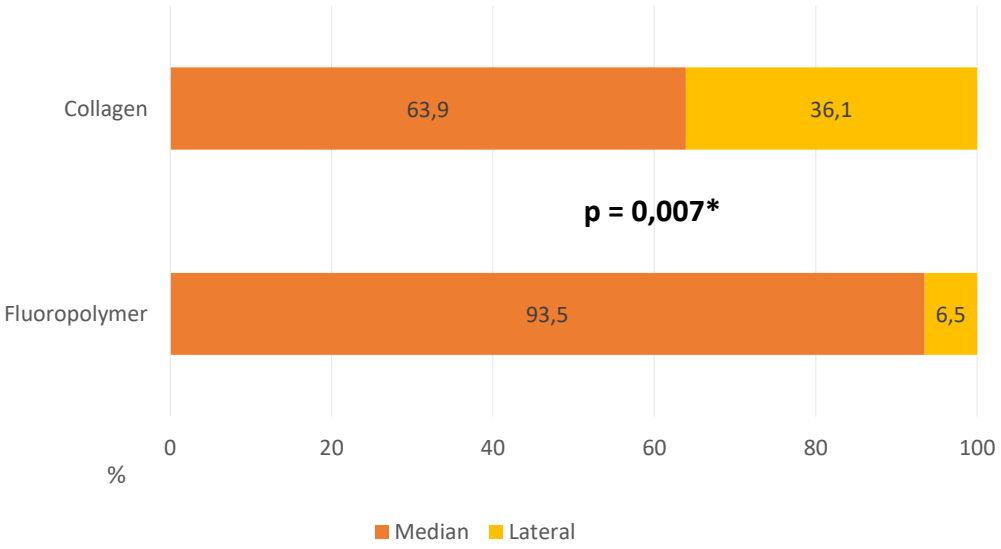


Figure 5.2.2 – The ratio of median and lateral hernias in groups of patients with postoperative ventral hernias

As in the treatment of patients with primary hernias, in patients with postoperative hernias, prolonged local anesthetics were significantly more often used when installing

fluoropolymer-coated implants (96.8% vs. 33.3% in the group with coated collagen implants, p <0.001) (Table 5.2.4, Fig. 5.2.3).

If the hernia gate suturing in the group where collagen-coated endoprostheses were used was performed only in 41.7% of patients, then in the group where fluoropolymer-coated implants were used, this procedure was performed in all patients (p <0.001) (Fig. 5.2.3).

Despite the fact that the size of the prostheses in the groups was significantly they did not differ, the ratio of their area and the area of the hernial gate turned out to be greater in the group with a fluoropolymer coating (11.5 (6.1 – 18.5) versus 9.4 (5.0 – 12.0) in the group with a collagen coating, p = 0.021) (Fig. 5.2.4).

When using endoprostheses with an anti-adhesive coating of collagen, 38.9% of cases showed more or less pronounced damage to the visceral layer. Minor injuries along the edges of the Parietene Composite and Parietex Composite endoprostheses were more common. When using FLUOREX endoprostheses, no visible damage to the substrate or coating was observed (p <0.001).

Table 5.2.4 – Operational parameters in groups of patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
The use of prolonged local anesthetics, abs. (%)	42 (62,7)	12 (33,3)	30 (96,8)	<0,001*
Hernia gate suturing, abs. (%)	46 (68,7)	15 (41,7)	31 (100,0)	<0,001*
Endoprosthesis area, cm^2, Me (Q1 – Q3)	300,0 (235,5 – 500,0)	300,0 (300,0 – 500,0)	300,0 (225,0 – 400,0)	0,490

The ratio of the area of the prosthesis to the area of the hernial gate, Me (Q1 – Q3)	9,7 (5,3 – 15,8)	9,4 (5,0 – 12,0)	11,5 (6,1 – 18,5)	0,021*
Damage to the visceral layer of the prosthesis, abs. (%)	14 (20,9)	14 (38,9)	0 (0,0)	<0,001*

* – statistically significant differences

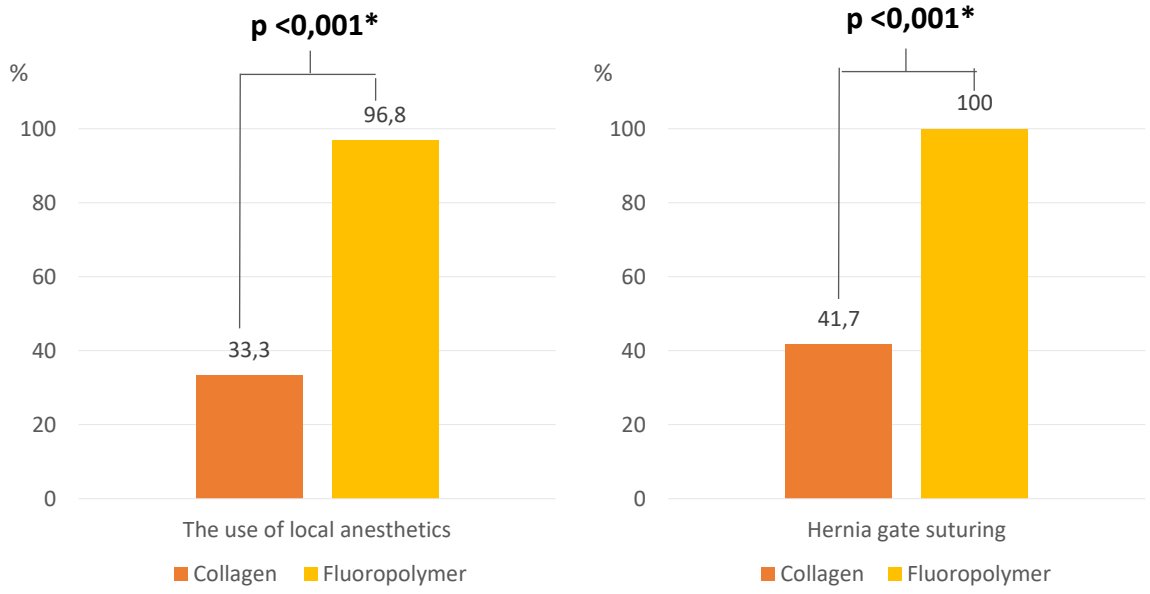


Figure 5.2.3 – Application of local prolonged anesthetics and hernial gate suturing in groups of patients with postoperative ventral hernias

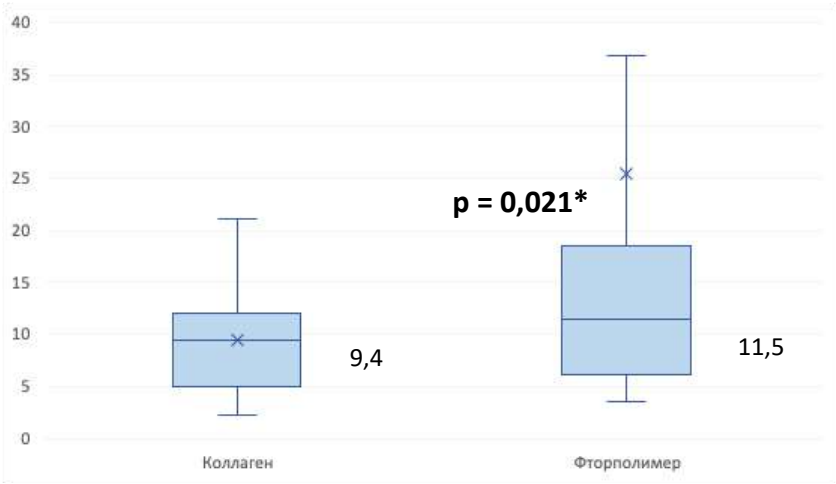


Figure 5.2.4 – The ratio of the area of the endoprosthesis and the area of the hernial gate in groups of patients with postoperative ventral hernias

The time of the operation and the duration of the patient's stay in the hospital did not significantly differ (Table 5.2.5). Simultaneous interventions were performed significantly less frequently when using fluoropolymer-coated endoprostheses (3.2% vs. 22.2%, p = 0.031) (Fig. 5.2.5). Laparoscopic cholecystectomy was performed in only 1 patient.

The price of an implant with a fluoropolymer coating was 20900.0 (16900.0 – 22300.0) rubles versus 45784.0 (35219.0 – 59220.0) rubles in the group with a collagen coating (p <0.001) (Fig. 5.2.6). The price of the device or consumable for fixation, on the contrary, turned out to be unreliably higher when using endoprostheses coated with fluoropolymer. It amounted to 29900.0 (3000.0 – 36700.0) rubles versus 23400.0 (23400.0 – 23400.0) rubles in the group where collagen-coated prostheses were used (p = 0.052) (Fig. 5.2.6).

The use of endoprostheses with a fluoropolymer coating turned out to be more economically feasible. This is demonstrated by the difference in the ratio of the cost of consumables and the cost of the completed treatment case. The index in the group where

collagen–coated endoprostheses were used was 1.6 (1.3 – 1.9), in the group where fluoropolymer–coated implants were used - 2.3 (2.2 - 6.3) (p <0.001) (Fig. 5.2.7).

Table 5.2.5 – Clinical and economic indicators in groups of patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
Operation time, min., Me (Q1 – Q3)	125,0 (110,0 – 140,0)	125,0 (108,8 – 136,2)	120,0 (110,0 – 140,0)	0,950
Hospital stay time, days, Me (Q1 – Q3)	4,0 (3,0 – 5,0)	4,0 (3,0 – 5,0)	3,0 (3,0 – 4,5)	0,377
Simultaneous operations, abs. (%)	9 (13,4)	8 (22,2)	1 (3,2)	0,031*
The cost of the endoprosthesis, rub., Me (Q1 – Q3)	27900,0 (20900,0 – 45784,0)	45784,0 (35219,0 – 59220,0)	20900,0 (16900,0 – 22300,0)	<0,001*
The cost of the device or consumables for fixing, rub., Me (Q1 – Q3)	23400,0 (23400,0 – 29900,0)	23400,0 (23400,0 – 23400,0)	29900,0 (3000,0 – 36700,0)	0,052
The ratio of the cost of the completed treatment case and the cost of consumables, Me (Q1 – Q3)	2,0 (1,6 – 2,2)	1,6 (1,3 – 1,9)	2,3 (2,2 – 6,3)	<0,001*

* – statistically significant differences

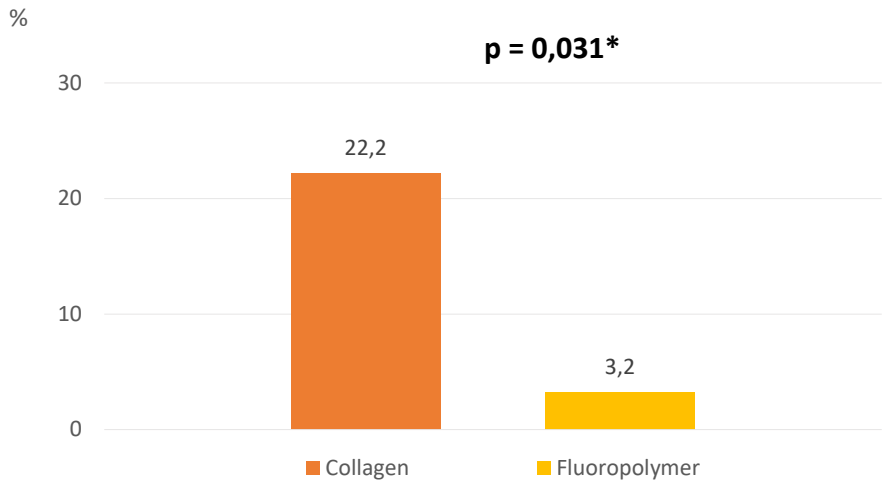


Figure 5.2.5 – The number of simultaneous operations in groups of patients with postoperative ventral hernias

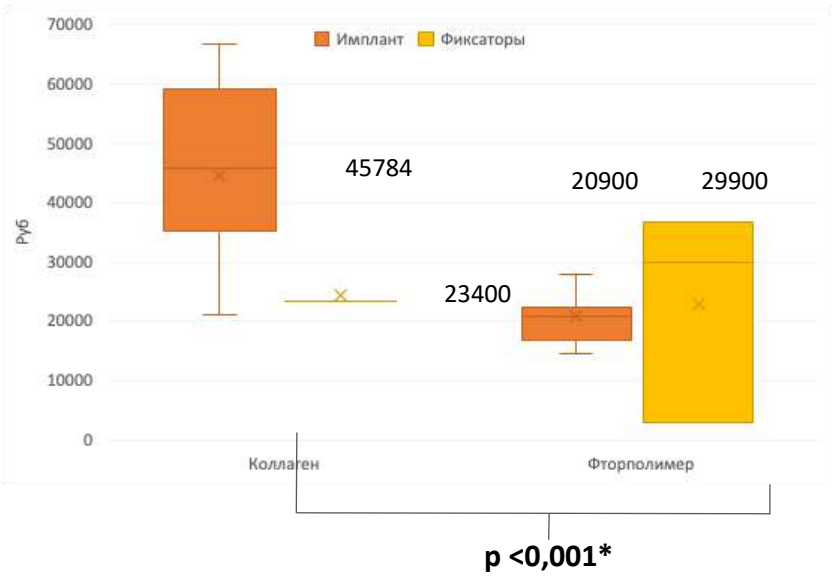


Figure 5.2.6 – The cost of an endoprosthesis and a device or consumables for fixation in groups of patients with postoperative ventral hernias

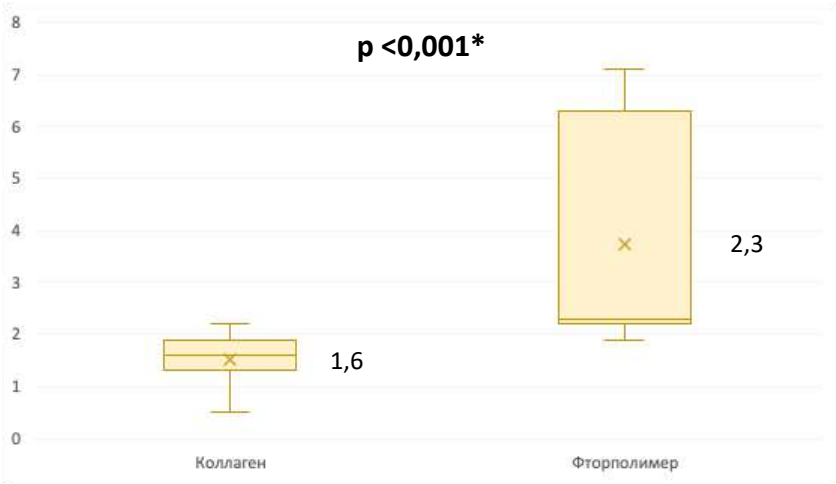


Figure 5.2.7 – The ratio of the cost of a completed treatment case and the cost of consumables in groups of patients with postoperative ventral hernias

During 67 interventions, only 1 significant intraoperative complication was noted (Table 5.2.6). A patient in the group where a collagen-coated implant was used had bleeding from a branch of the inferior epigastric artery. The bleeding was stopped by applying a transfascial ligature. Despite the fact that the bleeding was stopped visually, in the postoperative period, the patient was diagnosed with a hematoma in the space behind the right rectus muscle with a volume of about 80 cm2. This complication did not require any active interventions.

There were no significant differences in the number of early and late postoperative complications in the groups. Their number turned out to be less when using endoprostheses with fluoropolymer coating.

The complications mainly belonged to classes I and II according to Clavien-Dindo (13 cases) and did not require active surgical treatment tactics. In 2 more cases, they were assigned to Class III and required repeated surgery (Table 5.2.7).

Of the 7 early complications (19.4%) in the group where collagen–coated endoprostheses were used, seroma was noted in 4 cases, in 1 case – hematoma (previously

indicated), in 1 case – suppuration of a trocar wound, in 1 case - a fairly pronounced pain syndrome in the area of localization of titanium fixators. Punctures with gray were not performed. In case of suppuration, the contents were evacuated, followed by tamponing with napkins with antiseptic solutions before cleansing the wound. The intensity of the pain syndrome gradually decreased against the background of the use of nonsteroidal anti-inflammatory drugs and the subsequent course of physiotherapy.

The only complication that arose in the early period when using a fluoropolymer-coated endoprosthesis was manifested by the development of paresis on the 1st and 2nd days after surgery. During CT scan, a moderate amount of free fluid was detected in the pelvic area. With suspected perforation of the hollow organ, the patient was re-operated on day 2. There were no signs of perforation of the hollow organ or intestinal obstruction during relaparoscopy. It was noted that in areas of extensive dissection, a large gland was adjacent to the wound surface through the mesh cells. In the areas where the mesh implant lay on the intact peritoneum, this was not observed. The oil seal has been separated. In the future, the postoperative period proceeded without complications.

Of the 6 late complications (16.7%) in the group of patients who had a collagen-coated implant, 4 cases showed chronic seromas. In 2 cases, puncture was required. In 1 case, an infiltration was detected in the area of hernial defect suturing, which was resolved against the background of a course of antibacterial therapy. In 1 more case, a trocar hernia was diagnosed in the area of optical trocar insertion in the left lumbar region 3 months after the intervention. The latter has already been described in detail in the previous chapter.

When using fluoropolymer-coated endoprostheses in the long term, there was one case of chronic seroma after the removal of a large hernia, which required repeated punctures.

Table 5.2.6 – Group complications in patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Parameters, abs. (%)	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
Intraoperative	1 (1,5)	1 (2,8)	0 (0,0)	1,000
Early postoperative (up to 30 days)	8 (11,9)	7 (19,4)	1 (3,2)	0,060
Late postoperative	7 (10,4)	6 (16,7)	1 (3,2)	0,113

Table 5.2.7 – Severity of early and late postoperative complications (according to Clavien-Dindo) in patients with postoperative ventral hernias operated using various modifications of composite endoprostheses

Class, abs. (%)	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses	
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)
I	6	5	1
II	7	7	0
IIIA	0	0	0
IIIB	2	1	1
IVA	0	0	0
IVB	0	0	0
V	0	0	0

When using collagen-coated endoprostheses, 2 hernia recurrences were noted (5.6%). There were no relapses in the group where fluoropolymer-coated implants were used (Table 5.2.8). Adhesions in the implant placement area in both groups were observed

in about half of the cases. There were no significant differences in the frequency of relapses or adhesions.

Table 5.2.8 – Frequency of hernia recurrence and adhesions in the area of prosthesis localization in patients with postoperative ventral hernias after surgery using various modifications of composite endoprostheses

Parameters, abs. (%)	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
Recurrence of hernia	2 (3,0)	2 (5,6)	0 (0,0)	0,495
Adhesion formation in the area of the prosthesis	33 (49,3)	17 (47,2)	16 (51,6)	0,720

The parameters of the quality of life of patients in the study groups did not have significant differences (Table 5.2.9). The difference in all indicators was minimal.

Table 5.2.9 – Quality of life parameters in groups of patients with postoperative ventral hernias after surgery using various modifications of composite endoprostheses

Parameters	All patients (n = 67)	Anti-adhesive coating and modifications of endoprostheses		Reliability (p)
		Collagen (Parietene Composite, Parietex Composite, Symbotex) (n = 36)	Fluoropolymer (FLUOREX) (n = 31)	
General dissatisfaction with	20,0 ± 12,0	20,6 ± 12,1	19,4 ± 12,2	0,681

the quality of life, points, M ± SD				
Pain, Points, Me (Q1 – Q3)	2,0 (0,0 – 3,0)	1,5 (0,0 – 3,0)	2,0 (0,0 – 2,5)	0,936
Activity Restriction, Points, Me (Q1 – Q3)	15,0 (10,0 – 22,0)	17,5 (10,0 – 23,0)	15,0 (10,0 – 20,5)	0,577
Cosmetic dissatisfaction, points, Me (Q1 – Q3)	3,0 (0,0 – 5,0)	3,0 (0,0 – 4,2)	2,0 (0,0 – 5,0)	0,870

CHAPTER 6. DISCUSSION

Hernias of the anterior abdominal wall are one of the most common surgical pathologies. Elective surgeries occupy the first place in surgical hospitals in the country. Over the past 100 years, a large number of options for performing anterior abdominal wall plastic surgery have been proposed. None of them became "perfect" and did not solve the problem of relapse and possible complications. Nevertheless, the "gold standard" among the traditional open methods of treatment of ventral hernias is retromascular plastic surgery, among the minimally invasive, the most frequently performed technique is laparoscopic intraperitoneal plastic surgery (IPOM).

LapIPOM hernioplasty belongs to the category of low-traumatic and standardized techniques. It makes it possible to identify and eliminate not only the main hernial defect, but also other small fascial defects, the presence of which was not known before the operation [281]. In addition, when compared with traditional open hernioplasty, the operation gives an excellent cosmetic result.

As a rule, it does not take much time to perform the operation, since with intraabdominal installation of the prosthesis, it is not necessary to carry out extensive mobilization of abdominal wall tissues. The absence of the need for complex dissection significantly reduces the learning curve. With IPOM, it accounts for about 20 surgical interventions, while with competing endovideosurgical retromuscular plastic surgery (eTEP), at least 50 [139].

When compared with traditional hernia treatment methods, laparoscopic hernioplasty IPOM can reduce postoperative pain, the number of wound and infectious complications, with a comparable recurrence rate [128, 116].

Despite a number of undeniable advantages, the main "claim" to the IPOM technique remains the intra-abdominal arrangement of the mesh, which can provoke the formation of adhesions.

At the end of the XX century, at the stage of the introduction of the technique, due to the imperfection of mesh endoprostheses, the frequency of visceroparietal adhesions was in some cases more than 50%, while in most cases there were no indications of

clinically significant complications associated with adhesions [210]. As technologies for the production of composite mesh endoprostheses improved, the number of adhesions recorded after surgery decreased significantly [279].

A feature of the implants used in IPOM is the presence of a visceral coating that prevents the adhesion of abdominal organs. Unfortunately, modern composite endoprostheses, which effectively prevent adhesion formation, are characterized by high cost, which to a certain extent hinders the spread of IPOM hernioplasty, with all its known advantages. Also, dependence on Western manufacturers at some point may lead to the fact that in the absence of its own domestic anti-adhesive implant, it will be impossible to perform this type of operation in our country.

In light of this, the question arose of finding a domestic material and implant with anti-adhesive properties, ensuring the reliability and safety of treatment, while having a lower cost. From this position, our interest was attracted by implants made of polyester filaments with a fluoropolymer coating, which have high biocompatibility, anti-adhesive activity and resistance to infection.

Endoprostheses containing polytetrafluoroethylene and polyvinylidene fluoride fluoride compounds have been used for IPOM hernioplasty for quite a long time [239]. Despite their satisfactory anti-adhesive properties, their disadvantages are pronounced retraction, encapsulation and delayed integration into tissues due to the presence of a smooth microporous surface [315]. A number of solutions have been proposed to eliminate the latter problem. Firstly, improved integration is achieved by creating an uneven or macroporous surface made of the same material, as well as by including an additional layer of polypropylene in the implant. Another way to improve integration is to weave an implant from filaments of various chemical compositions [141]. For example, this principle is implemented in the DynaMesh implant, which contains more than 85% of polyvinylidene fluoride filaments and less than 15% of polypropylene. The first material provides anti-adhesive properties, the second improves integration. However, the adhesion formation during the use of this implant remains at a fairly high level [204].

There is an opinion that only the smooth, non-porous surface of the visceral layer of the endoprosthesis prevents adhesion [137]. The conducted research attempts to refute this position. The fact is that the application of a fluoropolymer coating to FLUOREX endoprostheses is not performed in the form of a separate anti-adhesive layer, as with most implants allowed to be installed in the abdominal cavity. At the first stage, the impregnation of individual threads is performed and the so-called pseudo-monofilament is created. At the second stage, after weaving, the impregnation of the already connected fabric is carried out, which makes it possible to eliminate inter-fiber gaps in the contact zone of the threads. At the same time, the mesh structure is preserved and visually the implant looks more like a standard endoprosthesis made of thin polypropylene than a composite endoprosthesis. However, it can also be additionally coated with a protective layer.

The closure of the inter-fiber gaps in the plexus area of the FLUOREX implant is a fundamental difference when compared with the DynaMesh endoprosthesis. It is possible that it is due to this that the anti-adhesive characteristics are improved.

During the pilot study, two variants of fluoropolymer-coated endoprostheses were taken. The first variant was represented by a standard FLUOREX mesh implant, the second additionally had an anti-adhesive layer of carboxymethyl cellulose. For the purpose of comparison, the most commonly used endoprostheses for intraperitoneal hernioplasty with a coating of hyaluronic acid and carboxymethylcellulose, collagen and Reperene were also taken. At the same time, it was decided to conduct a preliminary study of the properties of a plate made of decellularized pork peritoneum, since it was shown that biological endoprostheses in some cases cause minimal adhesions [369; 210]. A distinctive feature of the plate used was the possibility of creating a large area coating, which could potentially be used in the manufacture of large-sized biological endoprostheses.

The presented endoprostheses had significant differences in both structural and physical properties. Some of them had polypropylene as a part of the base, and another part had polyester. At the same time, the structure of the weave and the surface density differed significantly. If the surface density of FLUOREX endoprostheses ranges from

36 to 42 g/m^2, then for Ventralight ST it can reach up to 213 g/m^2, which, when comparing mechanical strength, will definitely lead to results in favor of the latest implant. As a result, no direct comparison of these properties was carried out.

As for the thickness, it was also minimal for FLUOREX endoprostheses, and maximum for Ventralight ST and Reperen. Despite this, the breaking load indicators for FLUOREX implants turned out to be higher than the permissible minimum recommended by the European Society of Herniologists for Prostheses during such operations (32 N). At the same time, high rates of rupture load may indirectly indicate the potential risk of developing a coarser scar in the implant area, which, in turn, may affect the elastic properties of the abdominal wall in the postoperative period.

If the breaking load and breaking elongation of endoprostheses such as Symbotex and Reperen were almost the same in both directions, then FLUOREX and Ventralight ST implants had high breaking load and lower breaking elongation along the hinge column. The presence of such properties associated with the type of weaving (anisotropy) must be taken into account when orienting the endoprosthesis on the abdominal wall.

An assessment of the performance characteristics showed that the FLUOREX fluoropolymer-coated implant had the best performance on a par with the imported collagen-coated endoprosthesis (Symbotex) most often used in IPOM hernioplasty. The separation of the edges of the fluoropolymer implant from the peritoneum, which occurred in a number of observations, can be explained by its lightness and, as a result, less rigidity, which, however, did not affect the increase in the frequency of adhesions. It is possible that a slight increase in the mass of the endoprosthesis will help eliminate this negative point. The slightly longer time it took to install the implant with a fluoropolymer coating and an anti-adhesive layer was due to the need to irrigate the carboxymethylcellulose coating with liquid.

The biological plate made of pork peritoneum turned out to be the least convenient to use, as it gave the impression of being heavier compared to other implants, besides it lacked the rigidity characteristic of other prostheses. It was also noted that when using spiral fixation, its twisting occurred quite often when screwing in the clamps. The same factor can explain the longer installation time. Since the separate use of a biological plate is not expected when performing hernioplasty, it can be assumed that such undesirable effects will be avoided when using it with a polypropylene mesh frame. Examples where a biological coating is fixed on the surface of a mesh implant are found in a number of publications [39].

The least pronounced signs of deformation and retraction were noted when using implants with sodium hyaluronate coatings with Ventralight ST carboxymethylcellulose and Symbotex collagen. This is confirmed by the results of other studies [236], the authors of which also indicate that the retraction of fluoropolymer endoprostheses is higher than that of composite implants made of polypropylene and collagen (51.0% vs. 33.6%). It should be noted that these implants have a higher weight (surface density) compared with the fluoropolymer-coated endoprostheses used in our study, they are therefore less susceptible to deformation. As for the pork peritoneum, the tendency to crease due to weak rigidity manifested itself already from the stage of fixation to the abdominal wall. At the same time, due to its high elasticity, this coating was even inclined to increase the area by the 90 days of the experiment, which further confirms the impossibility of isolated use of a biological plate when closing abdominal wall defects. It cannot be excluded that retraction in Reperene-coated prostheses was associated with more pronounced scarring processes resulting from a prolonged course of inflammation caused by a foreign body.

When integrated into tissues, the breaking load indicators turned out to be higher for almost all endoprostheses, with the exception of both FLUOREX implants. In a number of implants, they depended on the direction of rupture and differed along the loop row and the loop column. As expected, the Ventralight ST implant, which has a high surface density, demonstrated higher rates of rupture load in combination with abdominal wall tissue – about 65 N. Reperen 16 mesh endoprostheses, both FLUOREX and Symbotex variants had approximately similar results in the range from 33.6 to 42.7 N.

The indicators of the prosthesis-tissue complex during implantation of xenomaterial from decellularized porcine peritoneum turned out to be lower than those of mesh endoprostheses, but more than 2 times higher than those of the native peritoneum.

The absence of changes in the breaking load of FLUOREX prostheses may indicate less scarring of the abdominal wall tissues in the bed of these prostheses.

The maximum rupture elongation of the Reperen 16 endoprosthesis testified, rather, not to the elasticity of the formed scar, but to the elasticity of the implant itself, since its uniform tissue overgrowth was not noted. At the same time, the high figures of this indicator in the Ventralight ST endoprosthesis just indicated the formation of a very elastic scar. Interesting data were obtained for the Symbotex prosthesis, in which the discontinuous elongation along the loop row increased by 67.9%, and along the loop column by only 9.2%. A similar, but less pronounced difference was noted in the Ventralight ST endoprosthesis. In part, this property can be very useful, since the elasticity of the abdominal wall in the longitudinal and transverse directions differs.

The study confirmed that by 90 days after the implant was installed, the absorbable fixators made of poly-D, L-lactide almost completely retained their structure. At the same time, regardless of whether the spirals are resorbable or nonresorbable, a third of the implants had migration of some of the fixators. It was noteworthy that in one case, by the end of the experiment, when using a light grid with a fluoropolymer coating, half of the fixators were missing. This may occur due to weak skeletal properties compared to heavier endoprostheses. This is confirmed by the data of an experimental study by M.H.F. Schreinemacher et al., in which 50% of titanium and 72% of absorbable fixators isolated in the abdominal wall migrated by 90 days [335]. At the same time, this was observed much less frequently when using them with a grid. Perhaps a slight increase in weight or a change in the structure of the weave will avoid such a negative moment. This is important, since the free presence of even absorbable fixators in the abdominal cavity can lead to perforation of the gallbladder, intestinal fistulas and a number of other complications. It cannot be excluded that the migration of fixators may indirectly affect both the retraction of the endoprosthesis and the formation of adhesions. In our study, this parameter was not a risk factor for the development of these conditions.

The adhesions identified during the 1st series of the experimental study were not clinically significant. Since in most studies, adhesions in the abdominal cavity are evaluated on various scales, which in some cases prevents the obtaining of generalized results, our work presents data calculated using several scales of adhesion assessment most often used both in the experiment and in the clinic. In our opinion, integral scales evaluating several parameters of spike formation, in particular the M.P. Diamond scale [189], allow us to reflect the results most reliably.

Fluoropolymer-coated implants were not inferior in anti-adhesive properties to endoprostheses with Symbotex collagen or hyaluronic acid and Ventralight ST. carboxymethylcellulose. The latter have good anti-adhesive properties and are the most commonly used implants for intraperitoneal hernioplasty [154]. The reperen and the plate from the pork peritoneum, on the contrary, showed the worst result. This was noted both when calculating the number of implants with adhesions, and when evaluating the average scores on all scales of adhesion assessment.

The anti-adhesive properties of the FLUOREX implant were most likely realized due to high biological inertia, which reduces the severity of inflammation in contact with internal organs. This is supported by the fact that the implant with a fluoropolymer coating and carboxymethyl cellulose showed worse results. A number of studies have shown that adhesion can be influenced by other factors, such as the structural characteristics of the mesh [359]. It cannot be excluded that the good anti-adhesive effect of fluoropolymer-coated endoprostheses also occurs due to the absence of gaps between the implant filaments, as indicated earlier. It should also be mentioned that the implants were installed on an intact peritoneum. This provided a good source of remesothelization of the large-cell structure of FLUOREX. The structure of the FLUOREX mesh without a monolithic anti-adhesive layer plate contributed to faster and more effective reperitonization, which began along the entire surface of the mesh, from the center of each cell, and not from the periphery of the implant.

We noted that the location of the implants in close contact with the liver often caused the development of a pronounced adhesive process, regardless of the type of implant. Other authors also point to the presence of such a phenomenon [175]. In our

study, the occurrence of adhesions was noted even with the use of an endoprosthesis coated with hyaluronic acid and carboxymethyl cellulose Ventralight ST, which showed good results on other scales. At the same time, when installing the FLUOREX implant in the specified area, the adhesive process was less pronounced.

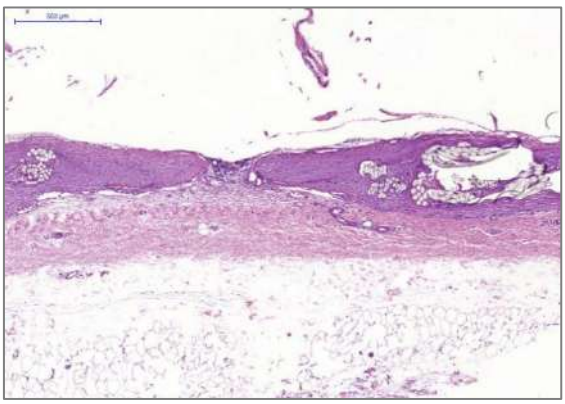
The dynamic assessment showed that spike formation tends to decrease in the studied periods, which does not contradict the data of other authors [274]. This was especially noticeable for Ventralight ST and Symbotex implants. The single "mooring" observed by the 45th day was absent in almost all cases by the end of the experiment.

The result of the analysis of the morphological characteristics of the experimental material [19] made it possible to divide the endoprostheses under study into three groups, basing the division on the composition, structure and spatial arrangement of the filaments in the mesh plane, the reaction of surrounding tissues to the material, fibroplastic (skeleton) processes, the reaction of the underlying peritoneum (Fig. 6.1), the ability to form a neoperitoneum (Fig. 6.2):

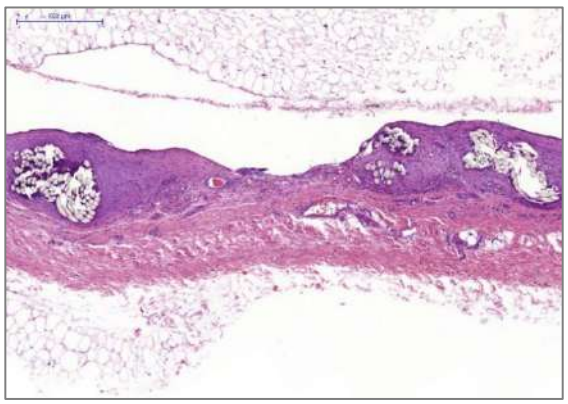
group 1 – endoprostheses with fluoropolymer coating FLUOREX and FLUOREX with an additional anti-adhesive layer of carboxymethylcellulose;

Group 2 – endoprostheses coated with hyaluronic acid and carboxymethylcellulose Ventralight ST and collagen Symbotex;

Group 3 – endoprostheses with Reperene coating and decellularized pork peritoneum.



a



b

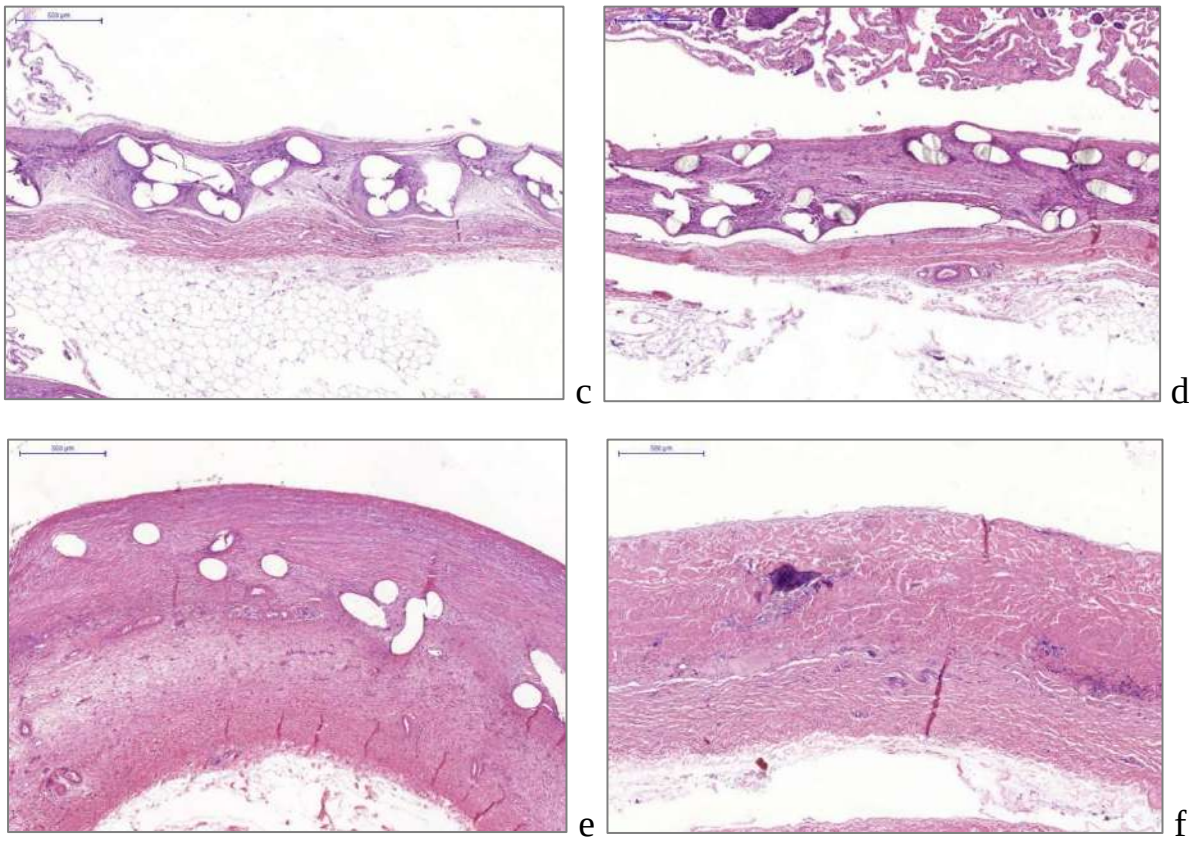
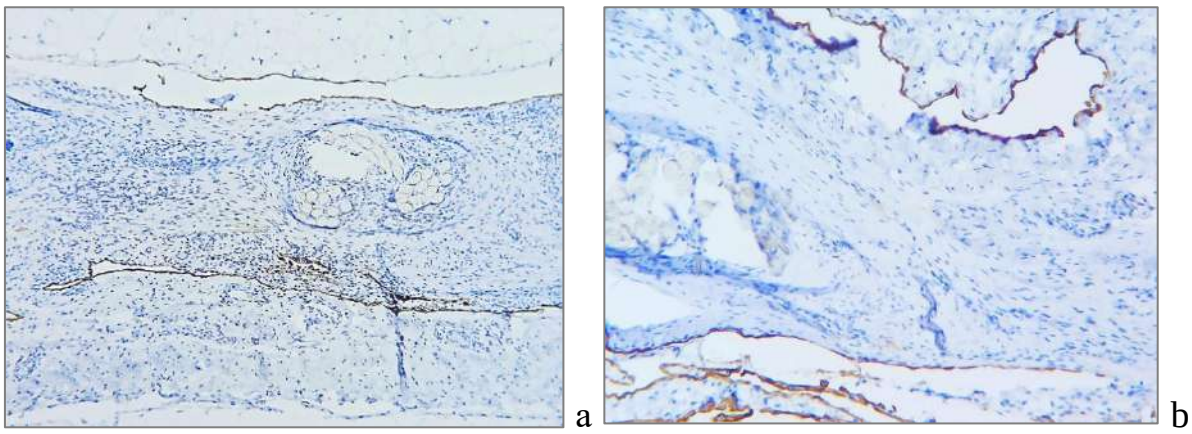


Figure 6.1. – Groups of endoprostheses with similar morphological characteristics. *Group 1 (a – FLUOREX; b – FLUOREX with an additional anti–adhesive layer of carboxymethylcellulose); group 2 (c – Ventralight ST; d – Symbotex); group 3 (e – Reperen 16-2; f - decellularized pork peritoneum). Staining with hematoxylin and eosin. ×30.*



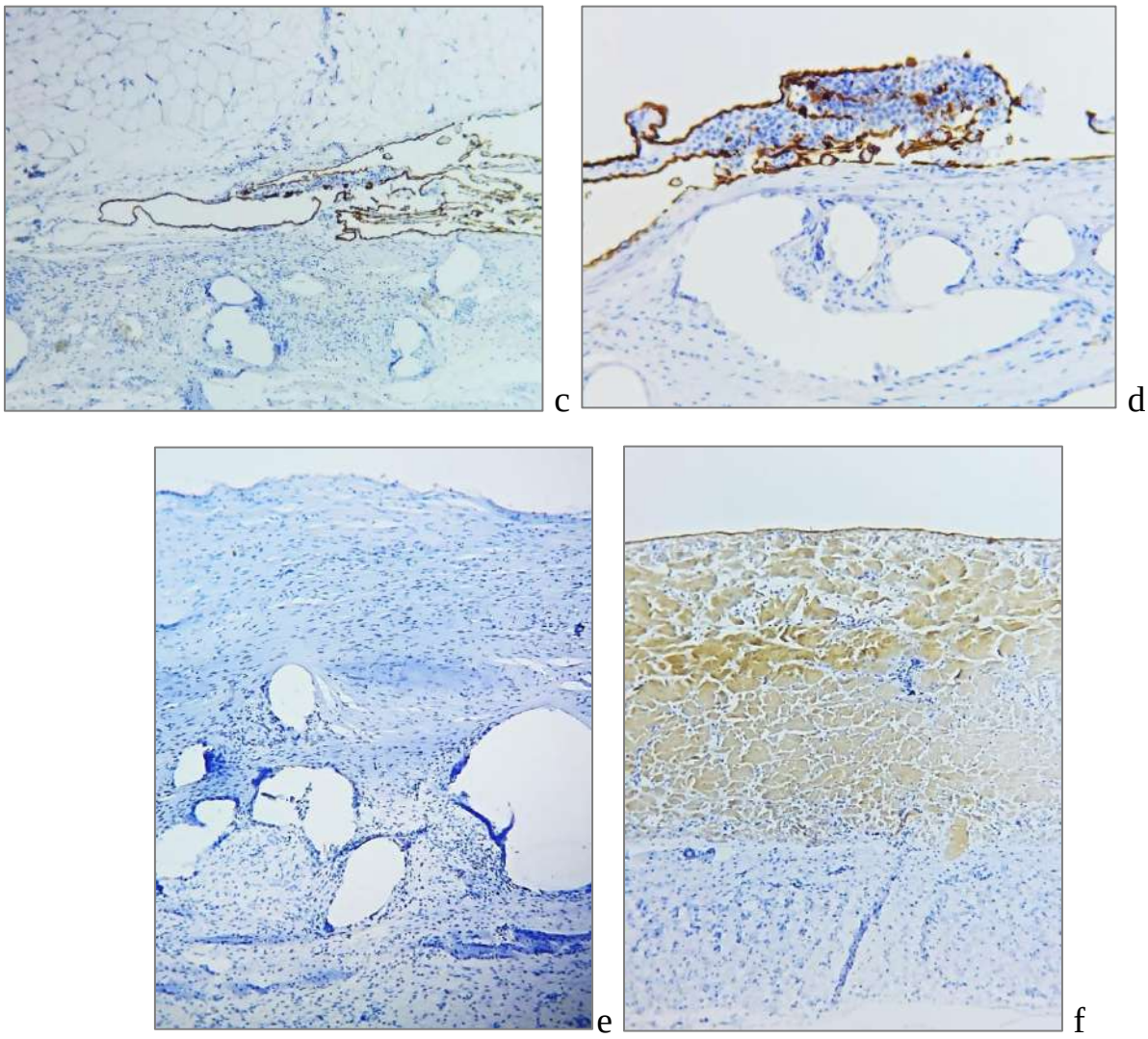


Figure 6.2. – The state of the basic peritoneum and neoperitoneum during implantation of endoprostheses. Mesothelial cells have a positive cytoplasmic staining in a golden brown color. *In group 1 (a – FLUOREX; b – FLUOREX with an additional anti-adhesive layer of carboxymethylcellulose), mesothelium growth is noted both on the surface of the endoprosthesis (neoperitoneum) and under it (basic peritoneum). In group 2 (c – Ventralight ST; d – Symbotex), there is no basic peritoneum on the background of a well-formed neoperitoneum. In group 3 (e – Reperen 16-2; f – decellularized porcine peritoneum) the neoperitoneum is insufficiently formed, and the basic peritoneum is absent. IHC reaction with PCK marker AE1/AE3. ×200.*

Morphometric analysis showed that the greatest thickness of the endoprosthesis-peritoneum layer was formed in group 3 (Reperen 16 and decellularized peritoneum). When comparing the results of morphometric analysis of groups 1 and 2, it was found that the thickness measured in the projection of the threads was slightly larger in group 1, but in this group, as a whole, the surface area not occupied by thread elements and not

blocked by an inflammatory fibroplastic reaction (basic peritoneum) turned out to be significantly larger than in group 2, where The fibroplastic reaction to the mesh overlapped the underlying peritoneum, almost completely eliminating it.

An analysis of the areas of filaments occupied in the endoprostheses under study (Table 6.1.) showed that the smallest area was in the Reperen 16 endoprosthesis, but the material itself caused the greatest fibroplastic reaction in general. In group 1, the area of the mesh filaments was in optimal proportion in terms of layout and distance from each other, which allowed the body to form a relatively dense fibrous framework around the filaments and leave room for the preservation of the basic peritoneum involved in the formation of the neoperitoneum. There are indications of the positive effect of a larger cell size on integration processes in the works of other authors [376].

When assessing inflammation, it is also possible to identify the characteristics of the body's response to various implantable materials. As is known, the severity of inflammation can affect both the quality of the endoprosthesis integration and the severity of adhesions in the area of its installation [221]. The first group was characterized by the absence of leukocyte infiltration. Group 2 was characterized by a pronounced leukocyte reaction, whereas group 3 was characterized by an even more pronounced leukocyte reaction and purulent-inflammatory processes (Reperen 16). The results of the assessment of inflammation in the thickness of the newly formed tissues surrounding the mesh filaments and the underlying peritoneum are shown in Table 6.1.

Table 6.1. – The ratio of the cellular elements of the inflammatory infiltrate, fibroplastic and vascular components in the thickness of the newly formed tissue surrounding the elements of the endoprosthesis and the underlying peritoneum

Endoprosthesis	The absolute number of cellular elements (M in 1 n/a). ×400								Total abs. cellularity per 1 pp. ×400
	Gr	Lf	Pl	Mf	M MC	Fb	Fc	Number of	

								vessels	
In the tissues around the endoprosthesis elements									
FLUOREX	1,10	55,80	0,77	26,67	2,50	45,53	59,27	52,67	241,3
FLUOREX with AC	0,60	32,13	1,57	21,97	1,20	51,97	87,77	41,70	238,7
Ventralight ST	8,90	45,80	1,45	42,45	1,95	25,88	99,18	68,33	293,9
Symbotex	5,23	59,93	6,27	31,97	0,93	19,37	89,63	66,17	279,5
Reperen 16	5,50	23,00	0,70	7,93	0,10	29,73	66,33	62,23	195,5
Pork peritoneum	0,20	21,50	0,00	18,95	4,95	6,30	17,50	35,30	104,7
In the underlying peritoneum									
FLUOREX	1,60	7,13	0,13	0,00	0,00	0,00	61,37	48,30	118,5
FLUOREX with AC	0,00	7,60	0,30	0,00	0,00	0,10	48,10	37,90	94
Ventralight ST	0,08	10,53	0,43	0,03	0,00	0,15	54,53	57,40	123,1
Symbotex	0,33	12,17	1,83	0,00	0,00	9,00	46,30	53,93	123,6
Reperen 16-2	16,53	37,20	2,70	6,93	0,00	15,00	56,70	71,10	206.2
Pork peritoneum	0,45	6,85	0,30	0,00	0,00	1,50	53,75	58,55	121,4

Gr – granulocytes (neutrophils and eosinophils), Lf – lymphocytes, Pl – plasma cells, Mf – macrophages, MMC – giant multinucleated cells of the type of foreign bodies, Fb – fibroblasts, Fc – fibrocytes, Cl. vessels – vascular cells to which endotheliocytes, smooth myocytes of the vascular wall, pericytes, AS – antiadhesive layer.

The optimal dependence of the fibroplasia reaction on the endoprosthesis material was observed in group 1. The reaction was clearly localized around the filaments, sufficiently pronounced for their muff-like envelopment with fibrous tissue of acceptable thickness, consisting of an adequate number of fibroblasts and fibrocytes, the bundles of which were located in different directions, but were oriented relative to the vector of the filaments. There was also no redundancy of formation and cross-growth foci that would overlap the spaces between the bundles of threads. The ratio of fibroblasts to fibrocytes in group 1 was 1-1.5:1. In the remaining groups, fibrocytes were strongly predominant and, consequently, the processes of fibroplasia were either inhibited or almost completed by the time of the study. This, in turn, could affect the further formation of the scar.

The total number of cellular elements in 10 visual fields at magnification ×400 also showed that there are common morphological features in the endoprosthesis groups. So, in group 1, the total number of cells was 241.3 (FLUOREX) and 238.7 (FLUOREX and carboxymethylcellulose), in group 2 - 279.5 (Symbotex) and 293.9 (Ventralight ST), which is 40-50 more cell units. The increase was mainly due to inflammatory infiltrate cells. In group 3 (Reperen 16 and decellularized peritoneum), on the contrary, lower cellularity was revealed compared with groups 1 and 2 and a small proliferation in the neoperitoneum zone compared with newly formed tissues around the elements of the endoprosthesis.

The vascular component also showed a group difference (Fig. 6.3.). In groups 1 and 2, there were processes similar in severity of the development of the neovascular and neolymphatic components, which are synchronous, and in group 3, dissociative, due to the difference in the components of the endoprosthesis.

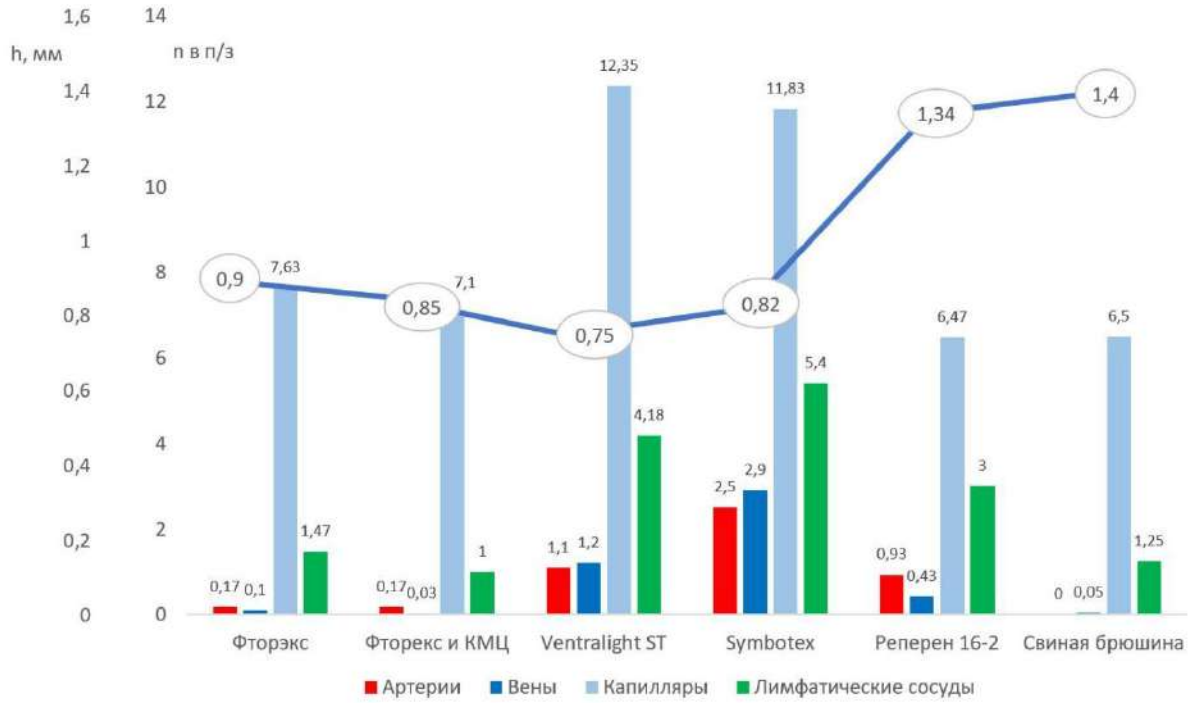


Figure 6.3. – Comparative characteristics of the number of newly formed vessels in the area of the endoprosthesis against the background of the severity of the processes of remodulation and fibroplasia. *The number of newly formed vessels is indicated in 1 n/a. at an increase of ×400, the thickness of the newly formed tissues h in mm.*

In group 1 (FLUOREX endoprostheses), the optimal ratio of newly formed arterial/venous/lymphatic vessels was noted relative to the thickness of the newly formed connective tissue around the elements of the endoprosthesis and the low severity of the current granulomatous inflammation, which correlated with intraoperative macroscopic assessment of the quality of endoprosthesis integration at this time. The vascular network was formed mainly by small capillary vessels, without the formation of large elements, which indicated an organic and correct adaptive restructuring of the local blood and lymph circulation system.

The maximum number of lymphatic vessels in the 2nd group of endoprostheses (Ventralight ST and Symbotex) was combined with signs of moderate chronic inflammation with more pronounced activity of the purulent-exudative component, which indicated the need for enhanced drainage function and indirectly indicated increased metabolic activity in tissues.

Also, in comparison with other groups, the formation of a more pronounced microcirculatory bed was noted in this group, which indicated the processes of prolonged angiogenesis. At the same time, the presence of vessels of a larger caliber in the newly formed tissues indicated a more stable vascular remodulation.

The predominance of the venous bed over the arterial one indirectly indicated the atypical restructuring of the vascular bed, which could reflect the phenomena of stagnation and be both a consequence and a cause of stagnant blood circulation. This, in turn, could contribute to maintaining the hypoxic state of tissues and provoke the growth of new adhesions.

In group 3 (Reperen 16 and decellularized peritoneum), the vessels were poorly represented, which, against the background of pronounced fibroplasia and the high thickness of the formed mesh-tissue-peritoneum layer, indicated a paradoxical and inadequate blood supply to the thickness of the formed layer. This discrepancy was combined with an unfavorable course and complications in the form of disorganization of newly formed connective tissue, metaplasia processes, the development of fibrinoid necrosis, progression and recurrence of the secondary inflammatory process.

According to the results of the IHC study, it was revealed that in group 1, the most common areas were those with the preservation of structures and layers of the base peritoneum under the mesh with the neoperitoneum. Mesothelial cells covered the entire surface of the implant, had a flattened appearance, were located in one layer, and there were no reactive changes. The rare and uneven adhesions that formed were represented by thin filamentous elements, with a scanty stroma with a small number of capillary vessels, the surface of which was evenly covered with cells of inactive mesothelium.

In group 2, mesothelium also predominantly covered the surface of the meshes completely, but there was a restructuring with the cancellation of the base sheet of the peritoneum, which is quite typical for this implant design [228]. The adhesions were also evenly covered with mesothelium, and often had reactive changes. Their uneven thickness and maturity, infiltration and signs of active growth were noted.

In group 3, on the contrary, extended areas not covered with mesothelium were often found, while the adhesions suitable for implants were covered with mesothelium, which was also more common at the places where adhesions were attached to the surface of implants. That is, in group 1, remesothelization occurred mainly due to the basic peritoneum, from under the implant, and in group 3 – due to mesothelium adhesions.

Based on the data obtained, it was concluded that early mesothelization, and as a result, a more favorable course of the mesh endoprosthesis integration process is influenced by the preservation of the base peritoneum, the absence of an anti-adhesive layer in the form of a plate.

In turn, as part of the first series of experiments, it was found that the FLUOREX mesh endoprosthesis has a unique structure: the presence of large cells, small surface density, no wickedness, which in turn ensures the rapid formation of a neoperitoneum on its surface.

Thus, the use of this type of mesh for intraperitoneal plastic surgery is safe from the point of view of the formation of the adhesive process and even causes fewer adhesions than Western composite anti-adhesive endoprostheses already available on the market and actively used. However, this stage had a number of limitations: the small size of the experimental samples, the absence of a hernia defect model, and a large number of meshes in the abdominal cavity of one experimental animal that were different in structure and materials. In this regard, it was decided to conduct the next stage of the study of the FLUOREX endoprosthesis.

In order to assess the possibility of safe use of large-sized mesh endoprostheses made of polyester with fluoropolymer coating FLUOREX in IPOM plastic under conditions of modeling and elimination of a hernial defect, the 2nd series of experiments was conducted. Various options for fixing this implant have also been studied.

In this series, the good performance characteristics of FLUOREX endoprostheses have been confirmed. The ease of use in all cases is rated as good. First of all, this was due to the lightness of the mesh, as a result of which in some cases it was possible to

position it on the abdominal wall even without the use of transfascial sutures. This was often observed in small prostheses that seemed to stick to the surface of the peritoneum.

The duration of the operation significantly depended on the use of transfascial sutures. If in the 1st animal, in which these sutures were not used to fix the endoprosthesis, the duration of the operation was 31 minutes, then in the 2nd and 3rd animals, in which transfascial ligatures were used during the operation, this time increased to 59 and 67 minutes. Adhesive fixation also required a little more time, since after applying the substance, it was necessary to wait for some time before polymerization.

All types of fixators used can be used to fix this type of endoprosthesis. At the same time, it should be borne in mind that ProTack spiral titanium fixators in some cases pass "through" the mesh (noted in 4 cases), and SecureStrap harpoon-type fixators with their insufficient entry into the tissue (and consequently their insufficient compression (2 cases)) they can cause bleeding. Also, in a number of cases, damage to the fibers of the mesh was observed without disturbing its frame with the sharp end of all types of mechanical clamps used.

The reason for the "sinking" of titanium retainers may be the large size of the mesh cells and its thinness, as a result of which a number of threads may break when exposed to the sharp end of the retainer. In most cases, the wireframe of the grid is not broken. To avoid this, you can install the end of the retainer strictly in the center of the grid cell. Also, in our opinion, it makes sense to make some design changes to the implant in the form of reducing the size of cells.

Harpoon-type clamps, the sharp ends of which entered two adjacent cells, turned out to be more convenient and having a minimal risk of damage to the grid. Two cases of non-intensive self-stopped bleeding that occurred during their use were associated with insufficient force applied to the instrument at the clipping stage.

Adhesive fixation for this version of the endoprosthesis when using a delivery device also turned out to be quite convenient. A mesh endoprosthesis, which does not have a separate anti-adhesive layer, allows you to apply glue while having both the working area and the entire prosthesis in the field of view. The bending end of the device

allows it to be positioned perpendicular to the surface of the mesh and the underlying peritoneum. To tear the prosthesis away from the peritoneum, significant physical effort was required. One of the disadvantages is leakage of glue when there is excess of it throughout the device, which increases the risk of it getting on internal organs. The latter can be avoided by placing a multi-layer sterile napkin on the organs located under the mesh during fixation. However, this type of fixation with IPOM, regardless of the type of implant, requires further study, including experimental research.

During laparoscopy and autopsy on the 90th day of the experiment, no visual signs of inflammation and deformation were observed. However, there was a fairly pronounced retraction. In 1 animal (in the absence of transfascial sutures) it was 36%. The retraction was even greater (52.3%) in the 3rd animal when using Glubran 2 surgical glue, despite the use of transfascial ligatures. It turned out to be minimal in the 2nd animal, in which an endoprosthesis of the maximum size (400 cm^2) was installed and transfascial sutures and absorbable harpoon-type fasteners were used.

Quite pronounced retraction of the implant in 1 animal can be explained by the absence of transfascial sutures [367] and the migration of a large number of fixators (12 out of 27). The latter may be due to the weak frame properties of the lightweight implant, which is not able to properly retain such fixatives. A number of authors have previously pointed out the fact that when spiral fixators are installed in the abdominal wall, their migration significantly increases [334]. Speaking about the migration of fixatives, it should be noted that their free presence in the abdominal cavity can cause a number of negative reactions. The greatest threat may be intestinal perforation [256], intestinal obstruction and the formation of intestinal fistulas.

The most pronounced retraction observed in the 3rd animal can be associated with the use of surgical glue. It cannot be ruled out that the cause of this is chronic inflammation, the presence of which has been indicated in a number of studies [204]. The latter, leading to more pronounced sclerotic processes, intensifies the retraction process. It also cannot be ruled out that in the experiment, the amount of glue used to fix the endoprosthesis was excessive; accordingly, continued research with dosage selection may give more acceptable results.

Despite the presence of adhesions in all experimental animals, this did not significantly affect their behavioral reactions or active weight gain. The least pronounced adhesion formation was observed when using absorbable harpoon-type fixators, the most pronounced when using surgical glue. If in the 1st and 2nd animals adhesions were found only at the edges and probably arose due to contact with parenchymal organs (liver, spleen), then in the 3rd animal they involved both the edges and the center. It is not possible to say unequivocally that they occurred precisely in the places where the endoprosthesis was fixed. However, most likely, adhesions are related specifically to the method of fixation, which is especially noticeable when using surgical glue [256]. It should be emphasized that in the suturing area of the simulated hernia defect in the first two animals, no adhesions were observed.

The conducted series of experiments showed that full-size endoprostheses with fluoropolymer coating FLUOREX do not cause clinically significant reactions and complications in large animals. The observed retraction and adhesion formation are most likely related to the fixation method. Optimal for this endoprosthesis is the use of harpoon-type fasteners, with the use of which these undesirable effects are less pronounced. The use of titanium spiral fixators is possible, but due to the lightness and coarse mesh size, they are not retained well enough in the tissues of the abdominal wall and are subject to migration, which, in turn, can cause complications. The use of surgical glue to fix this version of the endoprosthesis can be unsafe and also significantly increases the cost of the operation. Further research is needed to refine the adhesive fixation technique.

In order to confirm the effectiveness and safety of mesh endoprostheses made of polyester with fluoropolymer coating FLUOREX, the final, 3rd series of experiments was carried out [11]. A comparison was made with the endoprosthesis most commonly used in such operations, made of polyester with an anti-adhesive layer of collagen (Symbotex). Another objective of this stage was to assess the possibility of safe use of polyester threads with fluoropolymer coating FLUOREX for intraperitoneal fixation of the implant. The third series of experiments showed that the FLUOREX endoprosthesis in most parameters is not inferior to the Symbotex endoprosthesis traditionally used for IPOM plastic

surgery. At the installation stage, no differences were observed in the time of positioning and fixation. Both prostheses did not cause visually visible inflammation, and no migration of fixatives was observed during their use. Despite the fact that no significant differences were found in such indicators as the number of implants with deformation and retraction, the area of FLUOREX prostheses by 45 days was smaller than that of Symbotex prostheses, which indicates their greater tendency to retraction. These findings can be explained by the significant difference in surface density between FLUOREX (36-42 g/m^2) and Symbotex (66 g/m^2), which could affect the frame properties.

Another finding was a change in the size of endoprostheses after excision of the prosthesis-tissue complex from the abdominal wall. For FLUOREX endoprostheses, the area decreased slightly from 79.6% to 77.8%, while for Symbotex endoprostheses, on the contrary, it increased from 87.8% to 90.8%. It cannot be excluded that such changes are associated with the structure of the weave and the presence of anisotropy in the Symbotex implant.

Despite the fact that during the study, an IPOM endoprosthesis, such as Symbotex, which was repeatedly tested in the clinic for hernioplasty, was used, it was not possible to avoid adhesions. A comparison of the parameters of adhesion formation did not show significant differences, which did not contradict the results of the previously conducted first series of experiments. This confirms the fact that at the moment there is no composite prosthesis with ideal anti-adhesive properties and new technological solutions and further research in this direction are needed.

A comparison of the thickness of the resulting prosthesis-tissue complex showed that when using Symbotex, it turns out to be larger (1.2± 0.2 mm versus 0.8± 0.2 mm for FLUOREX, $p = 0.009$). The data did not match the results of the pilot study, where the thickness of the complex for these prostheses was the same and was 0.7 mm. Given the number of samples studied, in our opinion, the results of the 3rd series of the experiment should be more trusted. This is also supported by the fact that the thickness of the implants before their use was 0.31 mm for FLUOREX, and 0.59 mm for Symbotex. In fact, the thickness of the mesh initially differed by 2 times, which could subsequently lead to a difference in the thickness of the resulting prosthesis-tissue complex.

The difference in the thickness of the resulting prosthesis-tissue complex, in turn, can explain the difference in the indicators of the average breaking load and the average breaking elongation. These parameters turned out to be higher when using the Symbotex prosthesis. It can be assumed that an increase in the surface density of the FLUOREX prosthesis to figures comparable to those of the Symbotex prosthesis will lead to an equalization of the indicators of both the thickness of the prosthesis-tissue complex and the breaking load and tensile elongation.

Despite the fact that the thickness of the resulting complex and the strain parameters of the FLUOREX implant turned out to be smaller, this does not mean that this prosthesis cannot be used in IPOM hernioplasty. Firstly, these indicators were within acceptable limits. Secondly, on the contrary, a smaller thickness may indirectly indicate good integration with a less pronounced scarring process. For certain indications, for example, in patients with small primary hernias, the use of these implants will be shown in connection with a more physiological integration into the tissues of the abdominal wall. In the opposite situation, for example, in obese patients with postoperative hernias of medium size and high tension on the tissue, it will be more advisable to use a Symbotex endoprosthesis, which leads to the formation of a prosthesis-tissue complex of greater thickness and having a greater breaking load. It is also possible to use the FLUOREX endoprosthesis in such patients with a number of improvements, in particular, an increase in surface density, or when using a larger prosthesis.

As expected, the main advantage of the SecureStrap stapler turned out to be the speed with which the endoprosthesis was fixed to the abdominal wall. On average, it was 1.0 ± 0.0 minutes, while ligature application required at least 16.6 ± 2.3 minutes ($p < 0.001$). In the clinic, this advantage allows not only to facilitate the work of the operating surgeon, but also to significantly reduce the total duration of surgery and anesthesia, which has a beneficial effect on the patient's condition. The negative side of using a herniator is its cost, which is incomparable with the price of the suture material.

A visual assessment confirmed that SecureStrap fixers are not biodegradable by 45 days and are not prone to migration. Due to the design in the form of a "harpoon", according to the latter indicator, they have an advantage over spiral clamps, a certain part

of which, according to the results of the pilot study, is undergoing migration. Like stapler clamps, by the 45th day all suture ligatures were in place, and all nodes were sound, which testified primarily to the satisfactory mechanical qualities of the suture material itself.

Despite the absence of a significant difference in the number of endoprostheses with deformation and retraction phenomena by the 45 days of the experiment, the area of implants using non-absorbable suture fixation with FLUOREX thread turned out to be larger. The importance of this indicator should not be underestimated. In the clinical use of prostheses, its high values can give an advantage to the suture type of fixation by reducing the number of recurrences associated with the retraction process.

In our opinion, less pronounced retraction processes when using suture material may be associated with deeper stitching and, in some cases, with the capture of aponeurotic leaves of abdominal wall muscles. A large retraction when using stapler fixators may be due to their depth of penetration (up to 4 mm) and fixation only for the peritoneum and preperitoneal tissue, that is, those tissues that have lower skeletal properties compared to fascial tissues.

The indicators of adhesion formation during suture non-absorbable fixation practically did not differ from those when using absorbable stapler fixators.

The authors quite often associate the occurrence of adhesions with direct contact with the organs of the abdominal cavity, as a result of which it is possible to trace the course of adhesions directly with the fixation zone [204]. This is most noticeable when performing a repeat operation at an early date. In our case, a visual inspection on day 45 did not reveal adhesions directly with suture ligatures, which confirms the high biological inertia of the coating of FLUOREX filaments.

The conducted study did not reveal a significant effect of the fixation method on the thickness of the resulting prosthesis-tissue complex and strain parameters. A slightly higher breaking load when using FLUOREX filament may be associated with fixation with the filament for deeper, fascial-aponeurotic layers of the abdominal wall. It cannot be excluded that the fixation of FLUOREX endoprostheses with FLUOREX thread can

increase the average breaking load, the indicators of which, when comparing FLUOREX and Symbotex implants, were lower for the former.

In terms of effectiveness and safety, both fixation methods showed approximately equal results. At the same time, the SecureStrap gerniepler has an advantage in the speed of fixation, the FLUOREX thread has an advantage in the cost of consumables.

In parallel with a series of chronic experiments to study the anti-adhesive properties of the domestic FLUOREX endoprosthesis, we conducted a retrospective analysis in order to determine the optimal mesh endoprosthesis and its fixation method for intra-abdominal plastic surgery.

The clinical evaluation of the effect of the anti-adhesive coating of the endoprosthesis was carried out in 3 groups of patients. Implants with the most commonly used coatings such as collagen (group 1), hyaluronic acid and carboxymethylcellulose (group 2) and Reperene (group 3) were used. The groups were comparable in terms of gender, age, patient health indicators, duration of herniation, etiology and localization of hernias, and the presence of diastasis of the rectus abdominis muscles. A significant difference in the follow–up period in the group where Reperen endoprostheses were used (13 months versus 91 in the group with a coating of collagen and 90 - hyaluronic acid and carboxymethylcellulose) was due to the significantly later introduction of Reperen implants. Significantly lower hernial gate area values when using implants coated with hyaluronic acid and carboxymethylcellulose (median 4.0 cm^2 versus 24.0 cm^2 in the collagen coated group and 12.6 cm^2 in the Reperene coated group) were associated solely with the preferences of surgeons.

Concomitant diseases were 68.6% of patients. It was noteworthy that more than half of the subjects had some degree of obesity. It should be noted that, despite their age and in some cases the absence of concomitant pathology, all patients had certain risk factors for hernia formation. Approximately half of the patients had 2 risk factors, and another 11.7% had 3 or more risk factors.

When evaluating intraoperative parameters, such as the use of prolonged local anesthetics, the area of the endoprosthesis, the ratio of the area of the prosthesis to the

area of the hernial gate, damage to the visceral layer of the prosthesis, no significant differences were found in the groups. Significantly more frequent hernial gate suturing in the group of patients with Reperen endoprostheses was due to the fact that over the past 5 years the approach to performing intraperitoneal plastic surgery has changed, preference is given to the IPOM Plus method in almost all patients.

Of the clinical and economic indicators, such as the time of the operation, the time spent in the hospital and the cost of the endoprosthesis, there were significant differences in the groups only in the latter indicator. The lowest price (median 20900.0 rubles) turned out to be in the group of patients who used domestic prostheses with a coating of Reperene.

The incidence of intraoperative complications turned out to be at a lower level than in a number of studies [244]. It was 1.5%, and among the complications there were no cases of enterotomy or damage to parenchymal organs and large vessels. In all cases, these were injuries to the branches of the epigastric artery. This is often described in literary sources when it occurs either during transfascial ligatures along the lateral edges of the implant, or during stapler fixation [121].

Early postoperative complications, on the contrary, turned out to be slightly higher than the data of other authors [153; 244]. There were no significant differences between the groups according to this indicator, but their number increased due to the indicators of the group where the prosthesis with a coating of Reperene was used. Fortunately, all the early complications that occurred were no higher than Class II according to the Clavien-Dindo Classification and did not require repeated surgical interventions.

An assessment of the nature of complications showed that seromas were more common. According to other authors, their frequency in IPOM hernioplasty reaches 17,4% [125; 224; 205]. Our indicators turned out to be lower. When using a Reperen endoprosthesis, postoperative paresis occurred in 2 cases, which resolved against the background of conservative measures. In both cases, the prosthesis was fixed using cyanoacrylate glue and it was not possible to unambiguously judge the etiology of this process.

The frequency of late complications was approximately at the same level as early ones. It was 19.7%. According to this indicator, significant differences were obtained in the groups ($p = 0.025$). If in the group where prostheses with a coating of collagen or hyaluronic acid and carboxymethylcellulose were used, the indicators were 13.2% and 16.2%, respectively, then in the group with a Reperen prosthesis this figure reached 45.8%. As in the early postoperative period, seromas prevailed, the frequency of which did not exceed the results of other modern studies [205].

Among the late complications, 2 trocar hernias were identified, which required repeated intervention. Such severe complications as mesh migration or intestinal obstruction associated with the presence of an endoprosthesis or fixators were not observed in our study.

The rate of hernia recurrence (2.9%) corresponded to the data of other researchers [216; 200; 319; 126; 180]. The coating of the endoprosthesis did not affect this indicator, as well as the frequency of recurrence of diastasis. Also, in our study, there was no significant effect of the coating on viscero-parietal adhesions in the area of the prosthesis, however, the indicators were slightly worse for the Reperen endoprosthesis. The average frequency of detection of adhesions was comparable with the results of other studies [272; 162].

The study did not reveal the effect of the prosthesis coating on the quality of life of patients in the separated period. The results were slightly worse when using endoprostheses coated with Reperen. The difference depended more on the restriction of physical activity than on the severity of pain syndrome or cosmetic dissatisfaction.

The results of the evaluation of the effect of the anti-adhesive coating of the prosthesis on the studied parameters confirmed the data of other authors. Despite the fact that the domestic Reperen implant turned out to be significantly cheaper than foreign analogues, the results of its use in terms of the frequency of late complications turned out to be worse. At the same time, polyester endoprostheses with collagen coating had better results compared to the others, but they were distinguished by a higher cost.

In addition to evaluating the effect of the anti-adhesive coating of a mesh composite implant on the results of treatment of patients, we conducted a study of such a rather important factor as the method of its fixation. The first two groups of fixators are the most in demand. At the stage of formation of the IPOM technique, only non-absorbable fixators were used. Later, primarily due to the pain syndrome in the early postoperative period, bioabsorbable fixators were developed and implemented, which had high hopes for solving this problem [268]. The use of various variants of surgical glue has become another stage in the development of intraperitoneal plastic surgery [114; 171; 370]. However, at the moment, all fixation methods retain a number of significant drawbacks, which were the purpose of this retrospective clinical study to identify.

If the device of non–absorbable clamps was of the same type - they were a titanium spiral, then absorbable clamps could be either in the form of a "screw" or in the form of a "harpoon". Given the wide variety of these models, a separate assessment of the effect of the fixation device on the results of treatment was not carried out.

Non-absorbable fixators were used in the largest number of patients (65.7%). This is partly due to their good fixing properties, which allow them to be used on both unchanged and scar tissues, which are often found in postoperative hernias [5; 160]. The smallest number of patients and short follow-up periods were noted in the group where glue was used. This was due to the relative novelty of this technique and, accordingly, the small number or even complete lack of reliable evidence of its effectiveness and safety.

The selected groups of patients were comparable in terms of such indicators as gender, age, BMI, number of risk factors and duration of herniation. A significantly lower number of patients with postoperative hernias, obesity, concomitant diseases, previously performed operations on abdominal organs, and the complete absence of patients with lateral hernias in the group where absorbable fixators were used can be attributed to the concerns of surgeons related to their fixing properties. The same factor is due to the smaller size of the hernial defect and the greater ratio of the implant area and the area of the hernial gate. According to our observations, in some cases, when using heavier nets and working in scar tissue, absorbable fixators turned out to be ineffective and had to be replaced with non-absorbable ones. Other authors also point to this [320].

The shortest time spent on the operation and the shortest duration of hospitalization in the group where absorbable fixators were used can also be explained by the smaller size of hernial defects and the very small number of patients with postoperative hernias. At the same time, the longest duration of hospitalization of a patient using glue was probably associated with a significantly large number of early complications arising from its use.

A significant difference in the price of the fixing device was formed primarily due to the cost of surgical glue and a device for its delivery. If the prices of devices for installing non–absorbable and absorbable fixers were approximately comparable, then the price of glue exceeded them by more than 2 - 2.5 times.

Intraoperative complications, averaging only 1.5%, were associated solely with the positioning and fixation of the endoprosthesis. According to this indicator, there were no differences in the groups. The damage occurred either due to injury to the vessel by the retainer itself, or by a needle for transfascial ligatures. Fortunately, in all cases, the bleeding was stopped by applying additional stitches.

A significant difference in the groups was found only in the number of early (up to 30 days) complications ($p = 0.041$). There were fewer of them when using non-absorbable fixers (15.6%) and more when using glue (40.0%). It should be noted that in the group where glue was used, 2 cases of intestinal paresis were noted in the early postoperative period. This was not observed in other groups. It is not possible to unambiguously associate this undesirable phenomenon with surgical glue, since in this group, the vast majority of patients used a Reperen endoprosthesis, which could also have an impact on this process.

In the group of patients who used surgical glue, a greater number of late complications were also noted, however, there was no significant difference in this indicator. A slightly greater number of early and late complications when using surgical glue may be due to both a temporary local increase in temperature during its polymerization and the ingress of some amount onto the visceral peritoneum, and a longer inflammatory reaction [249; 314].

Of all the late complications, seromas prevailed in the groups – more than half of the cases. More often they occurred in response to absorbable fixatives, less often to surgical glue. Two complications of Class III and Clavien-Dindo Classification were not associated with fixation of the endoprosthesis.

The assessment of the frequency of hernia recurrence, recurrence of diastasis, viscero-parietal adhesions and quality of life did not reveal any differences between the groups. The recurrence rate and adhesion formation were slightly higher in the group with adhesive fixation, which does not contradict the data of other studies [184; 171; 145]. Also, in this group, the indicators of dissatisfaction with the quality of life were higher, formed primarily due to greater restrictions on physical activity.

The highest quality of life was found in patients after the use of absorbable fixators. However, this indicator was formed not due to a decrease in the severity of pain syndrome after their biodegradation (these indicators were at the same level in the groups), but most likely due to a larger number of "light" patients with small hernias and who underwent the least traumatic surgical intervention.

An assessment of the effect of fixation showed that any type of fixation does not insure the patient against the risk of certain adverse reactions and complications. Their number turned out to be less when using non–absorbable and absorbable fixators, and more when using glue. However, the study does not allow us to draw unambiguous conclusions about the lower safety of surgical glue, since in the study group it was used in most cases in combination with a Reperen endoprosthesis and in part the identified negative effects may be due to the influence of the endoprosthesis, not the glue. This issue requires further research.

Another negative side of adhesive fixation is its price, which exceeds the cost of other types by 2 – 2.5 times. This factor may lead to the fact that adhesive fixation will have to be abandoned, despite the presence of good long-term results.

The study shows that the fixation systems of prostheses from foreign manufacturers are far from perfect, but at the same time they have a significant cost, which is simply impossible to cover with MHI tariffs in some regions. Based on this, within the

framework of import substitution, there is a high need to develop cheaper domestic fixation systems. In a number of situations, for example, with small primary hernias, the way out of the situation may be the use of cheaper, but also more time-consuming methods of fixation, for example suture.

Having failed to identify a reliable advantage of one or another anti-adhesive endoprosthesis for intra-abdominal plastic surgery, we decided to conduct a multicenter non-randomized controlled clinical trial, the purpose of which was to evaluate the results of using FLUOREX fluoropolymer-coated endoprostheses in IPOM, to form a control group, to take data obtained using polyester prostheses with an anti-adhesive coating of collagen (Parietene Composite, Parietex Composite and Symbotex). This type is most often used for IPOM plastics. The results were evaluated separately in patients with primary and postoperative hernias.

This approach allows us to give a more accurate assessment of a number of parameters that may differ significantly. An example of this is the degree of adhesion formation in the implant area, depending on the volume of tissue dissection and adhesion. The correctness of our approach was subsequently confirmed in a number of clinical cases.

In patients, demographic, statistical parameters, health indicators and hernia parameters did not reveal significant differences, that is, the groups were comparable. The significant difference in the follow-up dates is due to the very recent introduction of fluoropolymer-coated endoprostheses into our practice. Another parameter for which there was a significant difference was the frequency of hernial gate suturing. If recently we have been trying to perform this procedure for all patients, then previously the hernial gates were more often not sutured, which was explained by the principles of non-tensioning hernioplasty.

Despite the fact that the sizes of the prostheses used in the groups did not differ, the ratio of the area of the prosthesis and the area of the hernial gate in the group of patients with FLUOREX implants turned out to be significantly larger. This means that in this group, larger implants were more often used in patients with small hernias. We

consciously did this, since at the experimental stage we obtained data on the presence of retraction in FLUOREX endoprostheses. In order to reduce the risk of recurrence, we deliberately took larger nets.

A positive aspect was the significant absence of visual signs of damage to the visceral layer in FLUOREX implants. The high frequency of collagen damage along the edge of the Parietene Composite and Parietex Composite prostheses is associated with its exit by 5-7 mm beyond the mesh layer. In newer Symbotex prostheses, when using which damage to the protective layer was detected in isolated cases, such a design has already been abandoned.

One of the indicators that marked the difference in patients with postoperative hernias was the ratio of median and lateral hernias. In the group where fluoropolymer-coated endoprostheses were installed, there were significantly fewer lateral hernias.

Such important clinical and economic parameters as the time of surgery and the duration of stay in the hospital after surgery did not differ in the study groups. The frequency of stapler use in the group where collagen implants were used turned out to be higher, therefore, it was possible to expect a reduction in the operation time. However, in this group, simultaneous operations were performed more often in patients with postoperative hernias. At the same time, when using FLUOREX endoprostheses, due to its lightness and the effect of "adhesion" to the peritoneum, there was practically no need to use transfascial sutures during positioning. All this made it possible to offset the difference in fixation speed when using a stapler and intracorporeal sutures.

The estimate of the cost of consumables during IPOM surgery in patients with primary hernias turned out to be significantly lower in the group where fluoropolymer-coated implants were used. This was due to the lower price of the endoprosthesis itself – 14,500 versus 26,481 rubles (more than 10,000 rubles), as well as the cost of consumables for fixation – 3,000 versus 23,400 rubles. The latter was achieved by the gradual abandonment of routine use in the IPOM of the herniator and the introduction of intracorporeal sutures with a fluoropolymer-coated thread. During the operation, an average of 2 threads were used, the cost of each was about 1,500 rubles. The ratio of the

cost of the current KSK tariff to the cost of consumables when using FLUOREX endoprostheses also turned out to be significantly less. It amounted to 17.9% of the tariff (ratio 5.6), while the price when working with collagen–coated prostheses was 47.6% (ratio 2.1).

The cost of consumables in patients with postoperative hernias when using fluoropolymer-coated prostheses also turned out to be lower, despite the fact that consumables for fixation were more expensive. Their price was 29900 rubles against 23400 rubles in the group where collagen-coated endoprostheses were used. A similar difference arose due to the more frequent use of a herniated stapler with non-absorbable staples, which significantly accelerates and simplifies surgery in patients with deformed abdominal wall, where the effect of "sticking" of the FLUOREX endoprosthesis was less pronounced. The price of prostheses with a fluoropolymer coating was 20,900 rubles, and with a collagen coating – 45,784 rubles.

The ratio of the cost of the completed treatment case and the price of consumables also turned out to be in favor of fluoropolymer-coated prostheses. For them, the price was 43.5% of the tariff (ratio 2.3), while the price when working with collagen–coated prostheses was 62.5% (ratio 1.6).

The absence of intraoperative complications in patients with primary hernias and their minimal number in patients with postoperative ones, in our opinion, was achieved through the participation in operations of abdominal surgeons with experience in performing more than 50 such operations. The number of early and late complications in the groups did not have significant differences, at the same time, they were less in the group of patients who used fluoropolymer-coated prostheses.

The total number of complications turned out to be less than in the retrospective study, in which a significant proportion of them occurred in the group where the Reperen endoprosthesis was used. As expected, in the group of patients who used collagen–coated implants, the frequency of early and late complications in the treatment of primary hernias was lower, and postoperative complications were higher, compared with the data of the general group from a retrospective study.

The spectrum did not differ from the complications indicated in other studies [289; 281; 212]. Most of them corresponded to Class I and II according to Clavien-Dindo and did not pose a significant threat to the health of patients.

In the treatment of patients with postoperative hernias, the only complication that occurred in the early period when using a fluoropolymer-coated endoprosthesis was manifested by the development of postoperative paresis. During relaparoscopy, it was noted that in areas of extensive dissection, a large omentum was adjacent to the wound surface through the mesh cells. In the areas where the mesh implant lay on the intact peritoneum, this was not observed. Based on this observation, we came to the conclusion that mesh prostheses without a separate anti-adhesive layer with a sufficiently large cell size are not recommended for use in areas with extensive wound surface after dissection or adhesiolysis. It cannot be excluded that some reduction in the cell size or the use of additional anti-adhesive barrier agents in patients with postoperative hernias will significantly reduce or neutralize such an effect.

Another complication observed in the group of patients with postoperative hernias and requiring repeated planned surgery was manifested by the development of a trocar hernia in the area where the optical port was installed.

A separate assessment of such significant indicators as the number of hernia recurrences and adhesions in the area of implant localization also showed no significant differences. No recurrence was noted in the treatment of primary hernias using both collagen-coated implants and fluoropolymer-coated prostheses. In the treatment of postoperative hernias, 2 recurrences (5.6%) were detected in the group where collagen-coated implants were used. The overall recurrence rate in all patients with postoperative hernias was 3%. The indicator turned out to be comparable with the data of other authors, giving figures from 1.4 to 6,4% [223; 160; 205; 207; 230; 326; 135; 187]. It should be noted that a number of studies provide data on the number of relapses in combined groups of patients with primary and postoperative hernias. A separate assessment of the results of treatment of postoperative hernias, as a rule, gives better results.

The assessment of adhesions, carried out using ultrasound techniques based on the assessment of sliding of the parietal and visceral peritoneum in the area of implant localization, also revealed no significant differences. As expected, the frequency of adhesions was higher in the treatment of patients with postoperative hernias. The results were slightly better for collagen-coated implants. In this case, it should be clarified that such implants are currently the most effective in preventing viscero-parietal adhesions of all existing ones [279; 169].

The use of fluoropolymer-coated endoprostheses did not worsen the quality of life of patients. When compared with the results in patients with collagen-coated prostheses, the difference was minimal both in assessing overall dissatisfaction with the quality of life, as well as the parameters of pain severity, activity restriction and cosmetic dissatisfaction.

Thus, the results of the study showed that when performing IPOM hernioplasty, fluoropolymer-coated prostheses are not inferior in efficiency and safety to collagen-coated endoprostheses. This is confirmed by the absence of differences in the number of complications, the frequency of relapses, the severity of adhesions in the area of the endoprosthesis and the quality of life after surgery.

The use of fluoropolymer-coated implants both by itself and in combination with intracorporeal sutures can significantly reduce the cost of surgery, which makes it possible to compensate for the cost of its implementation in patients with both primary and postoperative hernias when paying within the framework of regional CHI tariffs.

When using fluoropolymer-coated implants, transfascial sutures may be abandoned due to the presence of an "adhesion" effect to the peritoneum, which facilitates its positioning on the abdominal wall.

The use of fluoropolymer-coated endoprostheses in combination with intracorporeal fixation with filaments, without fixation with transfascial sutures, does not lead to an elongation of the operation time when compared with the standard technique using a herniator and transfascial sutures.

Fluoropolymer-coated endoprostheses can be recommended for use in IPOM hernioplasty in patients with primary hernias, as well as in patients with postoperative hernias without extensive dissection of abdominal wall tissues or adhesiolysis. The expediency of using such implants after extensive laparoscopic dissections with the presence of large wound surfaces requires confirmation in further studies.

CONCLUSIONS

1. Based on the basic principles of interaction of synthetic materials and tissues, an innovative anti-adhesive polyester endoprosthesis with a fluoropolymer coating has been developed for intraperitoneal plasty of the anterior abdominal wall, which has a minimum thickness, maximum softness, is devoid of capillarity and wickedness, while it has good form stability and is convenient for practical use.

2. Mesh endoprostheses with fluoropolymer coating are safe for intra-abdominal placement, as they have anti-adhesive properties due to the structure of the implant and its high biological inertia, which reduces the severity of inflammation in contact with internal organs.

3. Modern anti-adhesive endoprostheses have similar biomechanical properties and have good biocompatibility, however, the type of anti-adhesive coating has a significant effect on the repair process – the most favorable is absorbable.

4. The reparative process proceeds most favorably with a preserved peritoneum – the process of neoperitonesis goes along the entire surface of the endoprosthesis through the cells. In the presence of a non-absorbable anti-adhesive plate in a composite endoprosthesis, the process of neoperitonesis begins from the periphery of the mesh, as well as due to adhesions, most often represented by a strand of a large omentum. Also, the permanent anti-adhesive layer enhances the inflammatory response under the implant, which impairs its integration into the abdominal wall.

5. Polyester endoprostheses with fluoropolymer coating and polyester endoprostheses with an anti-adhesive collagen layer rarely cause a minimal adhesive process. Both types of implants cause mild inflammation of the surrounding tissue, however, the large-cell structure of the endoprosthesis with a fluoropolymer coating contributes to a more physiological process of early mesothelization.

6. The location of composite endoprostheses with a absorbable and non-absorbable anti-adhesive layer in close contact with parenchymal organs (liver, spleen) leads to the development of a pronounced adhesive process. The use of polyester endoprostheses with fluoropolymer coating in this field causes a less pronounced adhesive process.

7. Polyester endoprostheses with collagen coating have the best results among composite implants, in which the anti-adhesive effect is achieved due to the presence of a absorbable or non-absorbable anti-adhesive layer, but they are more expensive. None of the studied turnip controllers has a significant advantage over the others, while it has a high price, which increases the cost of the operation.

8. The use of an anti-adhesive polyester mesh endoprosthesis with fluoropolymer coating for intra-abdominal plastic surgery in patients with hernias of the anterior abdominal wall is safe and clinically effective.

9. The use of an anti-adhesive polyester mesh endoprosthesis with a fluoropolymer coating for intra-abdominal plastic surgery significantly reduces the cost of surgery. The design features of this endoprosthesis make it possible to use separate nodular sutures more widely to fix it to the anterior abdominal wall, especially in patients with small primary hernias. This increases the clinical and economic efficiency of laparoscopic intra-abdominal plasty of the anterior abdominal wall.

PRACTICAL RECOMMENDATIONS

1. All types of herniators can be used to fix the FLUOREX mesh endoprosthesis, however, due to the large size of the cell, spiral titanium fixators in some cases pass "through" the mesh.

2. When fixing the FLUOREX endoprosthesis, the end of the retainer should be placed strictly in the center of the mesh cell.

3. The optimal method for fixing the FLUOREX endoprosthesis is a geriatric device with harpoon-type fixators. If they do not enter the tissues sufficiently and, as a result, they are not compressed enough, bleeding may occur.

4. To reduce the cost of the IPOM operation, it is possible to use FLUOREX filaments to fix the endoprosthesis.

5. The installation of an anti-adhesive mesh endoprosthesis in places of prolonged contact with parenchymal organs should be avoided.

6. When using FLUOREX endoprostheses, due to their lightness and the effect of "adhesion" to the peritoneum, there is practically no need to use transfascial sutures during positioning.

7. Due to the light weight and large-mesh structure of the FLUOREX mesh, the degree of its retraction when integrated into the anterior abdominal wall may be higher than that of composite anti-adhesive endoprostheses with a large weight. It is necessary to take this into account when choosing the size of the FLUOREX grid.

8. Mesh prostheses without a separate anti-adhesive layer with a sufficiently large cell size are not recommended for use in areas with extensive wound surface after dissection or adhesiolysis.

9. FLUOREX anti-adhesive endoprosthesis with fluoropolymer coating is recommended for active use in IPOM plastic surgery in patients with umbilical hernias, white line hernias, and small postoperative hernias.

10. For IPOM hernioplasty, the use of composite endoprostheses with a permanent anti-adhesive layer should be avoided.

LIST OF ABBREVIATIONS

IPOM- intraperitoneal onlay mesh
TEP – total extraperitoneal plastic
eTEP- extended view total extraperitoneal plastic
TAR- transversus abdominis muscle release
SCOLA – subcutaneous onlay laparoscopic approach
Ultrasound – ultrasound examination
CT- computed tomography
IHC- immunohistochemistry

APPENDIX No. 1

Informed consent

Informed consent to the collection and processing of data, registration of patients with hernias of the anterior abdominal wall and diaphragm,_____
_____(Full name)

Address:_____
_____ Phone number:_____
_____ E-mail:_____
_____ Passport data:_____
__ sufficiently informed about the goals of the general registration of patients with hernias of the anterior abdominal wall and diaphragm; I agree with the transfer, collection and processing of personal anonymous personal data on treatment and long-term results of surgery to the National Herniological Registry. I discussed this in detail with the attending physician and have no questions.

(Full name of the doctor, address GUZ)_____
Personal data includes: contact information for future monitoring, clinical data on risk factors, general health status, features of surgical intervention and its type, data on the postoperative course in dynamics (early term, 1-5, 10 years old). This data will be processed anonymously and cannot be shared with anyone else. Data processing will be carried out in the scope of medical statistical research, does not imply commercial use. The research results will be used to improve the quality of medical care in clinics in the Russian Federation.

I can withdraw my consent at any time and without giving any reason.

Date _____
_____(Signature of the patient)

A reminder for patients

Registration of all patients with hernias (abdominal wall or diaphragmatic hernia - inguinal, umbilical, postoperative, hiatal hernias, epigastric, parastomal hernias)

Dear patients!

Hernias of the anterior abdominal wall and diaphragmatic hernias are among the most common diseases requiring surgical intervention.

In Germany alone, about 300,000 patients are operated on annually due to one of the diseases mentioned above. To date, there are many surgical techniques and materials available for the treatment of abdominal wall hernias and diaphragmatic hernias.

In addition, over the past few years, it has been revealed that some methods and techniques are especially effective in patients with hernias.

However, due to the intensive growth of the study of various materials and techniques, it is increasingly difficult to decide at the scientific level which method offers the best results for patients.

Such questions can be clarified only if all the methods used in various clinics are systematically recorded and anonymously recorded in databases and surgical results are received for study over many years.

To this end, a group of experts working in the field of herniology has developed a quality control program for the treatment of patients with hernias, the National Herniological Registry.

The aim of this study is to optimize the quality of treatment for patients with hernias of the anterior abdominal wall and diaphragm.

For this purpose, participating clinics and practices enter anonymous data concerning all types of operations performed for hernias of various localization into a single central database.

The results are evaluated and published in scientific advisory papers.

In order to get these new scientific ideas, it would be extremely important that you agree to the anonymous recording of your data.

In doing so, you would make an important contribution to further progress in the treatment of anterior abdominal wall hernias.

The benefit for you personally is that careful attention will be paid to the control of your surgical treatment.

We would be very grateful if you would support us in our efforts to ensure, as far as possible, optimal treatment and further improve existing treatment methods for each individual patient, giving your consent for follow-up during your illness.

We assure you that your contact information will only be used to request data during the postoperative period. They are anonymous, encrypted and not shared with anyone.

APPENDIX No. 2

Assessment of the quality of life using the EuraHS-QoL scale

FULL NAME _____ Age _____ Date of filling in _____ Date of the operation _____ The deadline for completing the survey (underline): before the operation, after 1 month, after 3 months, after 1 year I agree to take the questionnaire (signature) _____

Evaluate the quality of life by taking the following survey

INSTRUCTIONS

This questionnaire contains questions about your views on your health before and after performing surgery for an abdominal wall hernia. The information you provide will help you keep track of how you feel and how well you are coping with your usual loads. Answer each question by selecting a number corresponding to your current condition. If you have no pain, restrictions and you are satisfied with the cosmetic result, set 0. If you are experiencing very severe pain, significant limitations and are not satisfied with the cosmetic result, set 10. If you are not sure how to answer the question, please choose the answer that best reflects your opinion. If you are not completing one of these tasks, please mark X in the last column.

1. Pain in the hernia area

0 – no pain, 10 – very severe pain

Pain at rest (lying down)	0	1	2	3	4	5	6	7	8	9	10	
Pain during movement (walking, physical work, sports)	0	1	2	3	4	5	6	7	8	9	10	
The feeling of pain over the past week	0	1	2	3	4	5	6	7	8	9	10	

2. Restriction of activity due to pain or discomfort in the hernia area

0 – no restrictions, 10 – full restriction, X – you do not perform this action

Restriction of daily activity (when staying at home)	0	1	2	3	4	5	6	7	8	9	10	X
Restrictions outside the home (walking, driving)	0	1	2	3	4	5	6	7	8	9	10	X
Restrictions during sports activities	0	1	2	3	4	5	6	7	8	9	10	X
Restrictions on hard physical labor	0	1	2	3	4	5	6	7	8	9	10	X

3. Cosmetic discomfort

0 – very beautiful, 10 – very ugly

The shape of the abdomen	0	1	2	3	4	5	6	7	8	9	10	
View of the area where the hernia was located	0	1	2	3	4	5	6	7	8	9	10	

APPENDIX No. 3

Assessment of the severity of pain syndrome in the postoperative period using the Digital Pain Rating Scale (NRS)

FULL NAME _____ Age _____ Date of the operation _____ I agree to take the questionnaire (signature) _____

Give your assessment of the severity of pain after surgery on a 10-point scale

Before the operation _____ points

After surgery _____ points

After 1 day _____ points

After 2 days _____ points

After 3 days _____ points

After 4 days _____ points

After 5 days _____ points

Pain assessment criteria

Severity		Description
10	Unbearable	I'm in bed and I can't move because of the pain. I need someone to take me to the hospital to help me get rid of the pain
9	Heavy	My pain is all I can think about. I can barely speak or move because of the pain.
8	Strong	My pain is so intense that it's hard for me to think about anything else. It is difficult to talk and listen
7	Unmanageable	It hurts me all the time. It keeps me away from most activities
6	Disturbing	I think about my pain all the time. I quit many classes because of the pain
5	Distracting	I think about my pain most of the time. Due to the pain, I can't do some of the things I need to do every day
4	Moderate	I am constantly aware of my pain, but I can continue to do most of the daily chores
3	Uncomfortable	My pain bothers me, but most of the time I can ignore it
2	Weak	I have a slight pain. I am aware of my pain only when I pay attention to it
1	Minimal	My pain is barely noticeable
0	No pain	

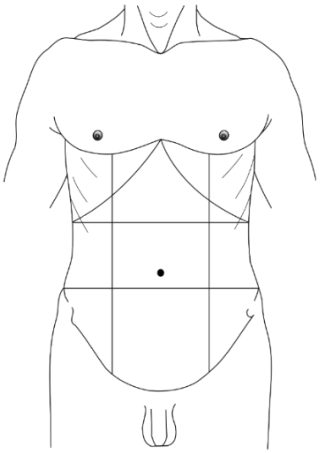
APPENDIX No. 4

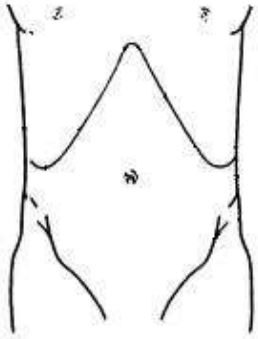
Ultrasound of the abdominal wall and underlying structures of the abdominal cavity

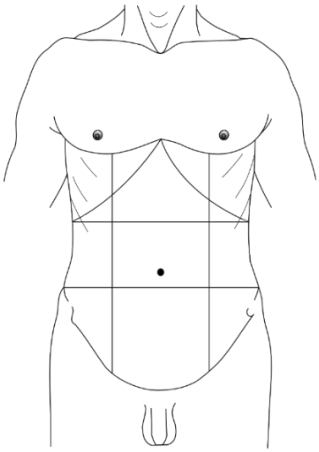
FULL NAME _____

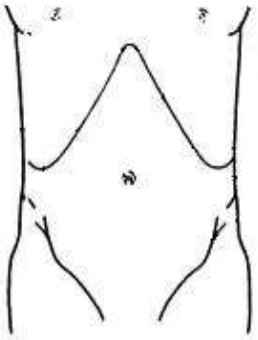
Age _____

Abdominal areas		**Straight -line longitudinal sliding**	**Angular displacement**	**The disturbed contour of the peritoneum**	**The fit of the intestine**	**Diastase**
Upper floor	Right hypochondrium	____ cm	Yes / No	Yes / No	Yes / No	____ cm
	Epigastrium	____ cm	Yes / No	Yes / No	Yes / No	
	Left hypochondrium	____ cm	Yes / No	Yes / No	Yes / No	
Middle floor	The right mesogastrium	____ cm	Yes / No	Yes / No	Yes / No	____ cm
	The umbilical zone	____ cm	Yes / No	Yes / No	Yes / No	
	Left mesogastrium	____ cm	Yes / No	Yes / No	Yes / No	
Lower floor	Right iliac region	____ cm	Yes / No	Yes / No	Yes / No	____ cm
	Suprapubic zone	____ cm	Yes / No	Yes / No	Yes / No	
	Left iliac region	____ cm	Yes / No	Yes / No	Yes / No	









Explanations

_____-
_____

_____-
_____

_____
_____

_____
_____

Doctor _____

REFERENCES

1. Abalyan, A. K. Features of the ratio of collagens in anterior abdominal wall aponeurosis in patients with postoperative ventral hernias and signs of connective tissue dysplasia / A. K. Abalyan, A. N. Aydemirov, A. Z. Vafin, E. V. Mashurova // Medical Bulletin of the North Caucasus. – 2016. – No. 2-2. – pp. 348-351.
2. Antropova, N. V. Causes of relapses of postoperative ventral hernias / N. V. Antropova, A. H. El-Said // Surgery. - 1990. – No. 7. – pp. 127-128.
3. Anurov, M. V. The influence of structural and mechanical properties of mesh prostheses on the effectiveness of hernial defects of the abdominal wall : dis. ... Doctor of Medical Sciences : 14.01.17 / Anurov Mikhail Vladimirovich - M., 2015. – 298 p.
4. Anurov, M. V. Comparison of the results of hernial defect plastic surgery with standard and light mesh endoprostheses with the same knitted weave / M. V. Anurov, S. M. Titkova, A. P. Ettinger // Bulletin of Experimental Biology and Medicine. - 2010. – vol. 150. – No. 10. – pp. 433-439.
5. Armashov, V. P. Prevention of adhesions in intraperitoneal hernioplasty (IPOM) / V. P. Armashov, N. L. Matveev, S. A. Makarov // Surgery. The magazine named after N. I. Pirogov. - 2020. – No. 9. – pp. 116-122. – DOI: 10.17116/hirurgia2020091116.
6. Armashov, V. P. The effect of the implant fixation method on adhesion formation in IPOM hernioplasty: a systematic review / V. P. Armashov, A. P. Ettinger, D. B. Lomaia, S. A. Makarov, N. L. Matveev // Evidence-based gastroenterology. - 2021. – Vol. 10. – No. 4. – pp. 38-56. – DOI: 10.17116/dokgastro20211004138.
7. Armashov, V. P. Is ultrasound diagnosis of peritoneal adhesions possible before abdominal surgery? / V. P. Armashov, A.M. Belousov, M. V. Vavshko, Sh. N. Madrakhimov, G. V. Armashov, N. L. Matveev // Innovative medicine of Kuban. - 2022. – No. 4. – pp. 75-81. – DOI: 10.35401/2541-9897-2022-25-4-75-81.
8. Armashov, V. P. Assessment of the effect of the fixation method and the implant placement zone on adhesion formation, deformation and retraction of the endoprosthesis during intra-abdominal placement in large animals / V. P. Armashov, A.M. Belousov, P.

A. Potapov, N. L. Matveev // Innovative medicine of Kuban. – 2023. – № 8 (4). – pp. 98-109. – DOI: 10.35401/2541-9897-2023-26-3-98-109.

9. Armashov, V. P. New hernias at implant fixation sites after IPOM hernioplasty / V. P. Armashov, D. B. Lomaia, A.M. Belousov, N. L. Matveev // Endoscopic surgery. – 2023. – № 29 (4). – pp. 57-66. – DOI: 10.17116/endoskop20232904157.
10. Armashov, V. P. Is it possible to diagnose peritoneal adhesions using magnetic resonance imaging and computed tomography before abdominal surgery? / V. P. Armashov, A.M. Belousov, M. V. Vavshko, V. A. Gorsky, V. V. Pavlenko, N. L. Matveev // Innovative medicine of Kuban. - 2023. – No. 1. – pp. 97-102. – DOI: 10.35401/2541-9897-2023-26-1-97-102.
11. Armashov, V. P. Results of the use of anti-adhesive barrier agents ADEPT and MESOGEL in intraperitoneal plastic surgery (IPOM) in an experiment / V. P. Armashov, A.M. Belousov, P. A. Potapov, D. D. Shkarupa, T. Yu. Anushchenko, T. S. Filipenko, K. O. Timofeeva, N. L. Matveev // Endoscopic surgery. – 2024. – № 30 (2). – pp. 48-65. – DOI: 10.17116/endoskop20243002148.
12. Outlev, K. M. Features of treatment of postoperative ventral hernias in morbid obesity / K. M. Outlev, V. V. Ivanov, V. S. Noskov, E. V. Kruchinin, A. R. Yusupov, E. L. Yanin // Medical science and education of the Urals. – 2011. – Vol. 12. – No. 3. – pp. 108-110.
13. Babazhanov, A. S. Analysis of the results of hernioalloplasty of ventral hernias / A. S. Babazhanov, G. K. Akhmedov, Z. Ya. Saidullaev, Sh. M. Kakhorov // World science: problems and innovations. – 2019. – pp. 224-227.
14. Baulin, A.V. Prosthetic hernioplasty in the treatment of primary and postoperative ventral hernias / A. V. Baulin [et al.] // Vestn. Pridnestrovian University. - 2014. – Vol. 2. – No. 2. – pp. 40-45.
15. Baulin, A.V. Development of new methods of hernioplasty / A.V. Baulin [et al.] // Izv. higher. studies. establishments. Volga region. region. Medical sciences. - 2012. – No. 2. – pp. 33-41.
16. Baulin, A.V. Experimental and clinical aspects of the use of polyester endoprostheses in hernioplasty / A.V. Baulin [et al.] // Vestn. Transnistria. Univ. Ser.: Med.-biol. and chemical sciences. – 2012. – № 2 (41). – pp. 38-52.

17. Baulin, A.V. Variants of aponeurotic and combined plastic surgery of postoperative and recurrent median ventral hernias / A.V. Baulin, V. A. Baulin, G. A. Zyulkin, A. E. Kvasov // Medical Almanac. – 2008. – No. S. – pp. 195-197.
18. Belousov, A.M. Safety of mesh endoprostheses with fluoropolymer coating: results of a pilot study / A.M. Belousov, V. P. Armashov, D. D. Shkarupa, T. Yu. Anushchenko, T. S. Filipenko, N. L. Matveev // Surgery. The magazine named after N. I. Pirogov. - 2023. – No. 2. – pp. 43-58. – DOI: 10.17116/hirurgia202302143.
19. Belousov, A.M. Histological changes in intraperitoneal plastic surgery (IPOM) with synthetic and biological endoprostheses. The results of a chronic experiment / A.M. Belousov, V. P. Armashov, D. D. Shkarupa, T. Yu. Anushchenko, T. S. Filipenko, N. M. Blum, P. A. Potapov, K. O. Timofeeva, A. A. Putulyan, N. L. Matveev // Surgery. The magazine named after N. I. Pirogov. - 2023. – No. 7. – pp. 37-50. – DOI: 10.17116/hirurgia202307137.
20. Belousov, A.M. The results of the clinical application of a mesh endoprosthesis with an anti-adhesive fluoropolymer coating for laparoscopic intraperitoneal plastic surgery of primary ventral hernias / A.M. Belousov, S. L. Nepomnyashchaya, V. N. Danilin, K. O. Timofeeva, V. P. Armashov, S. A. Makarov, N. L. Matveev // Surgery. The magazine named after N. I. Pirogov. - 2024. – No. 5. – pp. 86-94. – DOI: 10.17116/hirurgia202405186.
21. Belokonev, V. I. Possible predictors and morphological aspects of the development of seroma after hernia repair of the anterior abdominal wall / V. I. Belokonev [et al.] // Proceedings of the XI conference "Topical issues of herniology". – M., 2014. – pp. 17-19.
22. Belokonev, V. I. Complex treatment of patients with postoperative ventral hernia / V. I. Belokonev [et al.] // Journal named after N. I. Pirogov. - 2008. – No. 2. – pp. 42-47.
23. Belokonev, V. I. Pathogenesis and surgical treatment of postoperative ventral hernias, series "Difficult questions of surgery" / V. I. Belokonev, T. A. Fedorina, Z. V. Kovaleva [et al.]. – Samara: GP Perspektiva, 2005. – 183 p.
24. Blagovestnov, D. A. The results of surgical treatment of patients with primary median hernias of the anterior abdominal wall / D. A. Blagovestnov, A.V. Upyrev [et al.] //

Materials of a scientific and practical conference dedicated to the 20th anniversary of the Clinical Hospital of the Moscow Department of Internal Affairs of the Ministry of Internal Affairs of Moscow. - M., 2009. - pp. 171-173.

25. Bogdan, V. G. Morphological and clinical features of the use of endoprostheses in surgery of postoperative abdominal hernias / V. G. Bogdan // Military medicine. - 2015. – No. 2. – pp. 14-17.
26. Bogdan, V. G. Features of tissue response during implantation of surgical nets made of polypropylene and vicryl in the zone of a simulated defect of the anterior abdominal wall in a laboratory animal / V. G. Bogdan, I. A. Shved, Yu. M. Gain // Med. zhurn. – 2011. – No. 4. – pp. 37-42.
27. Bogdan, V. G. Postoperative ventral hernias: modern aspects of pathogenesis / V. G. Bogdan, D. V. Varikash // Military medicine. - 2017. – No. 4. – pp. 78-82.
28. Bogdan, V. G. Modern aspects of reconstructive and reconstructive surgery of postoperative abdominal hernias / V. G. Bogdan, Yu. M. Gain. – Minsk: BelMAPO, 2017. – 233 p.
29. Botezatu, A. A. Abdominoplasty in herniation of large and giant recurrent median hernias / A. A. Botezatu, R. I. Raileanu // Moscow Surgical Journal. – 2011. – No. 6. – pp. 14-17.
30. Botezatu, A. A. Reconstruction of the abdominal wall in hernioplasty of large and giant, recurrent median hernias / A. A. Botezatu // Bulletin of the Peoples' Friendship University of Russia. – Medicine. - 2013. – No. 1. – pp. 58-63.
31. Bulkina, N. V. Biological reactions of the body to bioimplants. Review / N. V. Bulkina [et al.] // Klin. dentistry. - 2016. – No. 2. – pp. 46-49.
32. Vereshchagin, D. M. Dynamics of the wound process in plastic surgery of postoperative hernias with an endoprosthesis : diss. ... Candidate of Medical Sciences : 14.00.27 / Dmitry Mikhailovich Vereshchagin. – Moscow, 2009. – 153 p.
33. Vinnik, Yu. S. Surgical treatment of hernias of the anterior abdominal wall / Yu. S. Vinnik [et al.]. – Krasnoyarsk. – 2011. – 260 p.

34. Vinnik, Yu. S. Modern view on the problem of treatment of patients with postoperative ventral hernias / Yu. S. Vinnik, A. A. Chaikin, Yu. A. Nazariants, S. I. Petrushko // Siberian Medical Review. – 2014. – № 6 (90). – pp. 5-14.

35. Vinogradov, A. A. Clinical and morphological characteristics of recurrence cases after alloplasty of postoperative ventral hernias / A. A. Vinogradov [et al.] // Acta Biomedica Scientifica. – 2010. – No. 3. – pp. 40-42.

36. Vlasov, A.V. The problem of wound complications in endoprosthetics of the abdominal wall for ventral hernias / A.V. Vlasov, M. V. Kukosh // Modern technologies in medicine. – 2013. – № 5 (2). – pp. 116-124.

37. Voskresensky, N. V. Surgery of abdominal wall hernias / N. V. Voskresensky, S. L. Gorelik. – M: Medicine, 1965. – 201 p.

38. Gogia, B. S. Morphofunctional aspects of recurrence of postoperative ventral hernias / B. S. Gogia [et al.] // Surgery. - 2016. – No. 12. – pp. 55-60.

39. Gorsky, V. A. The option of using a collagen plate for ventral hernias / V. A. Gorsky, A. S. Sivkov, M. D. Polivoda, A.V. Volenko, B. E. Titkov, G. V. Khachatryan, S. O. Shadsky // Practical medicine. – 2016. – 5 (97). – pp. 67-72.

40. Gostevskoy, A. A. Unresolved issues of prosthetics of the anterior abdominal wall in hernias / A. A. Gostevskoy // Bulletin of Surgery. - 2007. – Vol. 166. – No. 4. – pp. 114-117.

41. Gostevskoy, A. A. Postoperative ventral hernias / A. A. Gostevskoy. – M.: Moscow News Agency, 2008. – 129 p.

42. Darwin, V. V. Features of surgical tactics in patients with large and giant postoperative hernias / V. V. Darwin, N. A. Barbashinov, E. V. Bubovich // Proceedings of the IX scientific conference "Topical issues of herniology". - 2012. – pp. 69-71.

43. Degovtsov, E. N. Diagnosis and treatment of seroma after hernioplasty of the anterior abdominal wall using a mesh implant / E. N. Degovtsov, P. V. Kolyadko // Surgery. The magazine named after N. I. Pirogov. - 2018. – No. 1. – pp. 99-102. – DOI: 10.17116/hirurgia2018199-102.

44. Dibirov, M. D. Hernioplasty for ventral hernias in the elderly and senile age / M. D. Dibirov, I. A. Polyakov, A. A. Huseynov, M. I. Izmailov // Bulletin of the Dagestan State Medical Academy. – 2016. – No. 2. – pp. 49-55.
45. Dobrovolsky, S. R. Features of rehabilitation of patients after surgical treatment of postoperative ventral hernias / S. R. Dobrovolsky [et al.] // Moscow. surgeon. journal. – 2010. – No. 5. – pp. 38-42.
46. Egiev, V. N. Non-tensioning hernioplasty / V. N. Egiev [et al.] ; under the general editorship of V. N. Egiev. – M.: Medpraktika-M, 2002. – 148 p.
47. Egiev, V. N. The first results of the clinical application of "reinforced" polypropylene nets in the treatment of abdominal wall hernias / V. N. Egiev, D. V. Chizhov // Moscow. surgeon. journal. – 2013. – No. 3. – pp. 39-41.
48. Egiev, V. N. Comparison of the results of abdominal wall plastic surgery with "heavy" and "light" polypropylene endoprostheses in the treatment of postoperative ventral hernias / V. N. Egiev, S. N. Shurygin, D. V. Chizhov // Moscow. surgeon. journal. – 2012. – No. 2. – pp. 20-23.
49. Egiev, V. N. Comparative evaluation of materials for intra-abdominal plasty of ventral hernias: an experimental study / V. N. Egiev, V. K. Lyadov, S. Yu. Bogomazov // Surgery. - 2010. – No. 10. – pp. 36-40.
50. Egiev, V. N. Studying the dynamics of the tissue reaction of the anterior abdominal wall of animals to implantation of polypropylene and polytetrafluoroethylene nets / V. N. Egiev, G. P. Titova, S. N. Shurygin [et al.] // Herniology. - 2004. – No. 1. – pp. 31-33.
51. Ermolov, A. S. Morphology of synthetic mesh integration in abdominal wall plastic surgery for postoperative ventral hernia. Clinical research / A. S. Ermolov [et al.] // Materials of the XI conference "Topical issues of herniology". – M., 2014. – pp. 51-53.
52. Zhebrovsky, V. V. Atlas of operations for abdominal hernias / V. V. Zhebrovsky, F. N. Ilchenko. – Simferopol, 2004. – 315 p.
53. Zhukovsky, V. A. Polymer implants for reconstructive surgery / V. A. Zhukovsky // Innova. – 2016. – № 2 (3). – pp. 51-59.
54. Zhukovsky, V. A. Polymer endoprostheses for hernioplasty / V. A. Zhukovsky. St. Petersburg: Aesculapius Publishing House, 2011. – 98 p.

55. Zhukovsky, V. A. Polymer endoprostheses for hernioplasty: preparation, properties, possibilities of improvement / V. A. Zhukovsky // Vestn. surgeon named after I. I. Grekov. - 2011. – Vol. 170. – No. 2. – pp. 82-87.
56. Zhukovsky, V. A. Modern trends and approaches to the development of polymer endoprostheses for hernioplasty / V. A. Zhukovsky // Vestn. surgeon. – 2011. – vol. 170. – No. 1. – pp. 102-105.
57. Ivanov, I. S. Cytokine monitoring in a comparative clinical assessment of the use of synthetic endoprostheses in patients with hernias of the anterior abdominal wall / I.S. Ivanov [et al.] // Kursk. scientific and practical. vestn. "Man and his health." - 2008. – No. 4. – pp. 45-53.
58. Ivanov, S. V. Immunomorphological reaction of the body during prosthetics of the anterior abdominal wall using polypropylene mesh in patients with postoperative abdominal wall hernia / S. V. Ivanov [et al.] // Klin. surgery. - 2009. – No. 2. – pp. 22-24.
59. Ivanov, S. V. Investigation of cytokines in patients with postoperative ventral hernias during endoprosthetics with polytetrafluoroethylene and polyvinylidene fluoride / S. V. Ivanov [et al.] // News of surgery. - 2011. – Vol. 19. – No. 4. – pp. 42-47.
60. Ivanov, S. V. Comparative morphology of tissues when using prostheses made of polypropylene and polyvinylidene fluoride / S. V. Ivanov [et al.] // Cytology. – 2012. – vol. 54. – No. 2. – pp. 158-164.
61. Kim, V. Yu. Hernioplasty with an autodermal flap in recurrent and postoperative hernias / V. Yu. Kim, V. V. Volkov, E. S. Kashurov // Surgery. - 2001. – No. 8. – pp. 37-40.
62. Kiriyenko, A. I. Prevalence of hernias of the anterior abdominal wall: results of a population study / A. I. Kiriyenko, Yu. N. Shevtsov, A. S. Nikishkov [et al.] // Surgery. - 2016. – No. 8. – pp. 61-66. – DOI: 10.17116/hirurgia2016861-66.
63. Krayushkina, N. G. Planimetric changes in lymph nodes of laboratory animals under the influence of an alternating electromagnetic field of industrial frequency / N. G. Krayushkina, L. I. Alexandrova, V. L. Zagrebin, A. A. Nesterova, N. A. Muraeva // Bulletin of the Volgograd State Medical University. – 2012. – № 3 (43). – pp. 104-107.
64. Krymov, A. P. The doctrine of hernias. – Leningrad: Practical medicine, 1929. – 551 p.

65. Kuzin, N. M. Modern methods of treatment of inguinal hernias / N. M. Kuzin, K. D. Dalgatov // Bulletin of surgery. - 2002. – Vol. 161. – No. 5. – pp. 107-110.

66. Lavreshin, P. M. Optimization of treatment of patients with postoperative ventral hernias / P. M. Lavreshin, V. K. Gobedzhishvili, O. V. Vladimirova // Medical Bulletin of the South of Russia. - 2014. – No. 4. – pp. 69-73.

67. Lazarenko, V. A. Architectonics of collagen fibers in the skin and aponeurosis in patients with ventral hernias and without hernia disease / V. A. Lazarenko [et al.] // Kursk. scientific and practical. vestn. "Man and his health." - 2014. – No. 2. – pp. 41-45.

68. Lazarenko, V. A. The role of exogenous embryonic fibroblasts in the process of collagen formation during implantation of a synthetic prosthesis in an experiment / V. A. Lazarenko [et al.] // Kursk. scientific and practical. vestn. "Man and his health." – 2012. – No. 3. – pp. 23-29.

69. Lazarenko V. A. The ratio of collagen types in the prognosis of postoperative ventral hernias / V. A. Lazarenko, S. V. Ivanov, I. S. Ivanov, E. P. Rozberg, A.V. Tsukanov, L. P. Popova, D. V. Tarabrin, E. G. Obedkov // Surgery. The magazine named after N. I. Pirogov. - 2017. – No. 6. – pp. 33-36. – DOI: 10.17116/hirurgia2017633-36.

70. Lutsevich, O. E. Evolution of prosthetic materials in the treatment of inguinal hernias / O. E. Lutsevich [et al.] // Moscow. surgeon. journal. – 2014. – №. 2. – pp. 60-66.

71. Makarov, S. A. The place of laparoscopic IPOM surgery in the surgical treatment of median ventral hernias – lessons from seven years of prospective experience. Perioperative and early postoperative results / S. A. Makarov, V. P. Armashov, A.M. Belousov, A. S. Kupriyanova, N. L. Matveev // Endoscopic surgery. - 2022. – Vol. 28. – No. 2. – pp. 5-15. – DOI: 10.17116/endoskop2022280215.

72. Makarov, S. A. The place of laparoscopic IPOM surgery in the surgical treatment of median ventral hernias: lessons from seven years of prospective experience. Long-term results / S. A. Makarov, V. P. Armashov, A.M. Belousov, A. S. Kupriyanova, N. L. Matveev // Endoscopic surgery. - 2022. – Volume 28. – No. 3. – pp. 22-31. – DOI: 10.17116/endoskop20222803122.

73. Mammadov, R. A. Morphological assessment of the local reaction of the body when using mesh materials for prosthetics of the anterior abdominal wall / R. A. Mammadov // News of surgery. - 2013. – No. 1. – pp. 23-28.

74. Matveev, N. L. Minimally invasive technologies in herniology: it is impossible to save money / N. L. Matveev, A.M. Belousov, V. A. Bochkar, S. A. Makarov // Surgery. The magazine named after N. I. Pirogov. - 2020. – No. 8. – pp. 75-81. – DOI: 10.17116/hirurgia202008175.

75. Matveev, N. L. Critical review of modern means and methods of implant fixation in minimally invasive herniology / N. L. Matveev, S. A. Makarov, A. S. Kupriyanova, V. P. Armashov // Bulletin of the Medical Institute "REAVIS". Rehabilitation, Doctor and Health. - 2020. – No. 6. – pp. 55-65. – DOI: 10.20340/vmi-rvz.2020.6.7.

76. Melekhov, V. V. Investigation of the structure of a collagen matrix based on type 1 collagen by atomic force microscopy under various ionic conditions / V. V. Melekhov [et al.] // Technologies of living systems. – 2015. – vol. 12. – No. 4. – pp. 41-45.

77. Mishina, E. S. Reactive changes in the connective tissue of the anterior abdominal wall in the early postoperative period when using experimental samples of mesh endoprostheses with antibacterial coating / E. S. Mishina, M. A. Zatolokina, A. A. Netyaga, L. G. Klimova, V. A. Zhukovsky // Modern problems of science and education. – 2015. – № 2 (1). – P. 55.

78. Moshkova, T. A. Alloplasty of median ventral hernias with polypropylene nets / T. A. Moshkova // Vestn. surgery named after I. I. Grekov. - 2008. – vol. 167. – No. 4. – pp. 36-39.

79. Naumov, B. A. Morphological assessment of wound healing in various methods of plasty of anterior abdominal wall defects in experimental animals and herniation with prosthetic reconstructive plastic surgery in patients with impaired postoperative ventral hernias using fibrin glue / B.A. Naumov [et al.] // Annals of Surgery. - 2010. – No. 4. – pp. 37-45.

80. Netyaga, A. A. Lightweight or composite endoprostheses for hernioplasty; the choice of material based on the experimental study of their biocompatible properties / A. A. Netyaga [et al.] // Modern problems of science and education. - 2013. – No. 5. – p. 83.

81. Netyaga, A. A. Comparative experimental study of biomechanical properties of standard, lightweight and composite endoprostheses for abdominal wall plastic surgery after their implantation / A. A. Netyaga, A. O. Parfenov, V. A. Zhukovsky // Fundamental research. – 2013. – № 9–5. – P. 875–880.

82. Novikov, S. V. History of surgery of ventral hernias / S. V. Novikov // Surgery. Eastern Europe. – 2012. – № 4 (04). – pp. 104-110.

83. Pavelets, K. V. Features of preoperative preparation in patients with extensive and giant postoperative ventral hernias / K. V. Pavelets [et al.] // Bulletin of the I. I. Mechnikov Northwestern State Medical University. – 2011. – vol. 3. – No. 2. – pp. 32-36.

84. Parfenov, I. P. Biocompatibility of synthetic materials used in surgery of hernias of the anterior abdominal wall / I. P. Parfenov [et al.] // Scientific Bulletin of the Belarusian State University. Ser. Medicine. – 2010. – No. 22. – Issue. 12. – pp. 5-13.

85. Parshikov, V. V. Atension plastic: the current state of the issue, problems and prospects / V. V. Parshikov [et al.] // Vestn. Let's experiment. and a wedge. surgeon. – 2011. – vol. 4. – No. 3. – pp. 612-618.

86. Parshikov, V. V. Non-tensioning intraperitoneal plastic using an adhesive composition / V.V. Parshikov [et al.] // Bulletin of experimental and clinical surgery. – 2012. – № 5 (1). – pp. 76-79.

87. Podoluzhny, V. I. Chronic seromas in the supraponeurotic location of the prosthesis in patients with abdominal hernias / V. I. Podoluzhny, A. B. Karmadonov, A. A. Perminov // Bulletin of herniology. – 2006. – No. 2. – pp. 155-157.

88. Prokunin, A. P. On the anatomy and root treatment of femoral hernia: dis. on the step. Dr. med. / [Op.] A. Prokunin; (From the Institute of Topological Anatomy and Surgery. surgery Moscow. un-ta). – Moscow: Typo-lit. G. I. Prostakov, 1900. – 78 p.

89. Protasov, A.V. The influence of the implant material in inguinal hernioplasty on the reproductive function of men / A.V. Protasov, I. V. Vinogradov, A.V. Blokhin // Materials of the 9th All-Russian Conference "Topical issues of herniology". – M., 2012. – pp. 175-176.

90. Romanov, R. V. The current state of the problem of intraperitoneal abdominal wall plastic surgery with synthetic endoprostheses / R. V. Romanov [et al.] // Modern technologies in medicine. – 2012. – No. 4. – pp. 161-170.
91. Rutenburg, G. M. The choice of the hernioplasty method for various types of inguinal hernias / G. M. Rutenburg, A. B. Samoilov, A. N. Ovchinnikov // Herniology. - 2005. – No. 1. – pp. 3-7.
92. Sarbayeva, N. N. Activation of rat peritoneal macrophages on the surface of endoprostheses used for hernioplasty / N. N. Sarbayeva, Yu. V. Ponomareva, L. T. Volova // Technologies of living systems. - 2013. – Vol. 10. – No. 8. – pp. 84-90.
93. Sedov, V. M. Mesh implants made of polyvinylidene fluoride in the treatment of abdominal wall hernias / V. M. Sedov, A. A. Gostevskoy, S. D. Tarbaev [et al.] // Bulletin of Surgery named after I. I. Grekov. – 2008. – № 167 (2). – pp. 16-21.
94. Serov, V. V. Inflammation: a guide for doctors / V. V. Serov, V. S. Paukov. – M.: Medicine, 1995. – 640 p.
95. Sinenchenko, G. I. Postoperative hernias of the anterior abdominal wall and their surgical treatment / G. I. Sinenchenko [et al.]. – St. Petersburg: Albi-SPb. - 2009. – 176 p.
96. Sinchenko G. I. The choice of a method for plasty of the anterior abdominal wall in patients with postoperative ventral hernias / G. I. Sinchenko, I. V. Gaivoronsky, A. A. Kurygin // Bulletin of surgery. - 2005. – No. 6. – pp. 29-33.
97. Slavin, L. E. The influence of the alloplasty method on the results of treatment of postoperative ventral hernias / L. E. Slavin [et al.] // Bulletin of Herniology. - 2006. – No. 2. – pp. 171-176.
98. Slavin, L. E. Complications of abdominal hernia surgery / L. E. Slavin, I. V. Fedorov, E. I. Segal. – M.: Profile, 2005. – 176 p.
99. Smirnov, A.D. Tissue reaction to antimicrobial suture materials / A.D. Smirnov, Y. K. Krauklis, L. L. Plotkin // Military Medical Journal. - 1976. – No. 12. – pp. 68-69.
100. Sovtsov, S. A. Laparoscopic prosthetic hernioplasty of external abdominal hernias / S. A. Sovtsov, A. N. Pryakhin, O. B. Milyaeva // Annals of Surgery. - 2008. – No. 2. – pp. 50-52.

101. Sonis A. G. Prevention and treatment of infectious wound complications in prosthetic hernias / A. G. Sonis, B. D. Grachev, E. A. Stolyarov, I. V. Ishutov // Wounds and wound infections. The journal named after prof. B. M. Kostyuchenka. – 2014. – № 1(2). – pp. 16-23. – DOI: 10.25199/2408-9613-2014-1-2-16-23.

102. Styazhkina, S. N. Manifestations of connective tissue dysplasia in surgical practice / S. N. Styazhkina [et al.] // Health, demography, ecology of finno-the Ugric peoples. - 2012. – No. 2. – pp. 77-80.

103. Sukovatykh, B. S. Prevention of postoperative ventral hernias: the current state of the problem / B. S. Sukovatykh, N. M. Valuyskaya, N. V. Pravodnikova, E. V. Gerasimchuk, T. V. Mutova // Surgery. - 2016. – No. 3. – pp. 76-80.

104. Sukovatykh, B. S. Modern technologies for the prevention of postoperative adhesions / B. S. Sukovatykh, V. A. Zhukovsky, V. A. Lipatov, Yu. Yu. Blinkov // Bulletin of Surgery named after I. I. Grekov. – 2014. – № 173 (5). – pp. 98-104. – DOI: 10.24884/0042-4625-2014-173-5-98-104.

105. Surkov, N. A. Features of reparative processes of the anterior abdominal wall in the zone of implantation of a prolene mesh in an experiment / N. A. Surkov [et al.] // Annals of plastic, reconstructive and aesthetic surgery. - 2002. – No. 1. – pp. 52-61.

106. Tarasova, N. K. Analysis of the causes of recurrence of postoperative ventral hernias / N. K. Tarasova, S. M. Dynkov, V. N. Pozdeev, A. Yu. Teterin, G. Sh. Osmanova // Surgery. The magazine named after N. I. Pirogov. – 2019. – No. 10. – pp. 36-42. – DOI: 10.17116/hirurgia201910136.

107. Tarasova, N. K. Prevention of complications in the early postoperative period and recurrence in the treatment of patients with postoperative ventral hernias / N. K. Tarasova, S. M. Dynkov, A. Yu. Teterin, A. A. Kuznetsov // Annals of Surgery. - 2012. – No. 6. – P. 26-30.

108. Titova, E. V. Experimental and clinical substantiation of xenoplasty of ventral hernias: abstract. ... candidate of Medical Sciences : 14.01.17 / Titova Ekaterina Valeryevna. – Saransk, 2013. – 18 p.

109. Tkachenko, A. N. Prognosis and prevention of purulent complications in the treatment of postoperative ventral hernias: abstract of the dissertation of the Candidate of

Medical Sciences : 14.00.27 / Tkachenko Alexander Nikolaevich. – St. Petersburg, 1999. – 20 p.

110. Trisvetova, E. L. Strategy and tactics of treatment of patients with hereditary connective tissue disorders / E. L. Trisvetova // International reviews: clinical practice and health. – 2015. – № 2 (14). – pp. 80-92.

111. Fedoseev, A.V. Assessment of factors influencing the choice of surgical intervention in patients with hernias of the anterior abdominal wall / A.V. Fedoseev [et al.] // Vestn. Let's experiment. and the clinic. surgery. - 2011. – Vol. 4. – No. 2. – pp. 22-32.

112. Tsverov, I. A. Surgical treatment of patients with ventral hernias: current state / I. A. Tsverov, A.V. Bazaev // Sovrem. technologies in medicine. - 2010. – No. 4. – pp. 122-127.

113. Cherednikov, E. F. Results of the use of noninvasive assessment of intra-abdominal pressure in the surgical treatment of patients with postoperative median reversible hernias / E.F. Cherednikov [et al.] // System analysis and management in biomedical systems. - 2017. – Vol. 16. – No. 2. – pp. 328-334.

114. Yartsev, P. A. Complication of laparoscopic hernioplasty in ventral hernia / P. A. Yartsev, G. V. Pakhomova, I. E. Selina, M. V. Radygina, A.V. Zhiganov // Surgery. The magazine named after N. I. Pirogov. - 2010. – 8. – pp. 54-56.

115. Ah-Kee, E.Y. Patient awareness and symptoms from an incisional hernia / E.Y. Ah-Kee, T. Kallachil, P. J. O'Dwyer // International Surgery – 2014. – Vol. 99. – No. 3. – P. 241–246. – DOI: 10.9738/INTSURG-D-14-00039.1.

116. Al Chalabi, H. A systematic review of laparoscopic versus open abdominal incisional hernia repair, with meta-analysis of randomized controlled trials / H. Al Chalabi, J. Larkin, B. Mehigan, P. McCormick // Int J Surg. – 2015. – No. 20. – P. 65–74. – DOI: 10.1016/j.ijsu.2015.05.050.

117. Alessi, M.-C. Metabolic syndrome, haemostasis and thrombosis / M.-C. Alessi, I. Juhan-Vague // Thromb Haemost. – 2008. – Vol. 99. – No. 6. – P. 995–1000. – DOI: 10.1160/TH07-11-0682.

118. Amid, P. K. Long-term result and current status of the Lichtenstein open tension-free hernioplasty / P. K. Amid, I. L. Lichtenstein // Hernia. – 1998. – No. 2. – P. 89–94. – DOI: 10.1007/BF01207492.

119. Amid, P. K. Classification of biomaterials and their related complications in abdominal wall hernia surgery / P. K. Amid // Hernia. – 1997. – Vol. 1. – No. 1. – P. 15–21. – DOI: 10.1007/BF02426382.

120. Anderson, J. M. Foreign body reaction to biomaterials / J. M. Anderson, A. Rodriguez, D. T. Chang // Semin Immunol. –2008. – Vol. 20. – No. 2. – P. 86–100. DOI: 10.1016/j.smim.2007.11.004.

121. Antoniou, S. A. Meta-analysis of randomized trials comparing nonpenetrating vs mechanical mesh fixation in laparoscopic inguinal hernia repair / S. A. Antoniou, G. Köhler, G. A. Antoniou, F. E. Muysoms, R. Pointner, F.-A. Granderath // Am J Surg. – 2016. – Vol. 211. – No. 1. – P. 239–249. – DOI: 10.1016/j.amjsurg.2015.06.008.

122. Aquaviva, D. Considerations sur l'emploi des plaques de nylon Crinoplaques comme materiel de plastie parietale / D. Aquaviva, P. Bourret, F. Corti // Congrés Français de Chirurgie, 52éme Session. – Paris: Masson, 1949. – P. 453-457.

123. Aref-Adib, M. Preventing adhesions in laparoscopic surgery: the role of anti-adhesion agents / M. Aref-Adib, T. Phan, A. Ades // The Obstetrician & Gynaecologist. – 2019. – Vol. 21. – No. 3. – P. 185–192. – DOI: 10.1111/tog.12588.

124. Arish, H. A study to compare outcomes in patients undergoing intraperitoneal onlay meshplus and eTEP repair for ventral wall and incisional hernia / H. Arish, F. A. Masudi // Int Surg J. – 2023. – No. 10. – P. 1642-1646. –DOI: 10.18203/2349-2902.isj20232988.

125. Arita, N. A. Laparoscopic repair reduces incidence of surgical site infections for all ventral hernias / N. A. Arita, M. T. Nguyen, D. H. Nguyen, R. L. Berger, D. F. Lew, J. T. Suliburk, E. P. Askenasy, L. S. Kao, M. K. Liang // Surg Endosc. – 2015. – Vol. 29. – No. 7. – P. 1769–1780. – DOI: 10.1007/s00464-014-3859-1.

126. Arregui, M. E. Laparoscopic mesh repair of inguinal hernia using a preperitoneal approach: a preliminary report / M. E. Arregui, C. J. Davis, O. Yucel, R. F. Nagan // Surg Laparosc Endosc. – 1992. – Vol. 2. – No. 1. – P. 53–58.

127. Audebert, A. J. Role of microlaparoscopy in the diagnosis of peritoneal and visceral adhesions and in the prevention of bowel injury associated with blind trocar insertion / A. J. Audebert, V. Gomel // Fertil Steril. – 2000. – Vol. 73. – No. 3. – P. 631–635. – DOI: 10.1016/s0015-0282(99)00555-5.

128. Awaiz, A. Meta-analysis and systematic review of laparoscopic versus open mesh repair for elective incisional hernia / A. Awaiz, F. Rahman, M. B. Hossain, R. M. Yunus, S. Khan, B. Memon, M. A. Memon // Hernia. – 2015. – Vol. 19. – No. 3. – P. 449–463. – DOI: 10.1007/s10029-015-1351-z.

129. Bageacu, S. Laparoscopic repair of incisional hernia: a retrospective study of 159 patients / S. Bageacu, P. Blanc, C. Breton, M. Gonzales, J. Porcheron, M. Chabert, J. G. Balique // Surg Endosc. – 2002. – Vol. 16. – No. 2. – P. 345–348. – DOI: 10.1007/s00464-001-0018-2.

130. Bagul, A. G. Mesh migration causing strangulated intestinal obstruction after umbilical hernia repair / A.G. Bagul, M. Bendre // JMSCR. – 2015. – Vol. 3. – № 1. – P. 3986–3989.

131. Bansal, V. K. A prospective randomized study comparing suture mesh fixation versus tacker mesh fixation for laparoscopic repair of incisional and ventral hernias / V. K. Bansal, M. C. Misra, S. Kumar, Y. K. Rao, P. Singhal, A. Goswami [et al.] // Surg Endosc. – 2011. – Vol. 25. – No. 5. – P. 1431–1438. – DOI: 10.1007/s00464-010-1410-6

132. Barbaros, U. The comparison of laparoscopic and open ventral hernia repairs: a prospective randomized study / U. Barbaros, O. Asoglu, R. Seven, Y. Erbil, A. Dinccag, U. Deveci, S. Mercan // Hernia. – 2007. – Vol. 11. – No. 1. – P. 51–56. – DOI: 10.1007/s10029-006-0160-9

133. Bedi, A. P. Laparoscopic incisional and ventral hernia repair / A. P. Bedi, T. Bhatti, A. Amin, J. Zuberi // J Minim Access Surg. – 2007. – Vol. 3. – No. 3. – P. 83–90. – DOI: 10.4103/0972-9941.37190.

134. Beets, G. L. Foreign body reactions to monofilament and braided polypropylene mesh used as preperitoneal implants in pigs / G. L. Beets, P. M. Go, H. van Mameren // Eur J Surg. – 1996. –Vol. 162. – No. 10. – P. 823–825.

135. Beldi, G. Mesh shrinkage and pain in laparoscopic ventral hernia repair: a randomized clinical trial comparing suture versus tack mesh fixation / G. Beldi, M. Wagner, L. E. Bruegger, A. Kurmann, D. Candinas // Surg Endosc. – 2011. – Vol. 25. – No. 3. – P. 749–755. – DOI: 10.1007/s00464-010-1246-0.

136. Bellido Luque, J. A. Safety and effectiveness of self-adhesive mesh in laparoscopic ventral hernia repair using transabdominal preperitoneal route / J. A. Bellido Luque, A. Bellido Luque, J. Gomez Menchero, J. M. Suarez Grau, J. García Moreno, A. Tejada Gomez, J. Guadalajara Jurado // Surg Endosc. – 2017. – Vol. 31. – No. 3. – P. 1213–1218. – DOI: 10.1007/s00464-016-5094-4.

137. Bellón, J. M. In vitro mesothelialization of prosthetic materials designed for the repair of abdominal wall defects / J. M. Bellón, N. García-Honduvilla, R. López, C. Corrales, F. Jurado, J. Buján // J Mater Sci Mater Med. – 2003. – Vol. 14. – No. 4. – 359–364. – DOI: 10.1023/a:1022936016618.

138. Bellows, C. F. Repair of incisional hernias with biological prosthesis: a systematic review of current evidence / C. F. Bellows, A. Smith, J. Malsbury, W. S. Helton // Am J Surg. – 2013. – Vol. 205. – No. 1. – P. 85–101. – DOI: 10.1016/j.amjsurg.2012.02.019.

139. Belyansky, I. A novel approach using the enhanced-view totally extraperitoneal (eTEP) technique for laparoscopic retromuscular hernia repair / I. Belyansky, J. Daes, V. G. Radu, R. Balasubramanian, H. Reza Zahiri, A. S. Weltz, U. S. Sibia, A. Park, Y. Novitsky // Surg Endosc. – 2018. – Vol. 32. – No. 3. – P. 1525–1532. – DOI: 10.1007/s00464-017-5840-2.

140. Benhidjeb, T. Versorgung von narbenhernien: sublay- oder intra-peritoneale onlay-mesh (IPOM)-technik? / T. Benhidjeb, C. Benecke, M. Strik // Zentralbl Chir. – 2008. – Vol. 133. – No. 5. – P. 458–463. –DOI: 10.1055/s-2008-1076954.

141. Berger D. Postoperative complications after laparoscopic incisional hernia repair. Incidence and treatment / D. Berger, M. Bientzle, A. Müller // Surg Endosc. – 2002. – Vol. 16. – No. 12. – P. 1720–1723. – DOI: 10.1007/s00464-002-9036-y

142. Berger, D. Laparoskopische IPOM-Technik [Laparoscopic IPOM technique] / D. Berger // Chirurg. – 2010. – Vol. 81. – No. 3. – P. 211 – 215. – DOI: 10.1007/s00104-009-1819-4. (in German).

143. Berger, R. L. Development and validation of a risk-stratification score for surgical site occurrence and surgical site infection after open ventral hernia repair / R. L. Berger, L. T. Li, S. C. Hicks, J. A. Davila, L. S. Kao, M. K. Liang // J Am Coll Surg. – 2013. – Vol. 217. – No. 6. – P. 974–982. – DOI: 10.1016/j.jamcollsurg.2013.08.003.

144. Bezsilla, J. Hasfali sérvek laparoscopos műtéti technikája [Laparoscopic repair of abdominal wall hernias] / J. Bezsilla // Magy Seb. – 2010. – Vol. 63. –No. 5. – P. 327–332. – DOI: 10.1556/MaSeb.63.2010.5.6 (in Hungarian).

145. Binnebösel, M. Biocompatibility of prosthetic meshes in abdominal surgery / M. Binnebösel, K. T. von Trotha, P. L. Jansen, J. Conze, U. P. Neumann, K. Junge // Semin Immunopathol. – 2011. – Vol. 33. – No. 3. – P. 235–243. – DOI: 10.1007/s00281-010-0237-5.

146. Binnebösel M. Biocompatibility of prosthetic meshes in abdominal surgery / M. Binnebösel [et al.] // Semin. Immunopathol. – 2011. – Vol. 33. – № 3. – P. 235–243.

147. Biondo-Simões, M. de L. P. Adhesions on polypropylene versus Sepramesh® meshes: an experimental study in rats / M. de L. P. Biondo-Simões, V. C. de A. Pessini, P. H. C. Porto, R. R. Robes // Rev Col Bras Cir. – 2018. – Vol. 45. – No. 6. – DOI: 10.1590/0100-6991e-20182040

148. Biondo-Simões M. L. P. Comparative study of polyglactin 910 and simple catgut in the formation of intraperitoneal adhesions / M. L. P. Biondo-Simões, M. H. Oda, S. Pasqual, R. R. Robes // Acta Cir Bras. – 2018. – Vol. 33. – No. 2. – P. 102–109. – DOI: 10.1590/s0102-865020180020000001.

149. Bisgaard, T. A nationwide study on readmission, morbidity, and mortality after umbilical and epigastric hernia repair / T. Bisgaard, H. Kehlet, M. Bay-Nielsen, M. G. Iversen, J. Rosenberg, L. N. Jørgensen // Hernia. – 2011. – Vol. 15. – No. 5. – P. 541–546. – DOI: 10.1007/s10029-011-0823-z.

150. Bisgaard, T. A nationwide study on readmission, morbidity, and mortality after umbilical and epigastric hernia repair / T. Bisgaard, H. Kehlet, M. Bay-Nielsen [et al.] // Hernia. – 2011. – Vol. 15. – № 5. – P. 541–546. – DOI 10.1007/s10029-011- 0823-z.

151. Bittner, R. Update of Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS))-Part A / R.

Bittner, K. Bain, V. K. Bansal, F. Berrevoet [et al] // Surg Endosc. – 2019. – Vol. 33. – No. 10. – P. 3069–3139. – DOI: 10.1007/s00464-019-06907-7.

152. Bittner, R. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS])-Part III / R. Bittner, J. Bingener-Casey, U. Dietz, M. Fabian [et al.] // Surg Endosc. –2014. – Vol. 28. – No. 2. – P. 380–404. – DOI: 10.1007/s00464-013-3172-4.

153. Bittner, R. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)-part 1 / R. Bittner, J. Bingener-Casey, U. Dietz, M. Fabian [et al.] // Surg Endosc. –2014. –Vol. 28. – No. 1. – P. 2–29. – DOI: 10.1007/s00464-013-3170-6.

154. Bittner, R. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS]) – Part 2 / R. Bittner, J. Bingener-Casey, U. Dietz, M. Fabian [et al.] // Surg Endosc. – 2014. – Vol. 28. – No. 2. – P. 353–379. – DOI: 10.1007/s00464-013-3171-5.

155. Bolton, M. A. Measuring outcomes in plastic surgery: body image and quality of life in abdominoplasty patients / M. A. Bolton, T. Pruzinsky, T. F. Cash, J. A. Persing // Plast Reconstr Surg. – 2003. – Vol. 112. – No. 2. – P. 619–625. – DOI: 10.1097/01.PRS.0000070972.57000.08.

156. Borrazzo, E. C. Effect of prosthetic material on adhesion formation after laparoscopic ventral hernia repair in a porcine model / E. C. Borrazzo, M. F. Belmont, D. Boffa, D. L. Fowler // Hernia. – 2004. – Vol. 8. – No. 2. – P. 108–112. – DOI: 10.1007/s10029-003-0181-6.

157. Borzellino G. Detection of abdominal adhesions in laparoscopic surgery. A controlled study of 130 cases / G. Borzellino, G. De Manzoni, F. Ricci // Surg Laparosc Endosc. – 1998. – Vol. 8. – No. 4. – P. 273–276.

158. Bower, C. E. Complications of laparoscopic incisional-ventral hernia repair: the experience of a single institution / C. E. Bower, C. C. Reade, L. W. Kirby, J. S. Roth // Surg Endosc. – 2004. – Vol. 18. – No. 4. – P. 672–675. – DOI: 10.1007/s00464-003-8506-1.

159. Burdakov, V. Endoscopic transversus abdominis release in the treatment of midline incisional hernias: a prospective single-center observational study on 100 patients / V. Burdakov, A. Zverev, N. Matveev // Hernia. – 2022. – Vol. 26. – No. 5. – P. 1381–1387. – DOI: 10.1007/s10029-022-02641-7.

160. Burger, J. W. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia / J. W. Burger, R. W. Luijendijk, W. C. Hop, J. A. Halm, E. G. Verdaasdonk, J. Jeekel // Ann Surg. – 2004. – Vol. 240. – No. 4. – P. 578–583. – DOI: 10.1097/01.sla.0000141193.08524.e7.

161. Butler, C. E. Discussion: Anterior versus Posterior Component Separation: Which Is Better? / C. E. Butler // Plast Reconstr Surg. – 2018. – Vol. 142. – No. 3 (suppl). – P. 54S–55S. – DOI: 10.1097/PRS.0000000000004854.

162. Byrd, J. F. Evaluation of absorbable and permanent mesh fixation devices: adhesion formation and mechanical strength / J. F. Byrd, N. Agee, R. Z. Swan, K. N. Lau, J. J. Heath, I. H. Mckillop, D. Sindram, J. B. Martinie, D. A. Iannitti // Hernia. – 2011. – No. 15. – P. 553–558. – DOI: 10.1007/s10029-011-0826-9.

163. Carbonell, A. M. Posterior component separation during retromuscular hernia repair / A. M. Carbonell, W. S. Cobb, S. M. Chen // Hernia 2008. – Vol. 12. – № 4. – P. 359–362.

164. Cassar, K. Surgical treatment of incisional hernia / K. Cassar, A. Munro // Br J Surg. – 2002. – Vol. 89. – No. 5. – P. 534–545. – DOI: 10.1046/j.1365-2168.2002.02083.x.

165. Ceci, F. Chronic anemia due to transmural e-PTFE anti-adhesive barrier mesh migration in the small bowel after open incisional hernia repair: A case report / F. Ceci, L. D'Amore, E. Annesi, L. Bambi, M. R. Grimaldi, F. Gossetti, P. Negro // Int J Surg Case Rep. – 2018. – Vol. 53. – P. 54–57. – DOI: 10.1016/j.ijscr.2018.10.012.

166. Champetier, J. Treatment of postoperative ventral hernia: elementary biochemical basis / J. Champetier [et al.] // J. Chir. – 1978. – Vol. 115. – № 11. – P. 885– 890.

167. Chan, Y. W. Assessment of ideal ratio of mesh area to number of fixation tacks in laparoscopic ventral and incisional IPOM Plus hernia repair / Y. W. Chan, W. Fischer,

C. Pauzenberger, A. Dinnewitzer, C. Hollinsky // Surg Endosc. – 2021. – Vol. 35. – No. 3. – P. 1230–1237. – DOI: 10.1007/s00464-020-07493-9.

168. Chatzimavroudis, G. Evaluation of four mesh fixation methods in an experimental model of ventral hernia repair / G. Chatzimavroudis, S. Kalaitzis, N. Voloudakis, S. Atmatzidis, S. Kapoulas, I. Koutelidakis, B. Papaziogas, E. C. Christoforidis // J. Surg. Res. – 2017. – Vol. 212. – P. 253–259. – DOI: 10.1016/j.jss.2017.01.013.

169. Chelala, E. Eighty-five redo surgeries after 733 laparoscopic treatments for ventral and incisional hernia: adhesion and recurrence analysis / E. Chelala, Y. Debardemaeker, B. Elias, F. Charara, M. Dessily, J-L. Allé // Hernia. – 2010. – 2010. – Vol. 14. – No 2. – P. 123–129. – DOI: 10.1007/s10029-010-0637-4.

170. Chen, Y. The impact of mesh fixation with a collagen-fibrin sealant in a murine ventral hernia model / Y. Chen, K. Eraker-Aasland Hansen, M. Spasojevic, J. M. Naesgaard, D. Ignjatovic // Surg Laparosc Endosc Percutan Tech. – 2014. – Vol. 24. – No. 2. – P. 140–144. – DOI: 10.1097/SLE.0b013e31828fbf5e.

171. Chhabra, R. Transfascial suture hernia: a new complication after laparoscopic ventral hernia repair / R. Chhabra, E. R. Momin, P. Bhagtani, M. Kamat // Indian J Surg. 2021. – DOI: 10.1007/s12262-021-02761-x.

172. Choi, J. J. Use of mesh during ventral hernia repair in clean-contaminated and contaminated cases: outcomes of 33,832 cases / J. J. Choi, N. C. Palaniappa, K. B. Dallas, T. B. Rudich, M. J. Colon, C. M. Divino // Ann Surg. – 2012. – Vol. 255. – No. 1. – P. 176–180. – DOI: 10.1097/SLA.0b013e31822518e6.

173. Christoffersen, M. W. Less postoperative pain and shorter length of stay after robot-assisted retrorectus hernia repair (rRetrorectus) compared with laparoscopic intraperitoneal onlay mesh repair (IPOM) for small or medium-sized ventral hernias / M. W. Christoffersen, L. N. Jørgensen, K. K. Jensen // Surg Endosc. – 2023. – Vol. 37. – No. 2. – 1053–1059. – DOI: 10.1007/s00464-022-09608-w.

174. Chuback, J. A. Small bowel obstruction resulting from mesh plug migration after open inguinal hernia repair / J. A. Chuback, R. S. Singh, C. Sills, L. S. Dick // Surgery. – 2000. – Vol. 127. – No. 4. – P. 475–476. – DOI: 10.1067/msy.2000.104122.

175. Clarke, T. Fibrin glue for intraperitoneal laparoscopic mesh fixation: a comparative study in a swine model / T. Clarke, N. Katkhouda, R. J. Mason, B. C. Cheng, J. Algra, J. Olasky, H. J. Sohn, A. Moazzez, M. Balouch // Surg. Endosc. – 2011. – Vol. 25. – P. 737–748. – DOI: 10.1007/s00464-010-1244-2.

176. Criss, C. N. Functional abdominal wall reconstruction improves core physiology and quality-of-life / C. N. Criss, C. C. Petro, D. M. Krpata, C. M. Seafler, N. Lai, J. Fiutem, Y. W. Novitsky, M. J. Rosen // Surgery. – 2014. – Vol. 156. – № 1. – P. 176–182. – DOI: 10.1016/j.surg.2014.04.010.

177. Cunningham, H. B. Mesh migration following abdominal hernia repair: a comprehensive review / H. B. Cunningham, J. J. Weis, L. R. Taveras, S. Huerta // Hernia. – 2019. – Vol. 23. – No. 2. – P. 235–243. – DOI: 10.1007/s10029-019-01898-9.

178. Dauser, B. A novel glue device for fixation of mesh and peritoneal closure during laparoscopic inguinal hernia repair: short and medium-term results / B. Dauser, A. Szyszkowitz, G. Seitinger, R. H. Fortelny, F. Herbst // Eur Surg. –2017. – Vol. 49. – No. 1. – P. 27–31. – DOI: 10.1007/s10353-016-0450-0.

179. Davila, D. G. Improved immediate postoperative pain following laparoscopic inguinal herniorrhaphy using self-adhering mesh / D.G. Davila [et al.] // Surg. Endosc. – 2018. – Vol. 32. – P. 1160–1164.

180. Davila, D. G. Improved immediate postoperative pain following laparoscopic inguinal herniorrhaphy using self-adhering mesh / D. G. Davila, M. C. Helm, I. S. Pourladian, M. J. Frelich, A. S. Kastenmeier, J. C. Gould, M. I. Goldblatt // Surg Endosc. – 2018. – Vol. 32. – No. 3. – P. 1160–1164. –DOI: 10.1007/s00464-017-5787-3.

181. Davila, D. G. The increased cost of ventral hernia recurrence: a cost analysis / D. G. Davila, N. Parikh, M. J. Frelich, M. I. Goldblatt // Hernia. – 2016. – Vol. 20. – No. 6. – P. 811–817. – DOI: 10.1007/s10029-016-1515-5.

182. De Silva, G. S. Comparative radiographic analysis of changes in the abdominal wall musculature morphology after open posterior component separation or bridging laparoscopic ventral hernia repair / G. S. De Silva, D. M. Krpata, C. W. Hicks, C. N. Criss, Y. Gao, M. J. Rosen, Y. W. Novitsky // J Am Coll Surg. – 2014. – Vol 218. – No. 3. – P. 353–357. – DOI: 10.1016/j.jamcollsurg.2013.11.014.

183. Deeken, C. R. A review of the composition, characteristics, and effectiveness of barrier mesh prostheses utilized for laparoscopic ventral hernia repair / C. R. Deeken, K. M. Faucher, B. D. Matthews // Surg Endosc. – 2012. –Vol. 26. – No. 2. – P. 566–575. – DOI: 10.1007/s00464-011-1899-3.

184. Deeken, C. R. A review of the composition, characteristics, and effectiveness of barrier mesh prostheses utilized for laparoscopic ventral hernia repair / C. R. Deeken, K. M. Faucher, B. D. Matthews // Surgical Endoscopy. – 2012. – № 2 (26) – P. 566–575. – DOI 10.1007/s00464-011-1899-3.

185. Delibegovic, S. Formation of adhesion after intraperitoneal application of TiMesh: experimental study on a rodent model / S. Delibegovic, A. Koluh, E. Cickusic, M. Katica, J. Mustedanagic, F. Krupic // Acta Chirurgica Belgica. –2016. – Vol. 116. – No. 5. – P. 293–300. – DOI: 10.1080/00015458.2016.1179513

186. den Hartog D. Open surgical procedures for incisional hernias / D. den Hartog, A. H. Dur, W. E. Tuinebreijer, R. W. Kreis // Cochrane Database Syst Rev. – 2008. – DOI: 10.1002/14651858.CD006438.pub2.

187. Dey, S. Laparoscopic management of recurrent ventral hernia: an experience of 222 patients / S. Dey, R. Parthasarathi, S. C. Sabnis, R. Jain [et al.] // Hernia. – 2019. – Vol. 23. – No. 5. – P. 927–934. – DOI: 10.1007/s10029-019-01912-0.

188. Diamantis, T. Alterations of hemostasis after laparoscopic and open surgery / T. Diamantis, N. Tsiminikakis, A. Skordylaki, F. Samiotaki [et al.] // Hematology. – 2007. – Vol. 12. – No. 6. – P. 561–570. – DOI: 10.1080/10245330701554623.

189. Diamond, M. P. A model for sidewall adhesions in the rabbit: reduction by an absorbable barrier / M. P. Diamond, C. B. Linsky, T. Cunningham [et al.] // Microsurgery. – 1987. – Vol. 8. – No. 4. – P. 197–200. – DOI: 10.1002/micr.1920080406.

190. Díaz-Pizarro Graf, J. I. Laparoscopic transabdominal preperitoneal approach to place a polypropylene mesh on the abdominal wall: an experimental swine model of a technique that can be used for incisional hernia repair / J. I. Díaz-Pizarro Graf, M. Moreno Portillo, L. E. Cárdenas Lailson, M. E. Ramírez Solís [et al.] // Surg Endosc. – 2005. – Vol. 19. – No. 7. – P. 990–995. – DOI: 10.1007/s00464-003-8291-x.

191. Dilege, E. N-butyl cyanoacrylate versus conventional suturing for fixation of meshes in an incisional hernia model / E. Dilege, U. Deveci, Y. Erbil, A. Dinççağ, Seven R [et al.] // Journal of Investigative Surgery. – 2010. – Vol. 23. – No. 5. – P. 262–266. – DOI: 10.3109/08941939.2010.481008.

192. Dindo D. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey / D. Dindo, N. Demartines, P. A. Clavien // Ann Surg. – 2004. – Vol. 240. – No. 2. – P. 205–213. – DOI: 10.1097/01.sla.0000133083.54934.ae.

193. Duffy, A. J. Comparison of two composite meshes using two fixation devices in a porcine laparoscopic ventral hernia repair model / A. J. Duffy, N. J. Hogle, K. M. LaPerle, D. L. Fowler // Hernia. – 2004. – Vol. 8. – P. 358–364. – DOI: 10.1007/s10029-004-0258-x.

194. Dulucq, J. L. Traitement des hernies de l'aine par la mise en place d'un patch prothétique par laparoscopie. Voie totalement extrapéritonéale. Cah Chir. – 1991. – 79. – 15–16.

195. Earle, D. SAGES guidelines for laparoscopic ventral hernia repair / D. Earle, J. S. Roth, A. Saber, S. Haggerty [et al.] // Surg Endosc. – 2016. –Vol. 30. – No. 8. – P. 3163–3183. – DOI: 10.1007/s00464-016-5072-x.

196. Ecker, B. L. Laparoscopic versus open ventral hernia repair: longitudinal outcomes and cost analysis using statewide claims data / B. L. Ecker, L. E. Kuo, K. D. Simmons, J. P. Fischer [et al.] // Surg Endosc. – 2016. – Vol. 30. – No. 3. – P. 906–915. – DOI: 10.1007/s00464-015-4310-y.

197. Emans, P. J. Polypropylene meshes to prevent abdominal herniation. Can stable coatings prevent adhesions in the long term? / P. J. Emans, M. H. F. Schreinemacher, M. J. J. Gijbels, G. L. Beets [et al.] // Ann Biomed Eng. – 2009. – Vol. 37. – No. 2. – P. 410–418. – DOI: 10.1007/s10439-008-9608-7.

198. Eriksen, J. R. Laparoscopic intraperitoneal mesh fixation with fibrin sealant (Tisseel®) vs. titanium tacks: a randomised controlled experimental study in pigs / J. R. Eriksen, J. I. Bech, D. Linnemann, J. Rosenberg // Hernia. –2008. – Vol. 12. – P. 483–491. – DOI: 10.1007/s10029-008-0375-z.

199. Eriksen, J. R. Randomized clinical trial of fibrin sealant versus titanium tacks for mesh fixation in laparoscopic umbilical hernia repair / J. R. Eriksen, T. Bisgaard, S. Assaadzadeh [et al.] // Br J Surg. – 2011. – Vol. 98. – No. 11. – P. 1537–1545. – DOI: https://doi.org/10.1002/bjs.7646.

200. Eriksen, J. R. Pain, quality of life and recovery after laparoscopic ventral hernia repair / J. R. Eriksen, P. Poornoroozy, L. N. Jørgensen, B. Jacobsen [et // Hernia. – 2009. – Vol. 13. – No. 1. – P. 13–21. – DOI:10.1007/s10029-008-0414-9

201. Farmer, L. Adhesion formation after intraperitoneal and extraperitoneal implantation of polypropylene mesh / L. Farmer, M. Ayoub, D. Warejcka, S. Southerland [et al.] //Am Surg. – 1998. – Vol. 64. – No. 2. – P. 144–146.

202. Faylona, J. M. Evolution of ventral hernia repair / J. M. Faylona // Asian J Endosc Surg. – 2017. – Vol. 10. – No. 3. – 252–258. – DOI: 10.1111/ases.12392.

203. Fernández Lobato, R. Cost-benefit analysis comparing laparoscopic and open ventral hernia repair / R. Fernández Lobato, J. C. Ruiz de Adana Belbel, F. Angulo Morales, J. García Septiem [et al.] // Cir Esp. – 2014. Vol. 92. – No. 8. – P. 553–560. – DOI: 10.1016/j.ciresp.2013.04.012.

204. Fortelny, R. H. Adverse effects of polyvinylidene fluoride-coated polypropylene mesh used for laparoscopic intraperitoneal onlay repair of incisional hernia / R. H. Fortelny, A. H. Petter-Puchner, K. S. Glaser, F. Offner, T. Benesch, M. Rohr // Br J Surg. – 2010. – Vol. 97. – No. 7. – P. 1140–1145. –DOI: 10.1002/bjs.7082.

205. Franklin, M. E Jr. Laparoscopic ventral and incisional hernia repair: an 11-year experience / M. E. Franklin Jr, J. J. Gonzalez, J. L. Glass, A. Manjarrez //Hernia. – 2004. – Vol. 8. – No. 1. – P. 23–27. – DOI: 10.1007/s10029-003-0163-8.

206. Franklin, M. E. Laparoscopic ventral and incisional hernia repair / M. E. Franklin, J. R. Dorman, J. L. Glass, J. E. Balli, J. J. Gonzalez // Surg Laparosc Endosc. – 1998. – Vol. 8. – No. 4. – P. 294–299.

207. Frantzides, C. T. Minimally invasive incisional herniorrhaphy: a review of 208 cases / C. T. Frantzides, M. A. Carlson, J. G. Zografakis, A. K. Madan, R. E. Moore // Surg Endosc. – 2004. – Vol. 18. – No. 10. – P. 1488–1491. – DOI: 10.1007/s00464-004-8105-9.

208. Fuziy, R. A. Comparative study of four different types of intraperitoneal mesh prostheses in rats / R. A. Fuziy, R. Artigiani Neto, E. M. Caetano Junior [et al.] // Acta Cir Bras. – 2019. – Vol. 34. – No. 7. – DOI: 10.1590/s0102-865020190070000003.

209. Gaertner, W. B. Experimental evaluation of four biologic prostheses for ventral hernia repair / W. B. Gaertner, M. E. Bonsack, J. P. Delaney // J Gastrointest Surg. – 2007. – Vol. 11. – No. 10. – P. 1275–1285. – DOI: 10.1007/s11605-007-0242-8

210. Gaertner, W. B. Visceral adhesions to hernia prostheses / W. B. Gaertner, M. E. Bonsack, J. P. Delaney // Hernia. – 2010. – Vol. 14. – No. 4. – P. 375–381. – DOI: 10.1007/s10029-010-0659-y.

211. Ger, R. The management of certain abdominal herniae by intra-abdominal closure of the neck of the sac. Preliminary communication / R. Ger // Ann R Coll Surg Engl. – 1982. – Vol. 64. – No. 5. – P. 342–344.

212. Gómez-Menchero, J. Laparoscopic intracorporeal rectus aponeuroplasty (LIRA) technique versus intraperitoneal onlay mesh (IPOM plus) for ventral hernia repair: a comparative analysis / J. Gómez-Menchero, A. Balla, J. L. García Moreno, A. Gila Bohorquez [et al.] // Hernia. – 2023. – DOI: 10.1007/s10029-023-02858-0

213. Graf, J.I.D.-P. Laparoscopic transabdominal preperitoneal approach to place a polypropylene mesh on the abdominal wall: an experimental swine model of a technique that can be used for incisional hernia repair / J.I.D.-P. Graf, M. Moreno Portillo, L.E.C. Lailson [et al.] // Surgical Endoscopy. – 2005. – № 7 (19). – P. 990–995. – DOI 10.1007/s00464-003-8291-x.

214. Grant, P. J. Diabetes mellitus as a prothrombotic condition / P. J. Grant // J Intern Med. – 2007. – Vol. 262. – No. 2. – P. 157–172. – DOI: 10.1111/j.1365-2796.2007.01824.x.

215. Grolleau, J. L. Techniques de réparation pariétale des éventrations abdominales [Incisional hernia repair techniques for the abdominal wall] / J. L. Grolleau, P. Micheau // Ann Chir Plast Esthet. – 1999. – Vol. 44. – No. 4. – P. 339–355. (in French).

216. Halm, J. A. Intraperitoneal polypropylene mesh hernia repair complicates subsequent abdominal surgery / J. A. Halm, L. L. de Wall, E. W. Steyerberg [et al.] //

World J Surg. – 2007. – Vol. 31. – No. 2. – P. 423–429. – DOI: 10.1007/s00268-006-0317-9.

217. Halverson, A. L. Intraabdominal adhesion formation after preperitoneal dissection in the murine model / A. L. Halverson, W. L. Barrett, P. Bhanot, J. E. Phillips, A. R. Iglesias [et al.] // Surg Endosc. – 1999. – Vol. 13. – No. 1. – P. 14–16. – DOI: 10.1007/s004649900888.

218. Harsløf, S. Effect of fixation devices on postoperative pain after laparoscopic ventral hernia repair: a randomized clinical trial of permanent tacks, absorbable tacks, and synthetic glue / S. Harsløf, P. Krum-Møller, T. Sommer, N. Zinther [et al.] // Langenbecks Arch Surg. – 2018. – Vol. 403. – No. 4. – P. 529–537. – DOI: 10.1007/s00423-018-1676-z.

219. Hauters, P. Assessment of predictive factors for recurrence in laparoscopic ventral hernia repair using a bridging technique / P. Hauters, J. Desmet, D. Gherardi, S. Dewaele [et al.] // Surg Endosc. – 2017. – Vol. 31. – No. 9. – P. 3656–3663. – DOI: 10.1007/s00464-016-5401-0.

220. Hawn, M. T. Long-term follow-up of technical outcomes for incisional hernia repair / M. T. Hawn, C. W. Snyder, L. A. Graham, S. H. Gray [et al.] // J Am Coll Surg. – 2010. – Vol. 210. – No. 5. – P. 648–655. – DOI: 10.1016/j.jamcollsurg.2009.12.038

221. Hellebrekers, B. W. Pathogenesis of postoperative adhesion formation / B. W. Hellebrekers, T. Kooistra // Br J Surg. – 2011. – Vol. 98. – No. 11. – P. 1503–1516. – DOI: 10.1002/bjs.7657.

222. Hellinger, A. Development of an open prospective observational multicentre cohort study to determine the impact of standardization of laparoscopic intraperitoneal onlay mesh repair (IPOM) for incisional hernia on clinical outcome and quality of life (LIPOM-Trial) / A. Hellinger, F. Wotzlaw, V. Fackeldey, G. Pistorius [et al.] // Contemp Clin Trials Commun. – 2016. –Vol. 4. – P. 118-123. – DOI: 10.1016/j.conctc.2016.08.001.

223. Heniford, B. T. Laparoscopic repair of ventral hernias: nine years' experience with 850 consecutive hernias / B. T. Heniford, A. Park [et al.] //Ann Surg. – 2003. – Vol. 238. – No. 3. – P. 391–399. – DOI: 10.1097/01.sla.0000086662.49499.ab.

224. Hernández-Granados, P. European Hernia Society guidelines on management of rectus diastasis / P. Hernández-Granados, N. A. Henriksen, F. Berrevoet, D. Cuccurullo [et al.] // Br J Surg. – 2021. – Vol. 108. – No. 10. –P. 1189–1191. – DOI: 10.1093/bjs/znab128.

225. Heymann, F. Polypropylene mesh implantation for hernia repair causes myeloid cell-driven persistent inflammation / F. Heymann, K. T. von Trotha, C. Preisinger, P. Lynen-Jansen, A. A. Roeth [et al.] // JCI Insight. – 2019. – Vol. 4. – No. 2. – DOI: 10.1172/jci.insight.123862.

226. Hilling, D. E. Laparoscopic correction of umbilical hernias using a transabdominal preperitoneal approach: results of a pilot study. / D. E. Hilling, L. B. Koppert, R. Keijzer [et al.] // Surg Endosc. – 2009. – Vol. 23. – No. 8. – P. 1740–1744. – DOI: 10.1007/s00464-008-0177-5.

227. Holihan, J. L. Mesh Location in Open Ventral Hernia Repair: A Systematic Review and Network Meta-analysis / J. L. Holihan, D. H. Nguyen, M. T. Nguyen, J. Mo [et al.] // World J Surg. – 2016. – Vol. 40. – No. 1. – P. 89–99. – DOI: 10.1007/s00268-015-3252-9.

228. Hollinsky, C. Tensile strength and adhesion formation of mesh fixation systems used in laparoscopic incisional hernia repair / C. Hollinsky, T. Kolbe, I. Walter, A. Joachim, S. Sandberg [et al.] // Surg. Endosc. – 2010. – Vol. 24. – P. 1318–1324. – DOI: 10.1007/s00464-009-0767-x.

229. Howard, R. Costs associated with modifiable risk factors in ventral and incisional hernia repair / R. Howard, M. Thompson, Z. Fan, M. Englesbe [et al.] // JAMA Netw Open. – 2019. – No. 2 (11). – DOI: 10.1001/jamanetworkopen.2019.16330.

230. Huschitt, N. Die offene intraperitoneale Netzplastik zur Versorgung ventraler Bauchdeckendefekte--erste Ergebnisse bei der Implantation eines mit ePTFE beschichteten Polypropylenenetzes [Open intraperitoneal hernia repair for treatment of abdominal wall defects--early results by placement of a polypropylene-ePTFE-mesh] / N. Huschitt, M. Feller, E. Lotspeich, H. Gerngross, R. Schmidt // Zentralbl Chir. – 2006. – Vol. 131. – No. 1. – P. 57–61. – DOI: 10.1055/s-2006-921411 (in German).

231. Itani, K. M. F. Comparison of laparoscopic and open repair with mesh for the treatment of ventral incisional hernia: a randomized trial / K. M. F. Itani, K. Hur, L. T. Kim, T. Anthony [et al.] // Arch Surg. – 2010. – Vol. 145. – No. 4. – P. 322–328. – DOI: 10.1001/archsurg.2010.18.

232. Jamry, A. Assessment of adhesion formation after laparoscopic intraperitoneal implantation of Dynamesh IPOM mesh / A. Jamry, M. Jałyński [et al.] // Arch. Med. Sci. – 2013. – Vol. 9. – No. 3. – P. 487–492. – DOI: 10.5114/aoms.2013.35345.

233. Jangjoo, A. Mesh migration following abdominal hernia repair: A case report, and literature review / A. Jangjoo, M. E. Kalantari, T. Zandbaf // Caspian J Intern Med. – 2022. – Vol. 13. – No. 4. – P. 815–817. – DOI: 10.22088/cjim.13.4.815.

234. Jenkins, E. D. Prospective evaluation of adhesion characteristics to intraperitoneal mesh and adhesiolysis-related complications during laparoscopic re-exploration after prior ventral hernia repair / E. D. Jenkins, V. Yom, L. Melman, L. M. Brunt, J. C. Eagon, M. M. Frisella, B. D. Matthews // Surg Endosc. – 2010. – Vol. 24. – No. 12. – P. 3002–3007. – DOI: 10.1007/s00464-010-1076-0.

235. Joels, C. S. Evaluation of adhesion formation, mesh fixation strength, and hydroxyproline content after intraabdominal placement of polytetrafluoroethylene mesh secured using titanium spiral tacks, nitinol anchors, and polypropylene suture or polyglactin 910 suture / C. S. Joels, B. D. Matthews, K. W. Kercher [et al.] // Surg. Endosc. – 2005. – Vol. 19. – P. 780–785. – DOI: 10.1007/s00464-004-8927-5.

236. Jonas, J. The problem of mesh shrinkage in laparoscopic incisional hernia repair / J. Jonas // Zentralbl Chir. – 2009. – Vol. 134. – No. 3. – P. 209–213. –DOI: 10.1055/s-0028-1098779 (in German).

237. Jones, J. A. Proteomic analysis and quantification of cytokines and chemokines from biomaterial surface-adherent macrophages and foreign body giant cells / J. A. Jones, D. T. Chang, H. Meyerson, E. Colton [et al.] // J Biomed Mater Res A. – 2007. – Vol. 83. – No. 3. – P. 585–596. – DOI: 10.1002/jbm.a.31221

238. Junge, K. Adhesion formation of a polyvinylidenfluoride/polypropylene mesh for intra-abdominal placement in a rodent animal model / K. Junge, M. Binnebösel, R. Rosch

[et al.] // Surg Endosc. – 2009. – Vol. 23. – No. 2. – 327–333. – DOI: 10.1007/s00464-008-9923-y.

239. Junge, K. Influence of mesh materials on the integrity of the vas deferens following Lichtenstein hernioplasty: an experimental model / K. Junge, M. Binnebösel, R. Rosch [et al.] // Hernia. – 2008. – Vol. 12. – No. 6. – P. 621–626. – DOI: 10.1007/s10029-008-0400-2.

240. Kaafarani, H. M. Seroma in ventral incisional herniorrhaphy: incidence, predictors and outcome / H. M. Kaafarani, K. Hur, A. Hirter [et al.] // Am J Surg. – 2009. – Vol. 198. – No. 5. – P. 639–644. – DOI: 10.1016/j.amjsurg.2009.07.019.

241. Kapoulas, S. Safety and efficacy of absorbable and non-absorbable fixation systems for intraperitoneal mesh fixation: an experimental study in swine / S. Kapoulas, A. Papalois, G. Papadakis, G. Tsoulfas [et al.] // Hernia. –2021. – DOI: 10.1007/s10029-020-02352-x.

242. Karahasanoglu, T. Spiral Tacks May Contribute to Intra-Abdominal Adhesion Formation / T. Karahasanoglu, E. Onur, B. Baca, I. Hamzaoglu [et al.] // Surg. Today. – 2004. – Vol. 34. – P. 860–864. – DOI: 10.1007/s00595-004-2831-4.

243. Karatassas, A. Developing a mesh-tissue integration index and mesh registry database: the next step in the evolution of hernia repair / A. Karatassas, A. Anthony, J. Reid, L. Leopardi, P. Hewett [et al.] // ANZ J Surg. – 2018. –Vol. 88. – No. 6. – P. 528–529. – DOI: 10.1111/ans.14060.

244. Kingsnorth, A. N. Management of abdominal hernias / A. N. Kingsnorth, K. A. LeBlanc. – Springer, 2013. – 414 pp. – DOI: 10.1007/978-1-84882-877-3.

245. Kirchhoff, S. Detection of recurrent hernia and intraabdominal adhesions following incisional hernia repair: a functional cine MRI-study / S. Kirchhoff, R. Ladurner, C. Kirchhoff, T. Mussack [et al.] // Abdom Imaging. – 2010. – Vol. 35. – No. 2. – P. 224–231. – DOI: 10.1007/s00261-009-9505-z.

246. Klinge, U. PVDF as a new polymer for the construction of surgical meshes / U. Klinge, B. Klosterhalfen, A. P. Ottinger, K. Junge, V. Schumpelick // Biomaterials. – 2002. – Vol. 23. – No. 16. – P. 3487–3493. – DOI: 10.1016/s0142-9612(02)00070-4.

247. Klinge, U. The ideal mesh? / U. Klinge, J. K. Park, B. Klosterhalfen // Pathobiology. – 2013. – Vol. 80. – No. 4. – P. 169–175. – DOI: 10.1159/000348446.

248. Klinge, U. Experimental comparison of monofile light and heavy polypropylene meshes: less weight does not mean less biological response / U. Klinge // World J Surg. – 2007. – Vol. 31. – No. 4. – P. 867–868. – DOI: 10.1007/s00268-006-0670-8.

249. Klink, C. D. Do drainage liquid characteristics serve as predictors for seroma formation after incisional hernia repair? / C. D. Klink, M. Binnebösel, A. H. Lucas, A. Schachtrupp [et al.] // Hernia. – 2010. – Vol. 14. – No. 2. – P. 175–179. – DOI: 10.1007/s10029-009-0603-1.

250. Klosterhalfen, B. Pathologie traditioneller chirurgischer Netze zur Hernienreparation nach Langzeitimplantation im Menschen [Pathology of traditional surgical nets for hernia repair after long-term implantation in humans] / B. Klosterhalfen, U. Klinge, B. Hermanns, V. Schumpelick // Chirurg. – 2000. – Vol. 71. – No. 1. – P. 43–51. – DOI: 10.1007/s001040050007 (in German).

251. Köckerling, F. Laparoscopic IPOM versus open sublay technique for elective incisional hernia repair: a registry-based, propensity score-matched comparison of 9907 patients / F. Köckerling, T. Simon, D. Adolf [et al.] // Surg Endosc. – 2019. – Vol. 33. – No. 10. – P. 3361–3369. – DOI: 10.1007/s00464-018-06629-2.

252. Koehler, R. H. Minimal adhesions to ePTFE mesh after laparoscopic ventral incisional hernia repair: reoperative findings in 65 cases / R. H. Koehler, D. Begos, D. Berger, S. Carey, K. LeBlanc [et al.] // JSLS. – 2003. – Vol. 7. – No. 4. – P. 335–340.

253. Kosins, A. M. Evidence-based value of subcutaneous surgical wound drainage: the largest systematic review and meta-analysis / A. M. Kosins [et al.] // Plast. Reconstr. Surg. – 2013. – Vol. 132. – P. 443–450.

254. Kosins, A. M. Evidence-based value of subcutaneous surgical wound drainage: the largest systematic review and meta-analysis / A. M. Kosins [et al.] // Plast Reconstr Surg. – 2013. – Vol. 132. – No. 2. – P. 443–450. – DOI: 10.1097/PRS.0b013e3182958945.

255. Krpata, D. M. Posterior and open anterior components separations: a comparative analysis / D. M. Krpata, J. A. Blatnik, Y. W. Novitsky, M. J. Rosen // Am J Surg. – 2012. – T. 203. – No. 3. – P. 318–322.

256. Ladurner, R. Cyanoacrylate glue for intra-abdominal mesh fixation of polypropylene-polyvinylidene fluoride meshes in a rabbit model / R. Ladurner, I. Drosse, D. Bürklein, W. Plitz, G. Barbaryka, C. Kirchhoff [et al.] // J Surg Res. – 2011. – Vol. 167. – No. 2. – DOI: 10.1016/j.jss.2009.11.710.

257. Ladurner, R. Tissue attachment strength and adhesion formation of intraabdominal fixed meshes with cyanoacrylate glues / R. Ladurner, I. Drosse, S. Seitz, W. Plitz, G. Barbaryka, M. Siebeck, D. Bürklein, C. Kirchhoff [et al.] // Eur. J. Med. Res. – 2008. – Vol. 13. – No. 5. – P. 185–191.

258. Lanzafame, R. J. Preliminary assessment of postoperative adhesion formation after laser-assisted mesh fixation to the peritoneal surface / R. J. Lanzafame, I. Stadler, P. Brondon [et al.] // Journal of Laparoendoscopic & Advanced Surgical Techniques. – 2005. – Vol. 15. – No. 2. – P. 105–111. – DOI: 10.1089/lap.2005.15.105.

259. Leber, G. E. Long-term complications associated with prosthetic repair of incisional hernias / G. E. Leber, J. L. Garb [et al.] // Arch Surg. – 1998. – Vol. 133. – No. 4. – P. 378–382. – DOI: 10.1001/archsurg.133.4.378.

260. LeBlanc, K. Comparison of adhesion formation associated with Pro-Tack (US Surgical) versus a new mesh fixation device, Salute (ONUX Medical) / K. LeBlanc, R. Stout, M. Kearney, D. B. Paulson // Surg. Endosc. – 2003. – Vol. 17. – P. 1409–1417. – DOI: 10.1007/s00464-002-8632-1.

261. LeBlanc, K. A. Laparoscopic repair of incisional abdominal hernias using expanded polytetrafluoroethylene: preliminary findings / K. A. LeBlanc, W. V. Booth // Surg Laparosc Endosc. – 1993. – Vol. 3. – No. 1. – P. 39–41.

262. LeBlanc, K. A. Laparoscopic incisional and ventral hernioplasty: lessons learned from 200 patients / K. A. LeBlanc, J. M. Whitaker [et al.] // Hernia. –2003. – Vol. 7. – No. 3. – P. 118–124. – DOI: 10.1007/s10029-003-0117-1.

263. LeBlanc, K. A. Tack hernia: a new entity / K. A. LeBlanc // JSLS. –2003. – Vol. 7. – No. 4. – P. 383–387.

264. Lee, K. W. Effects of lifestyle on hemostasis, fibrinolysis, and platelet reactivity: a systematic review / K. W. Lee, G. Y. Lip // Arch Intern Med. – 2003. – Vol. 163. – No. 19. – P. 2368–2392. – DOI: 10.1001/archinte.163.19.2368.

265. Levy, J. H. Massive transfusion coagulopathy / J. H. Levy // Semin Hematol. – 2006. – Vol. 43. – No. 1 (suppl.). – P. S59–63. – DOI: 10.1053/j.seminhematol.2005.11.019.

266. Liang, M. K. Ventral Hernia Management: Expert Consensus Guided by Systematic Review / M. K. Liang, J. L. Holihan, K. Itani, Z. M. Alawadi, J. R. Gonzalez, E. P. Askenasy, C. Ballecer, H. S. Chong, M. I. Goldblatt [et al.] // Ann Surg. – 2017. – Vol. 265. – No. 1. – P. 80–89. – DOI: 10.1097/SLA.0000000000001701.

267. Lichtenstein, I. L. The tension-free hernioplasty / I. L. Lichtenstein, A. G. Shulman, P. K. Amid, M. M. Montllor // Am J Surg. – 1989. – Vol. 157. – No. 2. – P. 188–193. – DOI: 10.1016/0002-9610(89)90526-6.

268. Lijnen, H. R. Role of fibrinolysis in obesity and thrombosis / H. R. Lijnen // Thromb Res. – 2009. – Vol. 123. – No. 4 (suppl). – P. S46–49. – DOI: 10.1016/S0049-3848(09)70143-4.

269. Limperg, T. Ultrasound visceral slide assessment to evaluate for intra-abdominal adhesions in patients undergoing abdominal surgery – a systematic review and meta-analysis / T. Limperg, K. Chaves, N. Jesse [et al.] // J Minim Invasive Gynecol. – 2021. – Vol. 28. – No. 12. – P. 1993–2003. – DOI: 10.1016/j.jmig.2021.07.002.

270. Liu, H. Comparison of coated meshes for intraperitoneal placement in animal studies: a systematic review and meta-analysis / H. Liu, S. van Steensel, M. Gielen, T. Vercoulen, J. Melenhorst [et al.] // Hernia. – 2020. – Vol. 24. – No. 6. – P. 1253–1261. – DOI: 10.1007/s10029-019-02071-y.

271. Lobato, R. F. Estudio de coste-beneficio comparando la reparación de la hernia ventral abierta y laparoscópica / R. F. Lobato, J. C. R. de Adana Belbel, F. A. Morales, J. G. Septiem [et al.] // Cir Esp. – 2014. – Vol. 92. – No. 8. – P. 553–560. – DOI: 10.1016/j.ciresp.2013.04.012.

272. Losanoff, J. E. Entero-colocutaneous fistula: a late consequence of polypropylene mesh abdominal wall repair: case report and review of the literature / J. E. Losanoff, B. W. Richman, J. W. Jones // Hernia. – 2002. – Vol. 6. – No. 3. – P. 144–147. – DOI: 10.1007/s10029-002-0067-z.

273. Lucas, P. A. Formation of abdominal adhesions is inhibited by antibodies to transforming growth factor-beta1. / P. A. Lucas, D. J. Warejcka, H. E. Young, B. Y. Lee // J Surg Res. – 1996. – Vol. 65. – No. 2. – P. 135–138. DOI: 10.1006/jsre.1996.0355.

274. Majumder, A. Evaluation of a novel permanent capped helical coil fastener in a porcine model of laparoscopic ventral hernia repair / A. Majumder, M. Fayezizadeh [et al.] // Surg. Endosc. – 2016. – Vol. 30. – P. 5266–5274. – DOI: 10.1007/s00464-016-4874-1.

275. Mathes, T. Mesh fixation techniques in primary ventral or incisional hernia repair / T. Mathes, B. Prediger, M. Walgenbach, R. Siegel // Cochrane Database Syst Rev. – 2021. – Vol. 5. – No. 5. – DOI: 10.1002/14651858.CD011563.pub2.

276. Matthews, B. D. Assessment of adhesion formation to intra-abdominal polypropylene mesh and polytetrafluoroethylene mesh / B. D. Matthews, B. L. Pratt, H. S. Pollinger [et al.] // Journal of Surgical Research. – 2003. – Vol. 114. – No. 2. – P. 126–132. – DOI: 10.1016/S0022-4804(03)00158-6.

277. Mayhew, D. A review of ASA physical status – historical perspectives and modern developments / D. Mayhew, V. Mendonca, B. V. S. Murthy // Anaesthesia. – 2019. – Vol. 74. – No. 3. – P. 373–379. – DOI: 10.1111/anae.14569.

278. McCarthy JD, Twiest MW. Intraperitoneal polypropylene mesh support of incisional herniorraphy / J. D. McCarthy, M // Am J Surg. – 1981. – Vol. 142. –No. 6. – P. 707–711. – DOI: 10.1016/0002-9610(81)90317-2.

279. McGinty, J. J. A comparative study of adhesion formation and abdominal wall ingrowth after laparoscopic ventral hernia repair in a porcine model using multiple types of mesh / J. J. McGinty, N. J. Hogle [et al.] // Surg Endosc. – 2005. – Vol. 19. – No. 6. – P. 786–790. – DOI: 10.1007/s00464-004-8174-9.

280. McKernan, J. B. Laparoscopic repair of inguinal hernias using a totally extraperitoneal prosthetic approach / J. B. McKernan, H. L. Laws // Surg Endosc. – 1993. – Vol. 7. – No. 1. – P. 26–28. – DOI: 10.1007/BF00591232.

281. Megas, I. F. A propensity-score matched analysis of ventral-TAPP vs. laparoscopic IPOM for small and mid-sized ventral hernias. Comparison of perioperative data, surgical outcome and cost-effectiveness / I. F. Megas, C. Benzing, A. Winter, J. Raakow [et al.]

// Hernia. – 2022. – Vol. 26. – No. 6. – P. 1521–1530. – DOI: 10.1007/s10029-022-02586-x.

282. Meijer, E. J. The principles of abdominal wound closure / E. J. Meijer, L. Timmermans, J. Jeekel, J. F. Lange, F. E. Muysoms // Acta Chir Belg. – 2013. – Vol. 113. – No. 4. – P. 239–244. – DOI: 10.1080/00015458.2013.11680920.

283. Memisoglu, K. Mesh fixation devices and formation of intraperitoneal adhesions / K. Memisoglu, K. Saribeyoglu, S. Pekmezci, T. Karahasanoglu, B. Sen, I. Bayrak [et al.] // J. Laparoendosc. Adv. S. – 2006. – Vol.16. – No. 5. – P. 439–444. – DOI: 10.1089/lap.2006.16.439.

284. Miao, L. Physical characteristics of medical textile prostheses designed for hernia repair: a comprehensive analysis of select commercial devices / L. Miao, F. Wang, L. Wang, T. Zou [et al.] // Materials (Basel). – 2015. – No. 8 (12). – P. 8148–8168. – DOI: 10.3390/ma8125453.

285. Misiakos, E. P. Laparoscopic ventral hernia repair: pros and cons compared with open hernia repair / E. P. Misiakos, A. Machairas [et al.] // JSLS. – 2008. – Vol. 12. – No. 2. – P. 117–125.

286. Misiakos, E. P. Current trends in laparoscopic ventral hernia repair / E. P. Misiakos, P. Patapis, N. Zavras [et al.] // JSLS. – 2015. – Vol 19. – No. 3. – DOI: 10.4293/JSLS.2015.00048.

287. Morales-Conde, S. Ventral hernia repair in high-risk patients and contaminated fields using a single mesh: proportional meta-analysis / S. Morales-Conde, P. Hernández-Granados, L. Tallón-Aguilar [et al.] // Hernia. – 2022. – Vol. 26. – No. 6. – P. 1459–1471. – DOI: 10.1007/s10029-022-02668-w.

288. Morales-Conde, S. Retroprosthetic seroma after laparoscopic ventral hernia repair: incidence, risk factors and clinical significance / S. Morales-Conde, G. Suarez-Artacho, M. Socas-Macias, A. Barranco-Moreno // Hernia. –2015. – Vol. 19. – No. 6. – P. 943–947. – DOI: 10.1007/s10029-015-1352-y.

289. Morales-Conde, S. A new classification for seroma after laparoscopic ventral hernia repair / S. Morales-Conde // Hernia. – 2012. – Vol. 16. – No. 3. – P. 261–267. – DOI: https://doi.org/10.1007/s10029-012-0911-8.

290. Moreno-Egea, A. Which should be the gold standard laparoscopic technique for handling Spigelian hernias? / A. Moreno-Egea, A. Campillo-Soto, G. Morales-Cuenca // Surg Endosc. – 2015. – Vol. 29. – No. 4. – P. 856–862. – DOI: 10.1007/s00464-014-3738-9.

291. Moreno-Egea, A. Randomized clinical trial of laparoscopic hernia repair comparing titanium-coated lightweight mesh and medium-weight composite mesh / A. Moreno-Egea, A. Carrillo-Alcaraz, V. Soria-Aledo // Surg Endosc. –2013. – Vol. 27. – No. 1. – P. 231–239. – DOI: 10.1007/s00464-012-2425-y.

292. Mueller, M. D. An evaluation of laparoscopic adhesiolysis in patients with chronic abdominal pain / M. D. Mueller, J. Tschudi, U. Herrmann, Ch. Klaiber //Surg Endos. – 1995. – Vol. 9. – No. 7. – P. 802–804. – DOI: 10.1007/BF00190085

293. Muysoms, F. EuraHS: the development of an international online platform for registration and outcome measurement of ventral abdominal wall hernia repair / F. Muysoms, G. Campanelli, G. G. Champault, A. C. DeBeaux, U. A. Dietz, J. Jeekel, U. Klinge [et al.] // Hernia. – 2012. – Vol. 16. – No. 3. – P. 239–250. – DOI: 10.1007/s10029-012-0912-7.

294. Muysoms, F. Randomized clinical trial of mesh fixation with «double crown» versus «sutures and tackers» in laparoscopic ventral hernia repair / F. Muysoms, G. Vander Mijnsbrugge, P. Pletinckx, E. Boldo, I. Jacobs [et al.] // Hernia. – 2013. – Vol. 17. – No. 5. – P. 603–612. – DOI: https://doi.org/10.1007/s10029-013-1084-9.

295. Muysoms, F. E. «Suture hernia»: identification of a new type of hernia presenting as a recurrence after laparoscopic ventral hernia repair / F. E. Muysoms, K. K. Cathenis, D. A. Claeys // Hernia. – 2007. – Vol. 11. – No. 2. P. 199–201. – DOI: 10.1007/s10029-006-0170-7.

296. Muysoms, F. E. Classification of primary and incisional abdominal wall hernias / F. E. Muysoms, M. Miserez, F. Berrevoet, G. Campanelli, G. G. Champault, E. Chelala [et al.] // Hernia. – 2009. – Vol. 13. – No. 4. – P. 407–414. – DOI: 10.1007/s10029-009-0518-x.

297. Nguyen, D. H. Primary fascial closure with laparoscopic ventral hernia repair: systematic review / D. H. Nguyen, M. T. Nguyen, E. P. Askenasy [et al.] // World J Surg. – 2014. – Vol. 38. – No. 12. – P. 3097–3104. – DOI: 10.1007/s00268-014-2722-9.

298. Novitsky Y.W. Transversus abdominis muscle release: a novel approach to posterior component separation during complex abdominal wall reconstruction / Y.W. Novitsky, H.L. Elliott, S.B. Orenstein S.B. [et al.] // Am J Surg. – 2012. – Vol. 204. – No. 5. – P. 709–716.

299. Novitsky, Y. W. Transversus abdominis muscle release: a novel approach to posterior component separation during complex abdominal wall reconstruction / Y. W. Novitsky [et al.] // Am J Surg. – 2012. – Vol. 204. – No. 5. – P. 709–716. – DOI: 10.1016/j.amjsurg.2012.02.008.

300. Novitsky, Y. W. Outcomes of posterior component separation with transversus abdominis muscle release and synthetic mesh sublay reinforcement / Y. W. Novitsky, M. Fayezizadeh, A. Majumder [et al.] // Ann Surg. – 2016. – Vol. 264. – No. 2. – P. 226–232. – DOI: 10.1097/SLA.0000000000001673.

301. Novitsky, Y. W. Comparative evaluation of adhesion formation, strength of ingrowth, and textile properties of prosthetic meshes after long-term intra-abdominal implantation in a rabbit / Y. W. Novitsky, A. G. Harrell, J. A. Cristiano, B. L. Paton, H. J. Norton, R. D. Peindl, K. W. Kercher, B. T. Heniford // J Surg Res. – 2007. – Vol. 140. – No. 1. – P. 6–11. – DOI: 10.1016/j.jss.2006.09.015.

302. Ott, V. Late intestinal fistula formation after incisional hernia using intraperitoneal mesh / V. Ott, Y. Groebli, R. Schneider // Hernia. – 2005. – Vol. 9. – No. 1. – P. 103–104. – DOI: 10.1007/s10029-004-0271-0.

303. Pauli, E. M. Open ventral hernia repair with component separation / E. M. Pauli, M. J. Rosen // Surg Clin North Am. – 2013. – Vol. 93. – No. 5. – P. 1111–1133. – DOI: 10.1016/j.suc.2013.06.010.

304. Phillips, E. H. Incidence of complications following laparoscopic hernioplasty / E. H. Phillips, M. Arregui, B. J. Carroll, J. Corbitt, W. B. Crafton [et al.] // Surg Endosc. – 1995. – Vol. 9. – No. 1. – P. 16–21. – DOI: 10.1007/BF00187878.

305. Phillips, E. H. Laparoscopic preperitoneal inguinal hernia repair without peritoneal incision. Technique and early clinical results / E. H. Phillips, B. J. Carroll, M. J. Fallas // Surg Endosc. – 1993. – Vol. 7. – No. 3. – P. 159–162. – DOI: 10.1007/BF00594098.

306. Phillips, E. H. Reasons for early recurrence following laparoscopic hernioplasty / E. H. Phillips, R. Rosenthal, M. Fallas, B. Carroll, M. Arregui, J. Corbitt [et al.] // Surg Endosc. – 1995. – Vol. 9. – No. 2. – P. 140–144. – DOI: 10.1007/BF00191954.

307. Piccoli, M. Predictive factors of recurrence for laparoscopic repair of primary and incisional ventral hernias with single mesh from a multicenter study / M. Piccoli, F. Pecchini, G. Vetrone, R. Linguerri, G. Sarro, U. Rivolta, A. Elio, G. Piccirillo, G. Faillace, E. Masci [et al.] // Sci Rep. – 2022. – Vol.12. – No. 1. – DOI: 10.1038/s41598-022-08024-3.

308. Pierce, R. A. 120-day comparative analysis of adhesion grade and quantity, mesh contraction, and tissue response to a novel omega-3 fatty acid bioabsorbable barrier macroporous mesh after intraperitoneal placement / R. A. Pierce, J. M. Perrone, A. Nimeri, J. A. Sexton, J. Walcutt, M. M. Frisella, B. D. Matthews // Surgical Innovation. – 2008. – Vol. 16. – No. 1. – P. 46–54. – DOI: 10.1177/1553350608330479.

309. Poppas, D. P. Hydrogel coated mesh decreases tissue reaction resulting from polypropylene mesh implant: implication in hernia repair / D. P. Poppas [et al.] // Hernia. – 2016. – Vol. 20. – No 4. – P. 623–632.

310. Poppas, D. P. Hydrogel coated mesh decreases tissue reaction resulting from polypropylene mesh implant: implication in hernia repair / D. P. Poppas, J. J. Sung, C. M. Magro, J. Chen, J. P. Toyohara, B. J. Ramshaw, D. Felsen // Hernia. – 2016. – Vol. 20. – No. 4. – 623–632. – DOI: 10.1007/s10029-016-1481-y.

311. Postempski, P. E. Uber Radikaloperationen de Hernien / P. E. Postempski // Centralblatt fur Chirurgie. – 1890. – Vol. 34. – P. 653.

312. Poulose, B. K. Epidemiology and cost of ventral hernia repair: making the case for hernia research / B. K. Poulose, J. Shelton, S. Phillips [et al.] // Hernia. – 2012. – Vol. 16. – No. 2. – P. 179–183. – DOI: 10.1007/s10029-011-0879-9.

313. Pring, C. M. Laparoscopic versus open ventral hernia repair: a randomized controlled trial / C. M. Pring, V. Tran, N. O'Rourke, I. J. Martin // ANZ J Surg. – 2008. – Vol. 78. – No. 10. – P. 903–906. – DOI: 10.1111/j.1445-2197.2008.04689.x.

314. Ramirez, O. M. "Components separation" method for closure of abdominal-wall defects: an anatomic and clinical study / O. M. Ramirez, E. Ruas, A. L. Dellon // Plast Reconstr Surg. – 1990. Vol. 86. – No. 3. – P. 519–526. – DOI: 10.1097/00006534-199009000-00023.

315. Rauth, T. P. A comparative analysis of expanded polytetrafluoroethylene and small intestinal submucosa--implications for patch repair in ventral herniorrhaphy / T. P. Rauth, B. K. Poulose, L. B. Nanney, M. D. Holzman // J Surg Res. – 2007. – Vol. 143. – No. 1. – P. 43–49. – DOI: 10.1016/j.jss.2007.03.079.

316. Read, R. C. Francis C. Usher, herniologist of the twentieth century / R. C. Read // Hernia. – 1999. – Vol. 3. – P. 167–171. – DOI: 10.1007/BF01195320.

317. Reinpold, W. Mini- or less-open sublay (E/MILOS) operation vs open sublay and laparoscopic IPOM repair for the treatment of incisional hernias: a registry-based propensity score matched analysis of the 5-year results / W. Reinpold, C. Berger, D. Adolf, F. Köckerling // Hernia. 2023. – DOI: 10.1007/s10029-023-02847-3.

318. Reinpold, W. Classification of Rectus Diastasis – A Proposal by the German Hernia Society (DHG) and the International Endohernia Society (IEHS) / W. Reinpold, F. Köckerling, R. Bittner, J. Conze [et al.] // Front Surg. – 2019. – Vol. 6. – DOI: 10.3389/fsurg.2019.00001.

319. Reinpold, W. Mini- or less-open sublay operation (MILOS): a new minimally invasive technique for the extraperitoneal mesh repair of incisional hernias / W. Reinpold, M. Schröder, C. Berger, J. Nehls, A. Schröder, M. Hukauf, F. Köckerling, R. Bittner // Ann Surg. – 2019. – Vol. 269. – No. 4. –748–755. – DOI: 10.1097/SLA.0000000000002661.

320. Reynvoet, E. Laparoscopic ventral hernia repair: is there an optimal mesh fixation technique? A systematic review / E. Reynvoet, E. Deschepper, X. Rogiers, R. Troisi, E. Berrevoet // Langenbecks Arch Surg. – 2014. – Vol. 399. – No. 1. – P. 55–63. – DOI: 10.1007/s00423-013-1126-x.

321. Reynvoet, E. The use of cyanoacrylate sealant as simple mesh fixation in laparoscopic ventral hernia repair: a large animal evaluation / E. Reynvoet, S. Van Cleven, I. Van Overbeke, K. Chiers, P. De Baets, R. Troisi, F. Berrevoet // Hernia. – 2015. – Vol. 19. – P. 661–670. – DOI: 10.1007/s10029-015-1347-8.

322. Ribeiro, W. G. Comparative study of peritoneal adhesions after intraperitoneal implantation in rats of meshes of polypropylene versus polypropylene/polyglecaprone versus polyester/porcine collagen / W. G. Ribeiro, D. V. S. Rodrigues, F. F. M. Atta, I. S. F. Ramos, F. N. S. Frazão, O. J. M. Torres, M. B. Pitombo // Acta Cir Bras. – 2019. – Vol. 34. – No. 6. – DOI: 10.1590/s0102-865020190060000003.

323. Rives, J. A propos du traitement chirurgical des hernies de l'aine. Orientation nouvelle et perspectives thérapeutiques / J. Rives, H. Nicaise, B. Lardennois // Ann Med Reims. – 1965. – No. 2. – P. 193–200.

324. Rodríguez, M. Chemical adhesion barriers: do they affect the intraperitoneal behavior of a composite mesh? / M. Rodríguez, G. Pascual, S. Sotomayor, B. Pérez-Köhler, A. Cifuentes, J. M. Bellón // Journal of Investigative Surgery. – 2011. – Vol. 24. – No. 3. – P. 115–122. – DOI: 10.3109/08941939.2011.555059.

325. Rosenfeld, B. A. The effects of different anesthetic regimens on fibrinolysis and the development of postoperative arterial thrombosis. Perioperative Ischemia Randomized Anesthesia Trial Study Group / B. A. Rosenfeld, C. Beattie, R. Christopherson, E. J. Norris, S. M. Frank, M. J. Breslow, P. Rock, S. D. Parker, S. O. Gottlieb, B. A. Perler [et. al] // Anesthesiology. – 1993. – Vol. 79. – No. 3. – P. 435–443. – DOI: 10.1097/00000542-199309000-00005.

326. Rudmik, L. R. Laparoscopic incisional hernia repair: a review of the literature / L. R. Rudmik, C. Schieman [et al.] // Hernia. – 2006. – Vol. 10. – No. 2. – P. 110–119. – DOI: 10.1007/s10029-006-0066-6.

327. Sadava, E. E. Laparoscopic mechanical fixation devices: does firing angle matter? / E. E. Sadava, D. M. Krpata, Y. Gao, S. Schomisch [et al.] // Surg Endosc. – 2013. – Vol. 27. – No. 6. – P. 2076–2081. – DOI: 10.1007/s00464-012-2713-6.

328. Sahu, D. Transfascial suture in laparoscopic ventral hernia repair; friend or foe? / D. Sahu, S. Das, M. R. Wani, P. K. Reddy // J Minim Access Surg. –2015. – Vol. 11. – No. 2. – P. 157–159. – DOI: 10.4103/0972-9941.147367.

329. Sajid, M. S. A meta-analysis comparing tacker mesh fixation with suture mesh fixation in laparoscopic incisional and ventral hernia repair / M. S. Sajid, U. Parampalli, M. R. McFall // Hernia. – 2013. – Vol. 17. – No. 2. – P. 159–166. – DOI: 10.1007/s10029-012-1017-z.

330. Sakorafas, G. H. Open tension free repair of inguinal hernias; the Lichtenstein technique / G. H. Sakorafas, I. Halikias, C. Nissotakis, N. Kotsifopoulos [et al.] // BMC Surg. – 2001. – DOI: 10.1186/1471-2482-1-3.

331. Sauerland, S. Laparoscopic versus open surgical techniques for ventral or incisional hernia repair / S. Sauerland, M. Walgenbach, B. Habermalz, C. M. Seiler, M. Miserez // Cochrane Database Syst Rev. – 2011. – Vol. 3. – DOI: 10.1002/14651858.CD007781.pub2.

332. Scheidbach, H. Influence of titanium coating on the biocompatibility of a heavyweight polypropylene mesh. An animal experimental model / H. Scheidbach, A. Tannapfel, U. Schmidt, H. Lippert, F. Köckerling // Eur Surg Res. – 2004. – Vol. 36. – No. 5. – P. 313–317. – DOI: 10.1159/000079917.

333. Schoenmaeckers, E. J. Impact of the number of tacks on postoperative pain in laparoscopic repair of ventral hernias: do more tacks cause more pain? / E. J. Schoenmaeckers, R. J. de Haas, V. Stirler, J. T. Raymakers, S. Rakic // Surg Endosc. – 2012. – Vol. 26. – No. 2. – P. 357–360. –DOI: 10.1007/s00464-011-1876-x.

334. Schreinemacher, M. H. F. Degradation of mesh coatings and intraperitoneal adhesion formation in an experimental model / M. H. F. Schreinemacher, P. J. Emans, M. J. J. Gijbels [et al.] // BJS. – 2009. – Vol. 96. –No. 3. – P. 305–313. – DOI: 10.1002/bjs.6446.

335. Schreinemacher, M. H. F. Adhesions to sutures, tackers, and glue for intraperitoneal mesh fixation: an experimental study / M. H. F. Schreinemacher, K. W. Y. van Barneveld, E. Peeters, M. Miserez [et al.] // Hernia. – 2014. – Vol. 18. – P. 865–872. – DOI: 10.1007/s10029-013-1192-6.

336. Schug-Pass, C. Fixation of mesh to the peritoneum using a fibrin glue: investigations with a biomechanical model and an experimental laparoscopic porcine model / C. Schug-Pass, H. Lippert, F. Köckerling // Surg Endosc. –2009. – Vol. 23. – No. 12. – P. 2809–2815. – DOI: 10.1007/s00464-009-0509-0.

337. Schug-Pass, C. Does the additional application of a polylactide film (SurgiWrap) to a lightweight mesh (TiMesh) reduce adhesions after laparoscopic intraperitoneal implantation procedures? Experimental results obtained with the laparoscopic porcine model / C. Schug-Pass, F. Sommerer, A. Tannapfel [et al.] // Surg Endosc. – 2008. – Vol. 22. – No. 11. – P. 2433–2439. – DOI: 10.1007/s00464-008-9876-1.

338. Schug-Paß, C. A lightweight polypropylene mesh (TiMesh) for laparoscopic intraperitoneal repair of abdominal wall hernias / C. Schug-Paß, C. Tamme, A. Tannapfel, F. Köckerling // Surg Endosc. – 2006. – Vol. 20. – No. 3. – P. 402–409. – DOI: 10.1007/s00464-004-8277-3.

339. Sharma, A. Iatrogenic enterotomy in laparoscopic ventral/incisional hernia repair: a single center experience of 2,346 patients over 17 years / A. Sharma, R. Khullar, V. Soni, M. Baijal [et al.] // Hernia. – 2013. – Vol. 17. – No. 5. – P. 581–587. – DOI: 10.1007/s10029-013-1122-7.

340. Shell, D. H 4th. Open repair of ventral incisional hernias / D. H. Shell 4th, J. de la Torre [et al.] // Surg Clin North Am. – 2008. – Vol. 88. – No. 1. – P. 61–83. – DOI: 10.1016/j.suc.2007.10.008.

341. Shouldice E. B. The Shouldice repair for groin hernias / E. B. Shouldice // Surg Clin North Am. – 2003. – Vol. 83. – No. 5. – P. 1163–1187. – DOI: 10.1016/S0039-6109(03)00121-X.

342. Shubinets, V. Incisional hernia in the United States: trends in hospital encounters and corresponding healthcare charges / V. Shubinets, J. P. Fox, M. A. Lanni, M. G. Tecce [et al.] // Am Surg. – 2018. – Vol. 84. – No. 1. – P. 118–125. – DOI: 10.1177/000313481808400132.

343. Sigel, B. Technique of ultrasonic detection and mapping of abdominal wall adhesions / B. Sigel, R. M. Golub, L. A. Loiacono [et al.] // Surg Endosc. –1991. – Vol. 5. – No. 4. – P. 161–165. – DOI: 10.1007/BF02653253.

344. Sikkink, C. J. J. M. Adhesion formation and reherniation differ between meshes used for abdominal wall reconstruction / C. J. J. M. Sikkink, T. S. V. de Reilingh, A. W. Malyar, J. A. Jansen [et al.] // Hernia. – 2006. – Vol. 10. – No. 3. – P. 218–222. – DOI: 10.1007/s10029-006-0065-7.

345. Silecchia, G. Laparoscopic ventral/incisional hernia repair: updated Consensus Development Conference based guidelines [corrected] / G. Silecchia, F. C. Campanile, L. Sanchez, G. Ceccarelli, A. Antinori, L. Ansaloni, S. Olmi, G. C. Ferrari [et al.] // Surg Endosc. – 2015. – Vol. 29. – No. 9. – P. 2463–2484. – DOI: 10.1007/s00464-015-4293-8.

346. Slater, N. J. Biologic grafts for ventral hernia repair: a systematic review / N. J. Slater, M. van der Kolk, T. Hendriks [et al.] // Am J Surg. – 2013. – Vol. 205. – No. 2. – P. 220–230. – DOI: 10.1016/j.amjsurg.2012.05.028.

347. Smietański, M. Assessment of usefulness exhibited by different tacks in laparoscopic ventral hernia repair / M. Smietański, J. Bigda, K. Iwan, M. Kołodziejczyk, J. Krajewski, I. A. Smietańska [et al.] // Surg Endosc. – 2007. – Vol. 21. – No. 6. – P. 925–928. – DOI: 10.1007/s00464-006-9055-1.

348. Snyder, C. W. Patient satisfaction, chronic pain, and quality of life after elective incisional hernia repair: effects of recurrence and repair technique / C. W. Snyder, L. A. Graham, C. C. Vick, S. H. Gray [et al.] // Hernia. – 2011. –Vol. 15. – No. 2. – P. 123–129. – DOI: 10.1007/s10029-010-0750-4.

349. Sommer, T. DynaMesh® in the repair of laparoscopic ventral hernia: a prospective trial / T. Sommer, H. Friis-Andersen // Hernia. – 2013. – Vol. 17. –No. 5. – P. 613–618. – DOI: 10.1007/s10029-013-1090-y.

350. Sosin, M. The Perfect Plane: A systematic review of mesh location and outcomes, Update 2018 / M. Sosin, M. Y. Nahabedian, P. Bhanot // Plast Reconstr Surg. – 2018. – Vol. 142. – No. 3 (suppl). – P. 107S–116S. – DOI: 10.1097/PRS.0000000000004864.

351. Stoppa, R. E. The use of Dacron in the repair of hernias of the groin / R. E. Stoppa, J. L. Rives, C. R. Warlaumont, J. R. Palot [et al.] // Surg Clin North Am. – 1984. – Vol. 64. – No. 2. – P. 269–285. – DOI: 10.1016/s0039-6109(16)43284-6.

352. Suh, H. Evaluation of mesh fixation in laparoscopic ventral hernia repair / H. Suh, M. Magdy, S. Perera // ANZ J Surg. – 2019. – Vol. 89. – No. 6. – P. 772–774. – DOI: 10.1111/ans.14283.

353. Suwa, K. Is fascial defect closure with intraperitoneal onlay mesh superior to standard intraperitoneal onlay mesh for laparoscopic repair of large incisional hernia? / K. Suwa, T. Okamoto, K. Yanaga // Asian J Endosc Surg. – 2018. –Vol. 11. – No. 4. – P. 378–384. – DOI: 10.1111/ases.12471.

354. Tandon, A. Meta-analysis of closure of the fascial defect during laparoscopic incisional and ventral hernia repair / A. Tandon, S. Pathak, N. J. Lyons, Q. M. Nunes, I. R. Daniels, N. J. Smart // Br J Surg. – 2016. – Vol. 103. – No. 12. – P. 1598–1607. – DOI: 10.1002/bjs.10268.

355. Tandon, A. Parietex™ Composite mesh versus DynaMesh®-IPOM for laparoscopic incisional and ventral hernia repair: a retrospective cohort study / A. Tandon [et al.] // Ann R Coll Surg Engl. – 2016. – Vol. 98. – No. 8. – P. 568–573. – DOI: 10.1308/rcsann.2016.0292.

356. Tanprasert, P. Collagen deposition and inflammatory response associated with macroporous mesh shrinkage in incisional hernia repair: a rat model / P. Tanprasert, K. Tepmalai, B. Chakrabandhu [et al.] // J Invest Surg. – 2022. – Vol. 35. – No. 8. – P. 1635–1647. – DOI: 10.1080/08941939.2022.2087240.

357. ten Broek, RP. Preoperative nomogram to predict risk of bowel injury during adhesiolysis / R. P. ten Broek, C. Strik, H. van Goor // Br J Surg. –2014. – Vol. 101. – No. 6. – P. 720–727. – DOI: 10.1002/bjs.9479.

358. Timmermans, L. Meta-analysis of sublay versus onlay mesh repair in incisional hernia surgery / L. Timmermans, B. de Goede, S. M. van Dijk [et al.] // Am J Surg. – 2014. – Vol. 207. – No. 6. – P. 980–988. – DOI: 10.1016/j.amjsurg.2013.08.030.

359. Todros, S. Synthetic surgical meshes used in abdominal wall surgery: Part I-materials and structural conformation / S. Todros, P. G. Pavan, A. N. Natali // J Biomed Mater Res B Appl Biomater. – 2017. – Vol. 105. – No. 3. – P. 689–699. – DOI: 10.1002/jbm.b.33586.

360. Toffolo Pasquini, M. Ring closure outcome for laparoscopic ventral hernia repair (IPOM plus) in medium and large defects. Long-term follow-up / M. Toffolo Pasquini, P. Medina, R. Arrechea Antelo, R. Cerutti, E. A. Porto, D. E. Pirchi // Surg Endosc. – 2023. – Vol. 37. – No. 3. – P. 2078–2084. – DOI: 10.1007/s00464-022-09738-1.

361. Toffolo Pasquini, M. Laparoscopic ventral hernia repair: does IPOM plus allow to increase the indications in larger defects? / M. Toffolo Pasquini, P. Medina, L. A. Mata [et al.] // Hernia. – 2022. – Vol. 26. – No. 2. – P. 525–532. – DOI: 10.1007/s10029-021-02506-5.

362. Turcu, F. Adhesiolysis-related challenges for laparoscopic procedures after ventral hernia repair with intraperitoneal mesh / F. Turcu [et al.] // Chirurgia (Bucharest, Romania). – 2019. – Vol. 114. – No. 1. – P. 39. – DOI: 10.21614/chirurgia.114.1.39.

363. Tuveri, M. Repair of large abdominal incisional hernia by reconstructing the midline and use of an onlay of biological material / M. Tuveri, A. Tuveri, E. Nicolò // Am J Surg. – 2011. – Vol. 202. – No. 1. – P. 7–11. – DOI: 10.1016/j.amjsurg.2010.06.005.

364. Urban, E. Why make monofilament sutures out of polyvinylidene fluoride? / E. Urban, King M. W. [et al.] // ASAIO J. – 1994. – Vol. 40. – No. 2. – P. 145–156.

365. Utiyama, E. M. Polypropylene and polypropylene/polyglecaprone (Ultrapro(r)) meshes in the repair of incisional hernia in rats / E. M. Utiyama, M. B. S. Rosa [et al.] // Acta Cirurgica Brasileira. – 2015. – Vol. 30. – No. 6. – P. 376–381. – DOI: 10.1590/S0102-865020150060000001.

366. Van Hoef, S. Primary non-complicated midline ventral hernia: is laparoscopic IPOM still a reasonable approach? / S. Van Hoef, T. Tollens // Hernia. – 2019. – Vol. 23. – No. 5. – P. 915–925. – DOI: 10.1007/s10029-019-02031-6.

367. van't Riet, M. Prevention of adhesion formation to polypropylene mesh by collagen coating: a randomized controlled study in a rat model of ventral hernia repair / M. van't Riet, J. W. Burger, F. Bonthuis [et al.] // Surg Endosc. –2004. –Vol. 18. – No. 4. – 681–685. – DOI: 10.1007/s00464-003-9054-4.

368. van't Riet, M. Tensile strength of mesh fixation methods in laparoscopic incisional hernia repair / M. van't Riet, P. J. de Vos van Steenwijk, G. J. Kleinrensink [et al.] // Surg

Endosc. – 2002. – Vol. 16. – No. 12. – P. 1713–1716. – DOI: 10.1007/s00464-001-9202-7.

369. Voskerician, G. Human peritoneal membrane reduces the formation of intra-abdominal adhesions in ventral hernia repair: experimental study in a chronic hernia rat model / G. Voskerician, J. Jin, S. A. Hunter, C. P. Williams [et al.] // J Surg Res. – 2009. – Vol. 157. – No. 1. – P. 108–114. – DOI: 10.1016/j.jss.2009.03.055.

370. Warlaumont, C. Les hernies de l'aine: Place des prothèse en tulle de Dacron dans leur traitement. Thèse Méd. Amiens. – 1982. – P. 12.

371. Warren, J. A. Incisional hernia repair: minimally invasive approaches / J. Warren, M. Love // Surg Clin North Am. – 2018. – Vol. 98. – No. 3. – P. 537–559. – DOI: 10.1016/j.suc.2018.01.008.

372. Wassenaar, E. B. Subsequent abdominal surgery after laparoscopic ventral and incisional hernia repair with an expanded polytetrafluoroethylene mesh: a single institution experience with 72 reoperations / E. B. Wassenaar, E. J. P. Schoenmaeckers [et al.] // Hernia. – 2010. – Vol. 14. – No. 2. – 137–142. – DOI: 10.1007/s10029-009-0568-0.

373. Wéber, G. Kedvezőbb műtéti eredmények "onlay" hálóval, mint "sublay" helyzetben beültetettel. Varrattal, illetve hálóbeültetéssel történő hasfal-rekonstrukció prospektiv, randomizált, multicentrikus vizsgálata--ötéves utánkövetés eredeményei ["Onlay" mesh provides significantly better results than "sublay" reconstruction. Prospective randomized multicenter study of abdominal wall reconstruction with sutures only, or with surgical mesh results of a five-years follow-up] / G. Wéber, J. Baracs, O. P. Horváth // Magy Seb. –2010. – Vol. 63. – No. 5. – P. 302–311. – DOI: 10.1556/MaSeb.63.2010.5.3 (in Hungarian).

374. Wexler, M. J. The repair of inguinal hernia: 110 years after Bassini / M. J. Wexler // Can J Surg. – 1997. – Vol. 40. – No. 3. – P. 186–191.

375. Weyhe, D. Improving outcomes in hernia repair by the use of light meshes--a comparison of different implant constructions based on a critical appraisal of the literature / D. Weyhe, O. Belyaev, C. Müller, K. Meurer, K. H. Bauer, G. Papapostolou, W. Uhl //

World J Surg. – 2007. – Vol. 31. – No. 1. – P. 234–244. – DOI: 10.1007/s00268-006-0123-4.

376. Weyhe, D. Improving outcomes in hernia repair by the use of light meshes – a comparison of different implant constructions based on a critical appraisal of the literature / D. Weyhe [et al.] // World journal of surgery. – 2007. – Vol. 31. – № 1. – P. 234–244.

377. Wilson, P. Laparoscopic intraperitoneal onlay mesh (IPOM) repair using n-butyl-2-cyanoacrylate (Liquiband Fix8™) for mesh fixation: learning experience and short-medium term results / P. Wilson // Hernia. –2020. – Vol. 24. – No. 6. – P. 1387–1396. – DOI: s10029-020-02144-3.

378. Winny, M. Adhesion prevention efficacy of composite meshes Parietex®, Proceed® and 4DryField® PH covered polypropylene meshes in an IPOM rat model / M. Winny, L. Maegel, L. Grethe, T. Lippmann, D. Jonigk, H. Schrem [et al.] // Int J Med Sci. – 2016. – Vol. 13. – No. 12. – P. 936–941. – DOI: 10.7150/ijms.16215.

379. Winslow, E. Laparoscopic incisional hernia repair in a porcine model: What do transfixion sutures add? / E. Winslow, S. Diaz, K. Desai, T. Meininger, N. J. Soper, M. E. Klingensmith // Surg. Endosc. – 2004. – Vol. 18. – P. 529–535. – DOI: 10.1007/s00464-003-8519-9.

380. Yang, G. P. C. From intraperitoneal onlay mesh repair to preperitoneal onlay mesh repair / G. P. C. Yang // Asian J Endosc Surg. – 2017. – Vol. 10. –No. 2. – P. 119–127. – DOI: 10.1111/ases.12388.

381. Zhang, Y. Laparoscopic versus open incisional and ventral hernia repair: a systematic review and meta-analysis / Y. Zhang, H. Zhou, Y. Chai, C. Cao, K. Jin, Z. Hu // World J Surg. – 2014. – Vol. 38. – No. 9. – P. 2233–2240. – DOI: 10.1007/s00268-014-2578-z.

382. Zühlke, H. V. Pathophysiologie und klassifikation von adhäsionen [Pathophysiology and classification of adhesions] / H. V. Zühlke, E. M. P. Lorenz, E. M. Straub, V. Savvas // Langenbecks Arch Chir Suppl II Verh Dtsch Ges Chir. – 1990. – P. 1009-1016. – DOI: 10.1007/978-3-642-48163-5_212 (in German).

383. Zuvela, M. Central rupture and bulging of low-weight polypropylene mesh following recurrent incisional sublay hernioplasty / M. Zuvela, D. Galun, A. Djurić-

Stefanović, I. Palibrk, M. Petrović, M. Milićević // Hernia. – 2014. – Vol. 18. – No. 1. – P. 135–140. – DOI: 10.1007/s10029-013-1197-1.