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Research article

# DEVELOPMENT OF INNOVATIVE SYSTEM OF UNIVERSAL STENT GRAFT FOR ENDOVASCULAR TREATMENT OF ANEURYSM AND AORTIC DISPLACEMENT IN VARIOUS LOCATIONS

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***ABSTRACT***

This study presents the technology of developing a universal stent graft for endovascular treatment of aneurysms and aortic dissection of various localizations, without considering the vessel diameter. A self-expanding nitinol stent was used as the frame of the main trunk of the stent graft. During the study, several variants of the aortic linear graft were manufactured and tested. The optimal stiffness and diameter of the nitinol wire were selected based on the results. When creating a bifurcation module, special attention was paid to simplifying the positioning and "intravascular assembly" of the structure. Implantable modules have been developed for the prosthetics of the main branches of the aorta. Dacron, optimal in terms of fiber structure, was chosen as the material of the woven shell of the graft. Linear extensibility, compactness of the pile, and tensile strength during fenestration were evaluated. To determine the heparin-controlled surgical porosity, experimental samples of stent grafts were tested on a stand simulating arterial blood flow. The wall material of the developed device had a heparin-controlled surgical porosity of 50–150 mL/min/cm$^2$ at 120 mm Hg with the possibility of maintaining a controlled endolic. The graft wall created a pressure gradient of no more than 3 mm Hg, and the flow velocity indicators were quite sufficient for adequate perfusion of vital organs. After the inactivation of heparin, blood permeability became zero. The implantation technique of the developed product was implemented on a silicone aortic phantom simulating aneurysm expansion with and without dissection. The phantom contour was filled with a solution simulating the rheological properties of native blood. Pulsating blood flow was simulated using a perfusion pump. Under X-ray control, a stent graft was installed on five large biological samples (sheep). Implantation was performed in the aortic arch with prosthetics of the brachiocephalic trunk and the suprarenal aorta with prosthetics of the visceral branches. With the experiment, we hope that the result will allow us to minimally invasively help patients suffering from aneurysms of any localization.

**Keywords:** aneurysm; aneurysmal dilation; aortic dissection; endoprosthetics; endovascular treatment of aneurysms; universal modular stent graft; implantation; implantable modules.

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Научная статья

# РАЗРАБОТКА ИННОВАЦИОННОЙ СИСТЕМЫ УНИВЕРСАЛЬНОГО СТЕНТ-ГРАФТА ДЛЯ ЭНДОВАСКУЛЯРНОГО ЛЕЧЕНИЯ АНЕВРИЗМ И РАССЛОЕНИЯ АОРТЫ РАЗЛИЧНЫХ ЛОКАЛИЗАЦИЙ

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**Резюме**

Обосновывается технология разработки универсального стент-графта для эндоваскулярного лечения аневризм и расслоения аорты различной локализации, без учета диаметра сосуда. В качестве каркаса основного ствола стент-графта использован саморасширяющийся стент из нитинола. В ходе работы были изготовлены и апробованы несколько вариантов опытных образцов аортального линейного графта. Исходя из полученных результатов подобрана оптимальная жесткость и диаметр нитиноловой проволоки. При создании бифуркационного модуля особое внимание уделено упрощению процесса позиционирования и «внутрисосудистой сборки» конструкции. Для протезирования магистральных ветвей аорты разработаны имплантируемые модули — отведения. Материалом тканной оболочки графта был выбран оптимальный по структуре волокон лавсан. Оценивались линейная растяжимость, компактность ворса и прочность на разрыв при выполнении фенестрации. Для определения гепарин-контролируемой хирургической пористости опытные образцы стент-графтов испытывались на стенде, симулирующем модель артериального кровотока. Установлено, что материал стенки разработанного устройства обладает гепарин-контролируемой хирургической пористостью от 50 до 150 мл/мин/см$^2$ при давлении 120 мм рт. ст. с возможностью сохранения управляемого эндолика. Стенка графта создает градиент давления не более 3 мм рт. ст., а скоростные показатели потока вполне достаточны для адекватной перфузии жизненно важных органов. После инактивации гепарина проницаемость для крови становится нулевой. Методика имплантации разработанного изделия была отработана на силиконовом фантоме аорты, моделирующем аневризматическое расширение с расслоением и без него. Контур фантома был заполнен раствором, моделирующим реологические свойства нативной крови. Пульсирующий кровоток был смоделирован с использованием перфузионного насоса. Под рентгеноскопическим контролем стент-графт установлен пяти крупным биологическим объектам (баранам). Имплантация проводилась в дугу аорты с протезированием плечеголовного ствола и в супраренальный отдел аорты с протезированием висцеральных ветвей. Проведенные экспериментальные работы позволяют надеяться, что полученный результат позволит осуществлять помощь пациентам, страдающим аневризмами любой локализации, малоинвазивным способом.

**Ключевые слова:** аневризма; аневризматическое расширение; расслоение аорты; эндопротезирование; эндоваскулярное лечение аневризм; универсальный модульный стент-графт; имплантация; имплантируемые модули.

**Как цитировать:**

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ЭКО•ВЕКТОР

## BACKGROUND

Currently, treatment of patients with aortic aneurysm remains a problem [1–3]. Abdominal aortic aneurysm affects 2%–8% of the general population [4]. The incidence of aneurysm in the infrarenal abdominal aorta ranges from 37% [5] to 60% [6]. Globally, 17.7 million people die from this pathology [7]. In the USA, aortic aneurysm ranks 13 among causes of death [8].

The treatment approach for infrarenal abdominal aortic aneurysms is constantly being improved, which results in the emergence of new treatment methods. This field of medicine has particularly improved with the introduction of endovascular techniques [9]. Modern reviews of analytical materials on the comparison of endovascular methods of treating aortic aneurysms and open interventions favor endografts [7, 10, 11].

The prevalence of thoracic and thoracoabdominal aortic aneurysms over the past decade, considering improved diagnostics, has increased significantly and currently ranges from 5 to 10 cases per 100 thousand populations per year [8]. Despite the relative rarity of this pathology, an aortic aneurysm is considered more dangerous than a stroke. Even in the USA, a country with advanced medicine, more than 15 thousand people die from aortic ruptures annually, and half of them occur before an ambulance arrives. Aortic aneurysm is the tenth leading cause of death among older men. The risk of rupture of an aneurysm depends on its diameter. Thus, in cases with aortic dilatation of approximately 4 cm, the mortality rate is 5% annually, and if the diameter increases to 9 cm, the probability of death increases to 80% annually. Aortic aneurysm is among the most dangerous conditions that can lead to near-sudden death. Its insidiousness is attributed to patients' unawareness of its chronic presence time [6].

Surgical treatment is the main method of treating aneurysms, which is aimed not only at prolonging life while maintaining its quality but also at reducing the risk of new aortic complications. However, the rates of mortality and complications after open prosthetic repair of thoracic and thoracoabdominal aortic aneurysms, despite the progress and development in treatment technologies, remain significant even in centers with a large volume of surgical activity, i.e., at 20%–25% [8, 12, 13]. This is due not only to the traumatic nature of the surgery but also to the use of artificial circulation that involves systemic heparinization. The use of a temporary bypass in aortic surgery eliminates the administration of large heparin doses and can be considered an alternative to protect the "interested" internal organs [7, 14].

The development of endovascular and hybrid techniques for treating patients with thoracic and thoracoabdominal aortic aneurysms has provided a technological breakthrough in its treatment [15, 16]. Nevertheless, the world experience gained reveals that these treatment methods have fatal complications requiring no less complex decisions [17, 18]. During endovascular treatment, serious complications occur in 25% of cases, with a mortality rate of 4%–10% [13, 19]. Generally, this is due to the lack of widely available fenestrated endografts. Therefore, creating a universal graft that can enable intraoperative personalized fenestration is extremely relevant nowadays.

This study aimed to develop a universal stent graft for the endovascular treatment of aneurysms and aortic dissection of various locations, without taking into account the vessel diameter.

## MATERIALS AND METHODS

A braided self-expanding nitinol stent was used as a frame for the creation of a universal stent graft. The outer shell of the stent graft was fixed to the frame with interrupted sutures made of nonbiodegradable surgical threads. The frame of the main graft trunk was made of a braided nitinol self-expanding mesh, with a variable diameter of 20–50 mm and a length of 150–200 mm. The proximal and distal ends of the stent graft were marked with radiopaque markers. The cells were diamond-shaped and changed their configuration in accordance with the aortic diameter (Fig. 1).

During the study, another issue that had to be resolved was the development of a frame base for branch modules for aortic branch prosthetics in the implantation zone of the main trunk (Fig. 2, *a*).

During design modeling and testing its experimental models on a bench, the optimal shape of the module was

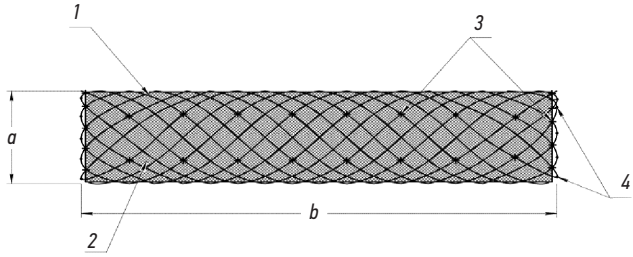


**Fig. 1.** One of the working variants of the main trunk of the stent graft: *1* — frame of the stent graft; *2* — outer shell; *3* — attachment of the shell to the frame; *4* — radiopaque markers; *a* — diameter of the stent graft; *b* — length of the stent graft
**Рис. 1.** Один из рабочих вариантов чертежа основного ствола стент-графта: *1* — каркас стент-графта; *2* — наружная оболочка; *3* — крепления оболочки к каркасу; *4* — рентгеноконтрастные маркеры; *a* — диаметр стент-графта; *b* — длина стент-графта

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chosen, similar to a "nail" with a restrictive cap that prevents the branch stent from jumping out of the main trunk and not protruding into its lumen (Fig. 2, *b*). The intraoperative radiographs during the test implantations of the prototypes into a silicone phantom and biological objects of animals and necropsy materials obtained after their sacrifice confirmed the advantages of this sample.

In a trial assembly of stent-graft models from modules of various configurations, the cell size of the main module cannot be less than 1 cm; otherwise, strangulation of the branch module occurs with subsequent stenosis of its lumen at the base (Fig. 2, *c*). With a cell size corresponding to the diameter lateral outlet, stenosis does not occur (Fig. 2, *d*). In addition, an excessively rigid frame limits significantly the ability of the structure to adapt to the internal topography of the aorta. Thus, based on the results, the optimal stiffness and diameter of the nitinol wire from which the product frame was made were selected.

The bifurcation module was developed to simplify and secure the procedure for positioning the structure during implantation. The length of the structure at maximum stretch was 30 mm, which inhibited the risk of blocking the orifices of the renal arteries during implantation. The self-expandability of the stent, if necessary, allows the proximal end of the structure to be completed with modules, similar to tiles. At the distal end, the graft was divided by a tie that divided the lumen into two equal parts with the formation of holes for the fixation of the iliac segments. For endoprosthesis replacement of the iliac segment, a linear stent graft was made and fixed into the lumen of the eight-shaped profile of the bifurcation module (Fig. 3).

The most difficult part was the choice of tissue covering for the wall graft. Initially, the requirements for the tissue coating of the stent-graft wall were based on certain biological and technological aspects. Dacron (polyethylene-terephthalate) was chosen, which was the most suitable for the goals and objectives of this study, because the vast experience in using this material in medical devices for vascular surgery has proven its strength and biological inertness. To ensure uniform coverage of the frame with variable dimensions, the linear elongation of the fabric in one direction must be at least 150% of the original length. Permeability to heparinized blood should be 100%, becoming zero after heparin inactivation. In addition, when choosing

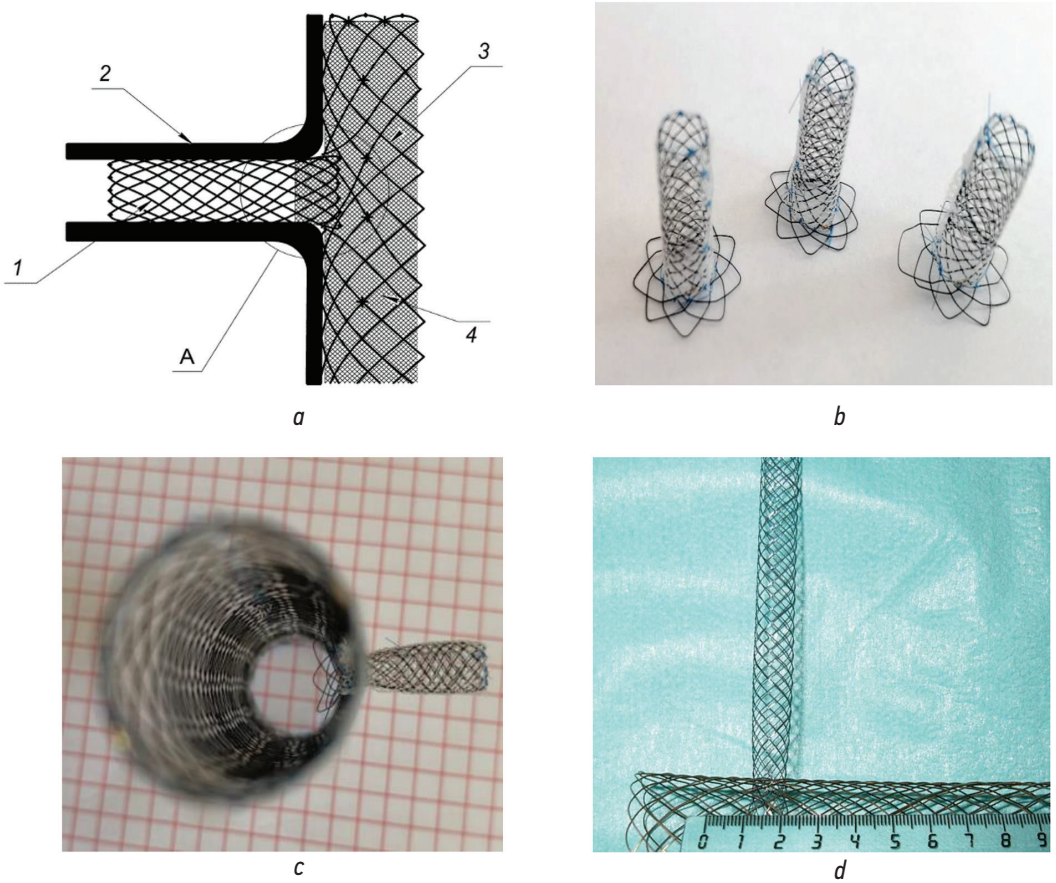



**Fig. 2.** Lead module: *a* — working drawing of the lateral branch: *1* — branch module; *2* — wall of the outgoing artery; *3* — frame mesh; *4* — shell of the stent graft; *b* — test samples of the lead modules; *c* — a prototype of the lateral branch, a cell of 5 mm; *d* — an experimental sample of lateral tap, cell 10 mm

**Рис. 2.** Модуль отведения: *a* — рабочий чертеж бокового ответвления: *1* — модуль-ответвление; *2* — стенка отходящей артерии; *3* — каркасная сетка; *4* — оболочка стент-графта; *b* — опытные образцы модулей-отведений; *c* — опытный образец бокового отвода, ячейка 5 мм; *d* — опытный образец бокового отвода, ячейка 10 мм

tissues, the degree of pile compactness was assessed as a predictor of stent-graft lumen thrombosis (Fig. 4).

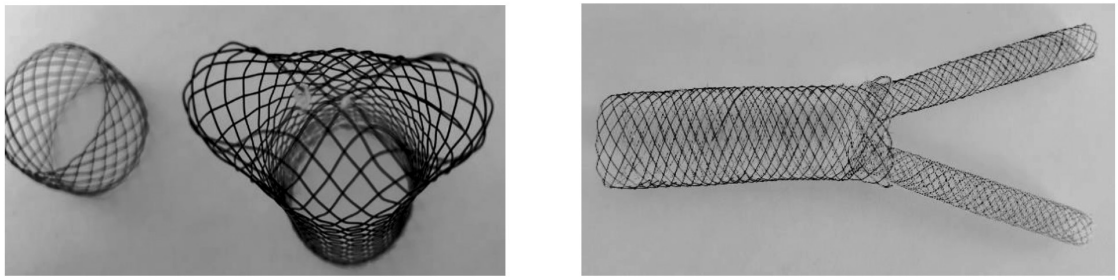
After the selection of lavsan, which had an optimal fiber structure, the tensile strength of the material was tested, which is an extremely important condition for the dilatation of the graft wall fenestration (Fig. 5).

Strength tests were performed. Specifically, a balloon catheter with a working diameter of 8 mm was inserted along a guidewire through a cell of a fragment of lavsan cloth fixed on the stand. Then, liquid was pumped into the balloon through a high-pressure syringe. The catheter was opened to its maximum diameter at a pressure of 10 atmospheres.

Based on the test results, a material was selected considering certain parameters. It should represent fibrous or monofilament threads, 0.05–0.1 mm thick, twisted in pairs, and woven into a chain. The woven threads also formed a mesh with 6–8-gonal cells, with a nominal diameter of 0.3–0.5 mm. The thickness of the resulting material did not exceed 0.2 mm. During balloon dilatation, ruptures of one or two threads were noted, without the formation of "runners". Owing to the weaving nature, the torn threads were tightly pulled together by loops of "chains" around the perimeter of the hole.

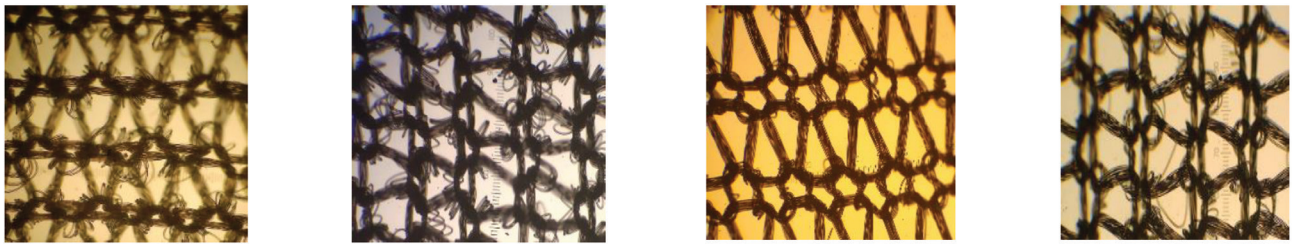
Separately, the porosity of the wall made of polyethyleneterephthalate fabric with different densities, weaving shapes, mesh sizes, diameters, and thread properties was tested.

To test the prototypes, a stand was assembled, which was a simulation model of the arterial system with arterial blood flow. To ensure the control of the volumetric velocity of blood flow, pressure, temperature, and time of blood



*a* *b*

**Fig. 3.** Frame of the bifurcation module: *a* — separately; *b* —assembled
**Рис. 3.** Каркас бифуркационного модуля: *a* — раздельно; *b* — в сборе



*a* *b* *c* *d*

**Fig. 4.** Lavsan microstructural analysis: *a*, *b* — lavsan with high thrombogenicity and rigidity; *c*, *d* — a sample that meets the requirements of the project (low fluffiness of threads and extensibility feature). Micrographs, magnification × 40
**Рис. 4.** Анализ микроструктуры лавсана: *a* и *b* — лавсан с высокой тромбогенностью и ригидностью; *c* и *d* — образец, удовлетворяющий требованиям проекта (низкая ворсистость нитей и особенность растяжимости). Микрофотографии (ув. × 40)

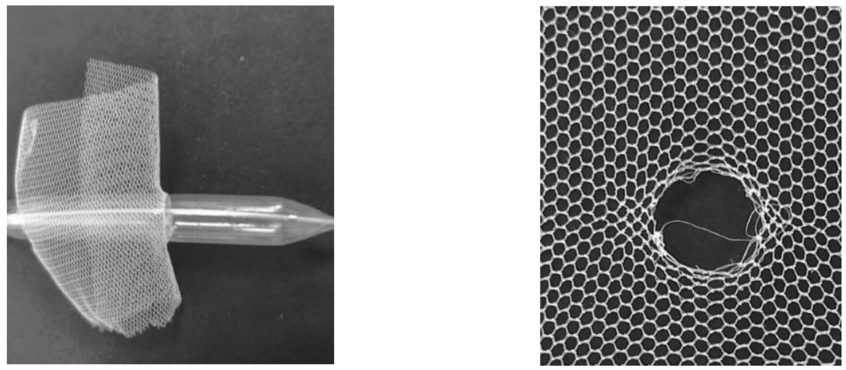


**Fig. 5.** Selected tissue sample: a local structural defect does not lead to the destruction of the structure outside the fenestration zone
**Рис. 5.** У выбранного образца ткани локальный дефект структуры не приводит к разрушению структуры вне зоны фенестрации

circulation along the circuit, the system was assembled based on the MaquetHL20 artificial blood circulation apparatus, and its standard equipment was used (Fig. 6).

The heparin-controlled surgical porosity of the wall material was assessed. The circuit was filled with heparinized blood at the rate of 5,000 units of heparin per 80 kg of body weight of a conditional patient. During the experiment, blood was continuously pumped through the system for 7600 s (2.1 h). Then, a blood test was taken for gas composition, the recalcification time was activated, and centrifugation was performed to eliminate signs of hemolysis (Fig. 7, *a*). Moreover, 0.5 mg of protamine sulfate was introduced into the system to neutralize the heparin. The maximum value of the pressure gradient between the main and outlet circuits and the time to reach it were monitored. The activation of the alarm indicated the creation of a vacuum in the outlet line and complete sealing of the lumen of the main circuit. All stages of the experiment were performed at least twice for each tissue sample.

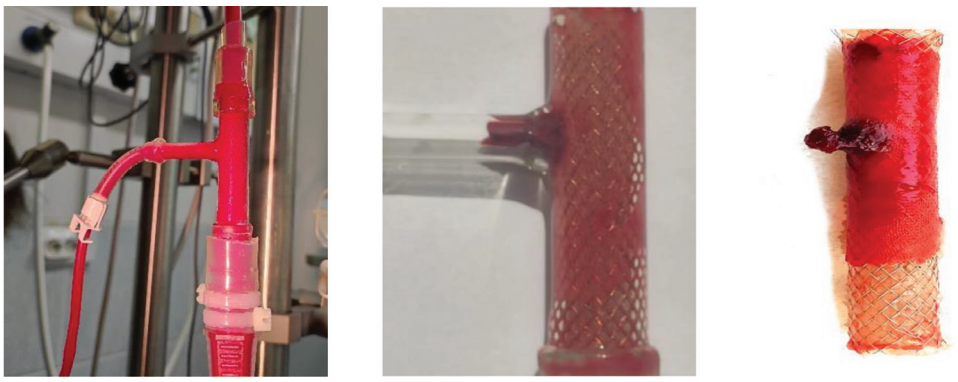
For the ease of stent-graft implantation, original linear segment delivery systems have been developed. A device for personalized fenestration and delivery of a lead module was also developed (Fig. 8).

*Stent graft installation technique*. The proposed stent graft for endoprosthetics of aortic aneurysms was installed utilizing an original delivery system with the use of heparin and an X-ray contrast agent (Omnipaque). The device was delivered to the installation site through a super-rigid guidewire previously installed in the aorta through its trunk to the orifice of the aortic branch. Positioning was performed in the RoadMap mode using radiopaque marks on the module. The wall of the main trunk of the stent graft was fenestrated with a hydrophilic guidewire opposite the orifice of the blocked aortic branch. This method of fenestration does not require additional surgical approaches to the peripheral parts of the involved vessels. Then, the branch module was inserted through the fenestrated wall into the branching artery along the guidewire, and it was opened forcefully

*a* *b*

**Fig. 6.** Simulation model of the arterial system with arterial blood flow: *a* — an experimental stent graft inside the vessel model; *b* —a stand based on the artificial circulation apparatus "MaquetHL20"

**Рис. 6.** Симуляционная модель артериальной системы с артериальным кровотоком: *a* — опытный стент-графт внутри модели сосуда; *b* — стенд на базе аппарата искусственного кровообращения «MaquetHL20»



*a* *b* *c*

**Fig. 7.** Heparin-controlled surgical porosity of the wall on a simulation model: *a* — sample in the contour at the heparinization stage; *b* — sealing of the contour after protamine sulfate administration; *c* — extracted sample after deheparinization

**Рис. 7.** Оценка гепарин-контролируемой хирургической пористости стенки на симуляционной модели: *a* — образец в контуре на этапе гепаринизации; *b* — герметизация контура после введения протамина сульфата; *c* — извлеченный образец после дегепаринизации

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after dilatation with a balloon catheter. Then, the balloon and guidewire were removed. Notably, this branching method was used for each blocked main branch. Heparinization and preservation of type IV endoleak continued until all necessary modules were installed.

## RESULTS AND DISCUSSION

*Bench tests*. Unlike most stent grafts, where the endoleak is undesirable, the proposed graft is designed to preserve temporarily a type IV endoleak. This method helps maintain the blood supply to vital organs during the implantation of the main trunk, the required number of peripheral modules until the blood supply is normalized, and the anatomy is obtained under X-ray guidance during implantation.

The optimal material for the outer shell of the product is a dacron fabric (polyethylene-terephthalate) based on monofilament threads up to 0.1 mm thick, double weave, with a cell diameter of 0.5 mm. The testing of prototype stent grafts on a bench simulating a model of arterial blood flow showed that the shell material of the developed device had heparin-controlled surgical porosity of 50–150 mL/min/cm$^2$ at a pressure of 120 mm Hg and enabled the preservation of a manageable type II endoleak. In the presence of heparin, the graft wall creates a pressure gradient of 3–5 mm Hg, and the flow rates are quite sufficient for adequate perfusion of vital organs and the creation of an X-ray "road map" compared with using X-ray contrast agent, which is necessary for accurate fenestration and further prosthetics of the main branches of the aorta.

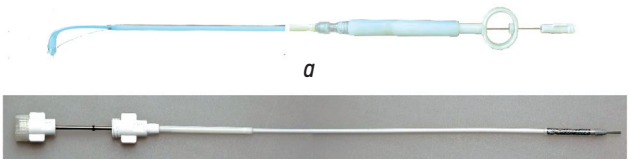
Moreover, 5–10 s after blood deheparinization, the porosity of the selected graft wall material becomes null. This enables the complete isolation of the aneurysm cavity from the blood flow in the stent graft lumen and elimination of a type IV endoleak.

*Testing using a phantom (demonstration of the stages of product implantation)*. Aneurysmal dilatation with and without dissection was simulated on a silicone aortic phantom (Fig. 9).

The contour of the silicone aortic phantom was filled with a blood replacement solution that simulated the rheological properties of native blood. A perfusion pump was used to create pulsatile blood flow with a maximum pressure of 200 mm Hg (Fig. 10).

By using a Phillips Veradius mobile angiographic unit, the process of endoprosthesis replacement of the abdominal aorta was simulated. A stent graft was implanted along a super-rigid guidewire passed through the iliac artery into the abdominal aorta, which was positioned and installed in the zone of simulated dilatation so that the upper border of the structure was at the level of the renal arteries. Omnipaque enable control. After installation, the stent was post-dilated with a large-diameter balloon (Fig. 11).

Then, the development of the technology of implanting a stent graft into the aortic arch was developed, followed by the fenestration of the main trunk of the product and endoprosthetics of the brachiocephalic arteries.



*a*

*b*

**Fig. 8.** Related devices: *a* — an example of a catheter with a perforator bent at the required angle; *b* — a folded module–a lead in the delivery system
**Рис. 8.** Сопутствующие устройства: *a* — пример катетера с перфоратором, изогнутым под необходимым углом; *b* — сложенный модуль-отведение в системе доставки

*Testing on animals (experimental part)*. After bench experiments under fluoroscopic control, five large experimental animals (rams) were implanted with the product into the aortic arch and into its suprarenal section with endoprosthetics of large branches originating

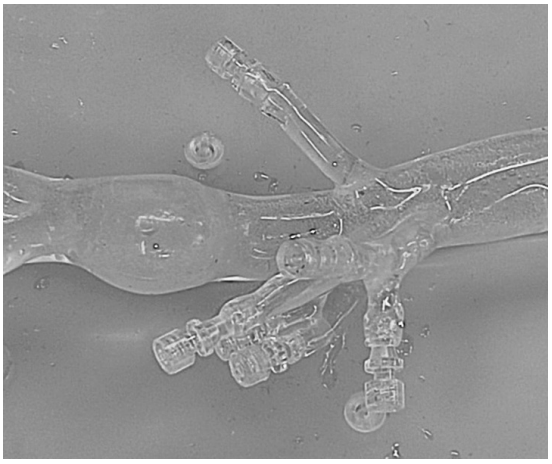


**Fig. 9.** Silicone model of the aneurysm
**Рис. 9.** Силиконовая модель аневризмы

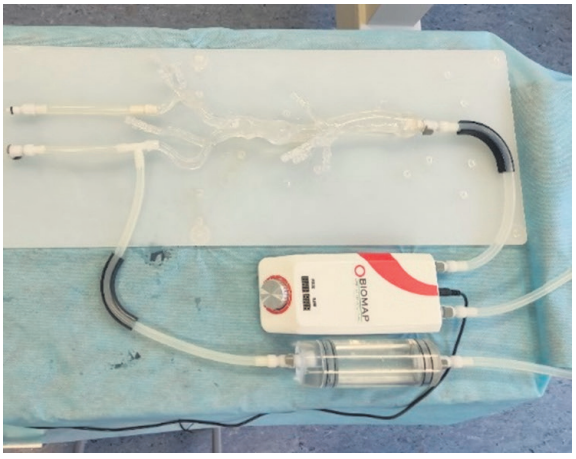


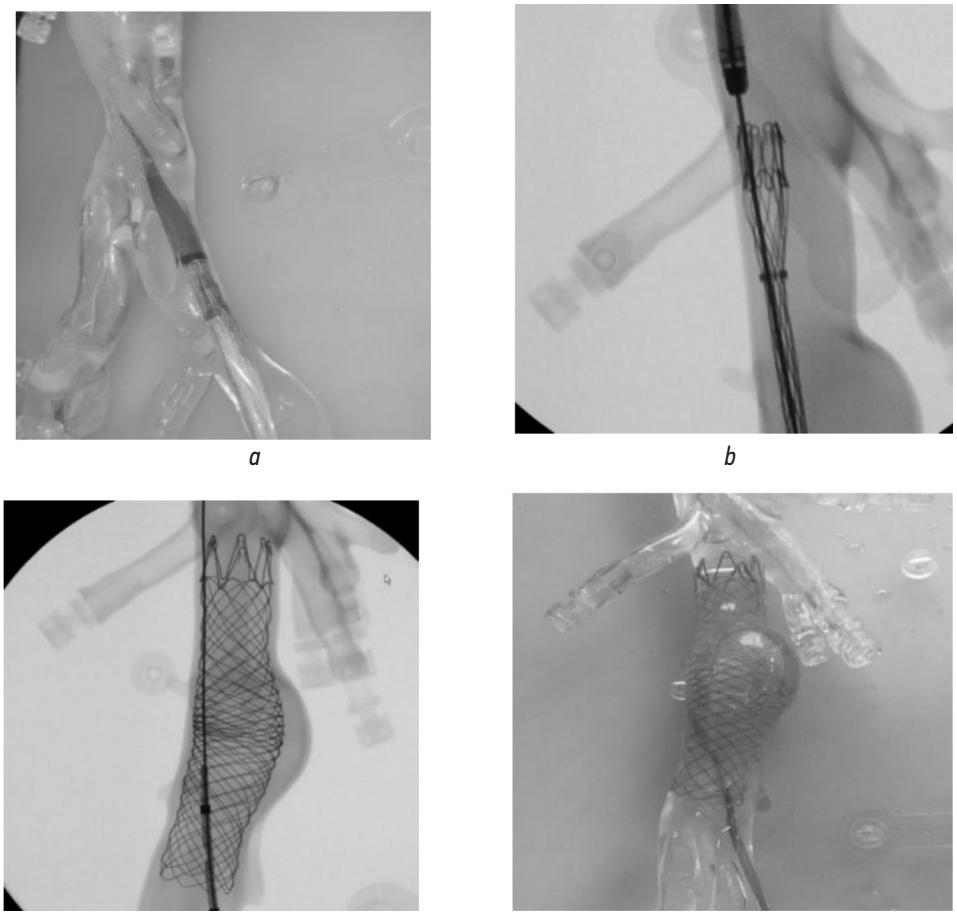
**Fig. 10.** Perfusion pump in the phantom
**Рис. 10.** Перфузионный насос в фантоме

in this location. In all cases, endotracheal anesthesia was used for pain relief. Before the implantation, an intravenous bolus heparin was administered at a starting dose of 100 U/kg of body weight.

*Endoprosthetics of the aortic arch*. Under angiographic control, through a transfemoral approach, the main trunk of the structure was retrogradely inserted into the aortic arch. For positioning, the implantation level was proximal to the brachiocephalic trunk (Fig. 12, *a*). The control image clearly visualized the brachiocephalic trunk. This demonstrates sufficient permeability of the graft wall for blood and contrast agent (Fig. 12, *b*). Then, by focusing on the created RoadMap mask, in the area of the orifice of the brachiocephalic trunk, a guidewire with a guide catheter was used to fenestrate the outer membrane, the guidewire was inserted into the arterial lumen, and the guide catheter was removed (Fig. 13, *a*). Then, the fenestrated part was dilated with a balloon catheter (Fig. 13, *b*). The outlet module of the stent graft on a balloon with the appropriate diameter was inserted into the prepared hole along the guidewire, and the balloon was inflated. In this case, the proximal end of the module was securely fixed in the cell of the main trunk (Fig. 13, *c*). The balloon was removed along with the guide. During the acquisition of the control image, the structure was passable, and the orifice of the brachiocephalic trunk was clearly visualized. No endoleak was noted (Fig. 13, *d*).

*Endoprosthesis replacement of the suprarenal abdominal aorta.* Under X-ray control, along a guidewire, the main trunk of a universal stent graft was implanted into the site of origin of the celiac trunk and superior mesenteric artery (Fig. 14, *a*). During control aortography with heparin, the orifices of the visceral branches, blocked by the installed stent, were clearly visualized (Fig. 14, *b*), which created the RoadMap mask.

Alternately, personalized fenestration of the graft wall was performed in the projection of the orifices of the celiac trunk and superior mesenteric artery. Balloon dilatation of the fenestrated openings was subsequently performed with the implantation of lead modules into the visceral branches (Figs. 15 and 16). After their installation, dilatation with a balloon catheter was mandatory. In the control image, the structure was passable, and the visceral branches were

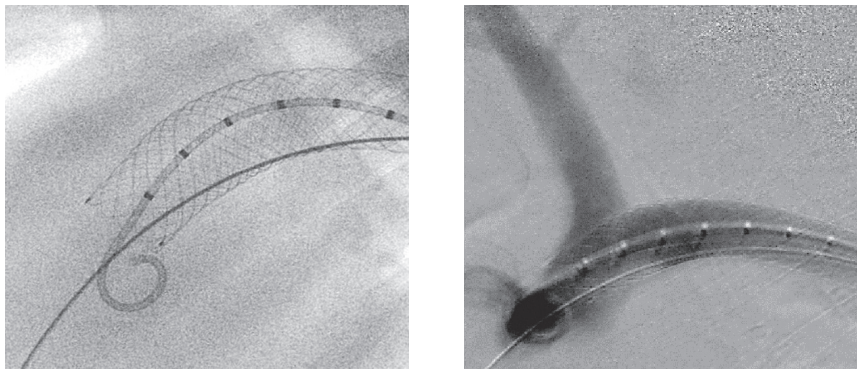


*a* *b*

*c* *d*

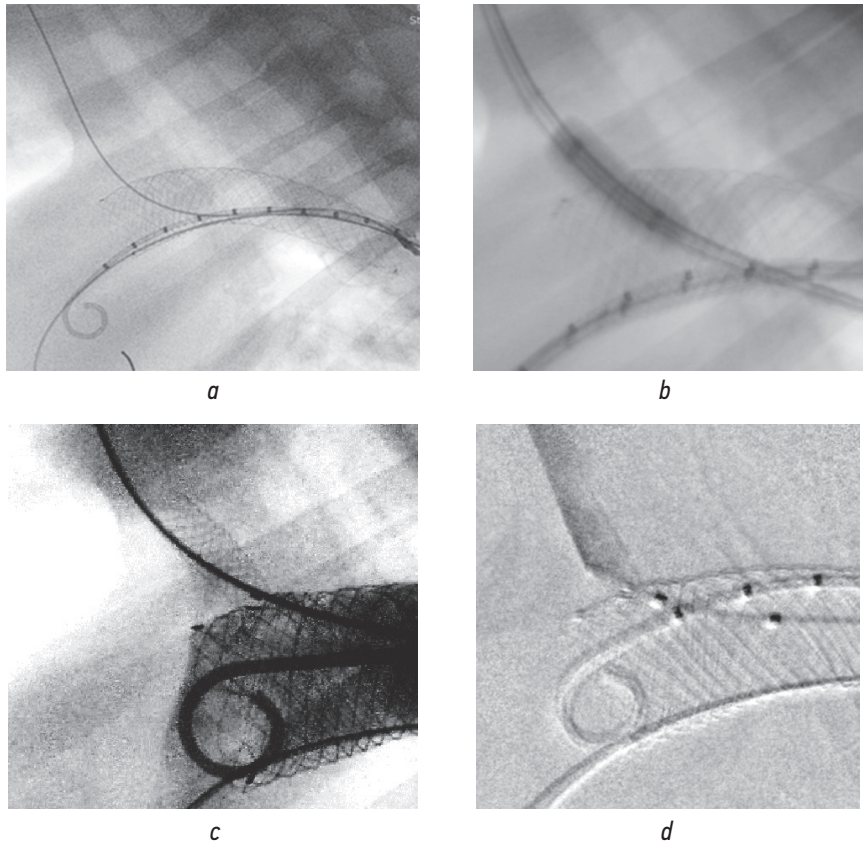
**Fig. 11.** Stages of stent graft implantation: *a* — the stent graft in the delivery system is inserted into the abdominal aorta model; *b* — the system is positioned below the mouths of the renal arteries (model); *c* — the stent graft is implanted in the aneurysm zone; *d* — appearance of the product implanted in the silicone model of the abdominal aneurysm aorta

**Рис. 11.** Этапы имплантации стент-графта: *a* — стент-графт в системе доставки заведен в модель брюшной аорты; *b* — система спозиционирована ниже устьев почечных артерий (модель); *c* — стент-графт имплантирован в зону аневризмы; *d* — внешний вид изделия, имплантированного в силиконовую модель аневризмы брюшной аорты



*a* *b*

**Fig. 12.** Aortic arch replacement: *a* — stent graft implanted into the aortic arch; *b* — control angiogram of the brachiocephalic trunk
**Рис. 12.** Эндопротезирование дуги аорты: *a* — стент-графт имплантирован в дугу аорты; *b* — контрольная ангиограмма плечеголовного ствола



*a* *b*

*c* *d*

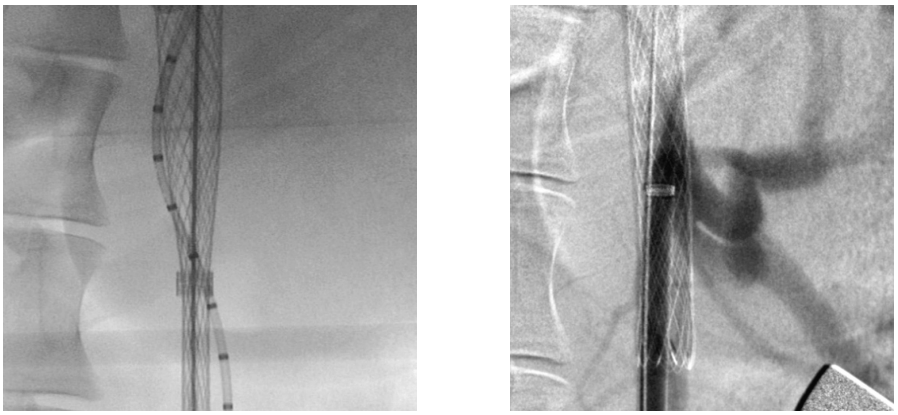
**Fig. 13.** Stages of branching of a stent graft implanted in the aortic arch: *a* — personalized fenestration of the graft wall; *b* — balloon dilatation of fenestration; *c* — discharge module at the mouth of the brachiocephalic trunk; *d* — control angiogram
**Рис. 13.** Этапы бранширования стент-графта, имплантированного в дугу аорты: *a* — персонифицированная фенестрация стенки графта; *b* — баллонная дилятация фенестрации; *c* — отводящий модуль в устье плечеголовного ствола; *d* — контрольная ангиограмма

clearly contrasted without signs of residual stenosis in the fenestrated area (Fig. 17).

All animals survived, and no neurological disorders developed. No problems associated with impaired visceral circulation were recorded. The follow-up of the operated animals lasted 21 days, after which they were sacrificed, and necropsy material was obtained. All structures were passable, and the walls of the grafts were impermeable to liquids, including blood (Fig. 18).

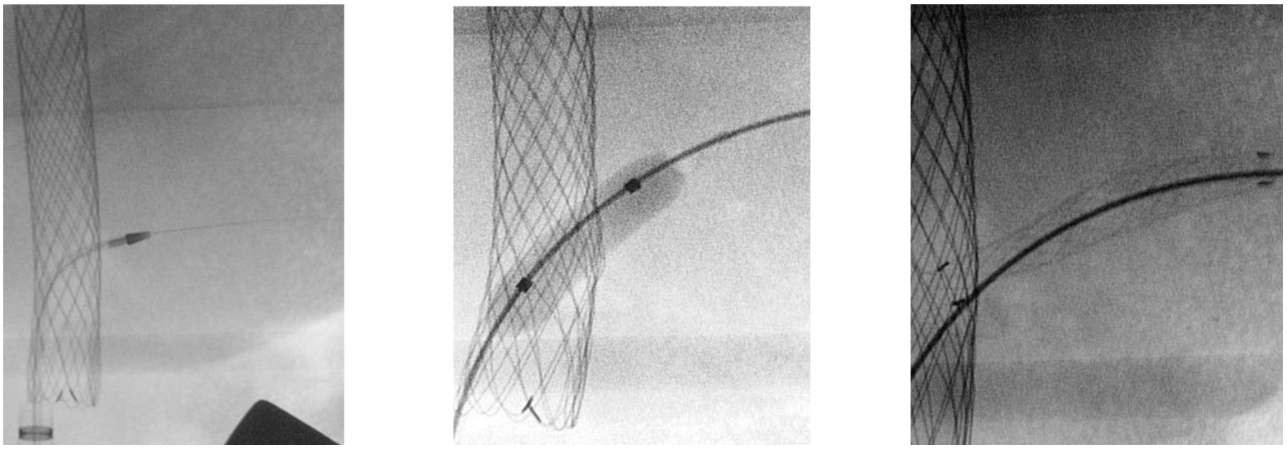
## CONCLUSION

The findings of the experimental studies suggested that the presented product is a prototype of a universal stent graft for the treatment of aortic aneurysms of any location, regardless of the diameter and anatomy of the aorta. The modularity of the frame and its ability to adapt to changes in the diameter and topography of the artery will significantly expand the capabilities of the endovascular



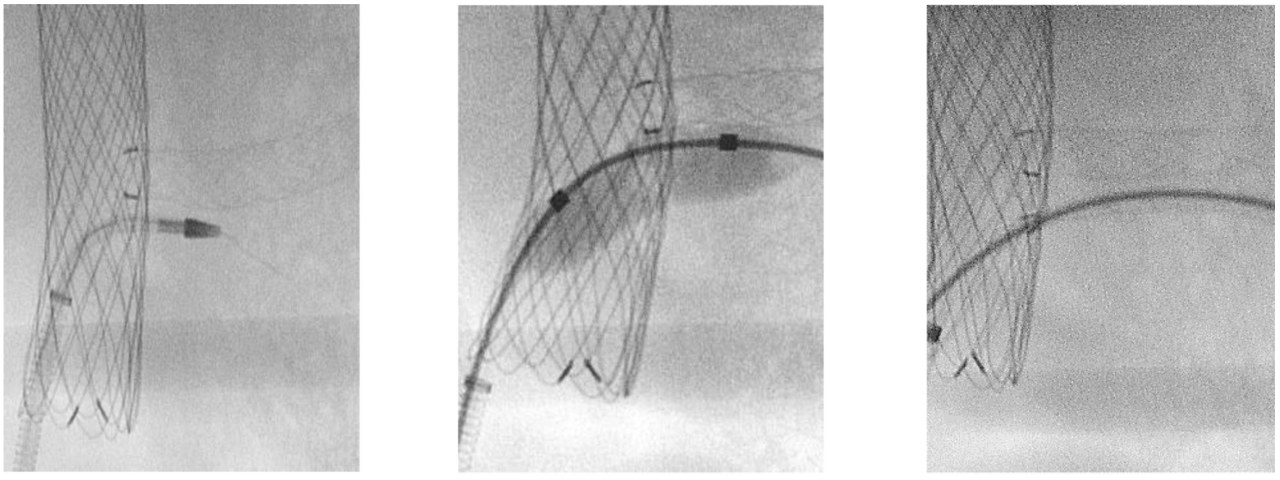
*a* *b*

**Fig. 14.** Endoprosthetics of the suprarenal aorta: *a* — implantation of the main trunk; *b* — control angiogram
**Рис. 14.** Эндопротезирование супраренального отдела аорты: *a* — имплантация основного ствола; *b* — контрольная ангиограмма



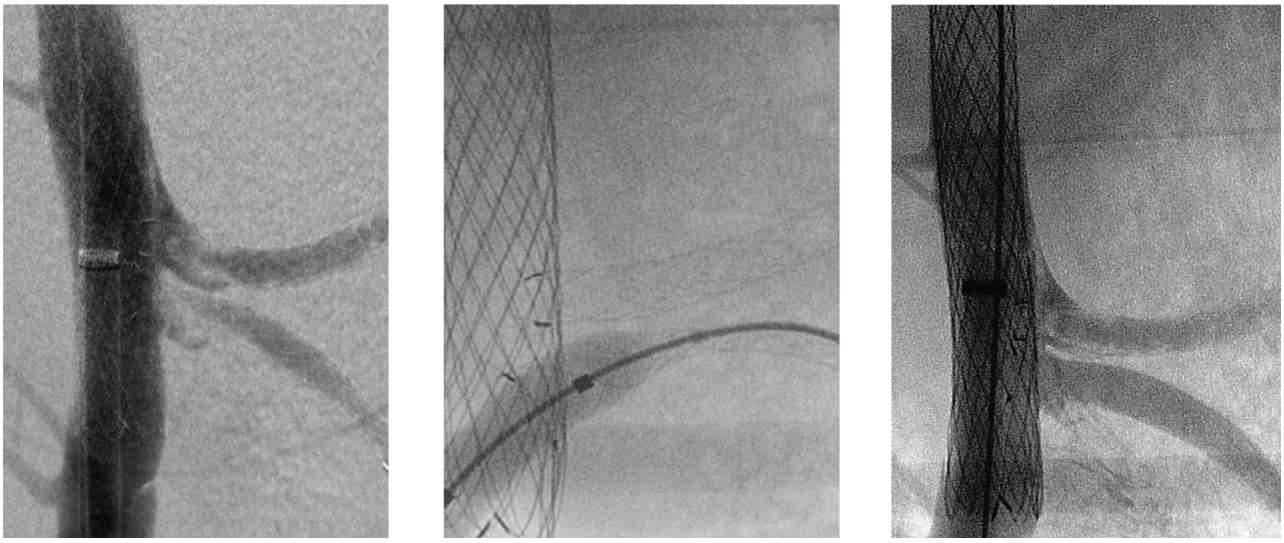
*a* *b* *c*

**Fig. 15.** Branching of the ventral trunk mouth: *a* — personalized fenestration over the ventral trunk mouth; *b* — balloon dilatation of fenestration; *c* — implantation of visceral branching
**Рис. 15.** Бранширование устья чревного ствола: *a* — персонифицированная фенестрация над устьем чревного ствола; *b* — баллонная дилятация фенестрации; *c* — имплантация висцеральной бранши



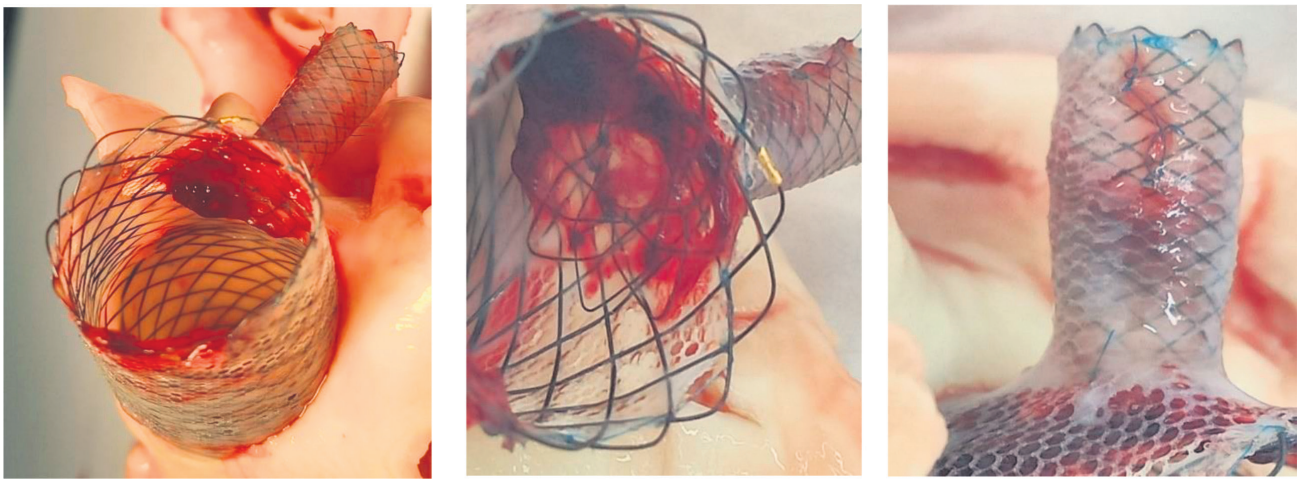
*a* *b* *c*

**Fig. 16.** Stages of endoprosthetics in the suprarenal aorta (continued): *a* — personalized fenestration over the mouth of the superior mesenteric artery; *b* — balloon dilation of the fenestration opening; *c* — implantation of the module into the superior mesenteric artery
**Рис. 16.** Этапы эндопротезирования супраренального отдела аорты (продолжение): *a* — персонифицированная фенестрация над устьем верхней брыжеечной артерии; *b* — баллонная дилатация фенестрационного отверстия; *c* — имплантация модуля в верхнюю брыжеечную артерию



*a* *b* *c*

**Fig. 17.** Angiograms after prosthetics of visceral branches: *a* — control after implantation; *b* — post-dilation of modules; *c* — control snapshot
**Рис. 17.** Ангиограммы после протезирования висцеральных ветвей: *a* — контроль после имплантации; *b* — постдилятация модулей; *c* — контрольный снимок



*a* *b* *c*

**Fig. 18.** Sectional material 21 days after implantation: *a* — main part and the lead module; *b* — fenestration zone of the graft wall; *c* — lead module
**Рис. 18.** Секционный материал через 21 день после имплантации: *a* — основная часть и модуль-отведение; *b* — зона фенестрации стенки графта; *c* — модуль-отведение

technique for treating patients with multilevel thoracic and abdominal aortic aneurysms.

The original design of the stent graft will simplify the positioning and implantation procedure and reduce the length and traumatic nature of the surgical intervention. Owing to the ability of the wall material to control the permeability to blood and the time and degree of ischemia of the internal organs, which blood supply comes from the branches of the aorta entering the implant zone, will be significantly reduced.

## REFERENCES


**1.** Abugov SA, Ponomarenko VB. Aortic aneurysm: diagnosis and treatment. *Therapeutic archive*. 2010;82(9):59–63. (In Russ.).

**2.** Bazhenova YV, Drantusova NS, Shanturov VA, Podashev BI. Computed tomography in the diagnosis of aortic aneurysm. *Siberian medical journal (Irkutsk)*. 2014;130(7):37–41. (In Russ.).

**3.** Belov YV, Rybakov KN, Gubarev IA, et al. Surgical treatment of patients with aortic valve defect in combination with ascending aorta expansion less than 5 cm (literature review). *Moscow Surgical Journal*. 2019;(5):38–45. (In Russ.). DOI: 10.17238/issn2072-3180.2019.5.38-45

**4.** van Puijvelde GHM, Foks AC, van Bochove RE, et al. CD1d deficiency inhibits the development of abdominal aortic aneurysms in LDL receptor deficient mice. *PLoS One*. 2018;13(1):e0190962. DOI: 10.1371/journal.pone.0190962

**5.** Lisina EV, Volkova SYu. Anevrizma aorty kak sluchainaya nakhodka. *Universitetskaya meditsina Urala*. 2019;5(2):62–63. (In Russ.).

**6.** Kuz'michev DE, Skrebov RV, Shakirov II, Vil'tsev IM. Postmortal'naya diagnostika anevrizmy aorty. *Zdravookhranenie Yugry: opyt i innovatsii*. 2019;(1):42–44. (In Russ.).

**7.** Yegemberdiyev TZh, Baubekov AA, Matkherimov AZh, et al. Preventive "before and after" surgical treatment of aortic aneurysms and peripheral arteries (literature review). *Bulletin of surgery in Kazakhstan*. 2018;(2):25–30.

**8.** Gaponov DP, Chernov II, Gorbunov MG, et al. Hybrid surgical procedures of dissected thoracoabdominal aortic aneurysm. *Astrakhan medical journal*. 2014;9(3):130–134. (In Russ.).

**9.** Chupin AV, Deryabin SV, Chigasov VA. Embolization of the internal iliac artery during endovascular repair of abdominal aortic aneurysms. *Angiology and vascular surgery*. 2019;25(4):82–89. (In Russ.).

**10.** Timaran DE, Knowles M, Ali T, Timaran CH. Fenestrated endovascular aneurysm repair among octogenarians at high and standard risk for open repair. *J Vasc Surg*. 2017;66(2):354–359. DOI: 10.1016/j.jvs.2016.11.064

**11.** Manunga J, Sullivan T, Garberich R, et al. Single-center experience with complex abdominal aortic aneurysms treated by open or endovascular repair using fenestrated/branched endografts. *J Vasc Surg*. 2018;68(2):337–347. DOI: 10.1016/j.jvs.2017.11.093

**12.** Arakelyan VS, Papitashvili VG. Aneurysms of the descending thoracic and thoracoabdominal aorta: results of open surgeries. *Annals of Surgery*. 2016;21(5):300–305. (In Russ.). DOI: 10.18821/1560-9502-2016-21-5-300305

**13.** Kawatou M, Minakata K, Sakamoto K, et al. Comparison of endovascular repair with branched stent graft and open repair for aortic arch aneurysm. *Interact Cardiovasc Thorac Surg*. 2017;25(2):246–253. DOI: 10.1093/icvts/ivx111

**14.** Belov YuV, Charchyan ER, Stepanenko AB, et al. Surgical treatment of thoracoabdominal aortic aneurysms. *Pirogov Russian Journal of Surgery*. 2015;(12):33–38. (In Russ.). DOI: 10.17116/hirurgia20151233-38

**15.** Svetlikov AV, Galkin PA. Stentgrafting of aortic aneurysms: past, current situation and future. *The hospital*. 2014;(1):33–40. (In Russ.)

**16.** Shin SH, Starnes BW. Bifurcated-bifurcated aneurysm repair is a novel technique to repair infrarenal aortic aneurysms in the setting of iliac aneurysms. *J Vasc Surg*. 2017;66(5):1398–1405. DOI: 10.1016/j.jvs.2017.02.044

**17.** Gallitto E, Gargiulo M, Faggioli G, et al. Impact of iliac artery anatomy on the outcome of fenestrated and branched endovascular aortic repair. *J Vasc Surg*. 2017;66(6):1659–1667. DOI: 10.1016/j.jvs.2017.04.063

**18.** Lee MJ, Daniels SL, Drake TM, Adam IJ. Risk factors for ischaemic colitis after surgery for abdominal aortic aneurysm: a systematic review and observational meta-analysis. *Int J Colorectal Dis*. 2016;31(7):1273–1281. DOI: 10.1007/s00384-016-2606-6

**19.** Shutze Sr WP, Shutze R, Dhot P, et al. Sex as an independent risk factor for long-term survival after endovascular aneurysm repair. *J Vasc Surg*. 2019;69(4):1080–1089. DOI: 10.1016/j.jvs.2018.07.057


## СПИСОК ЛИТЕРАТУРЫ


**1.** Абугов С.А., Пономаренко В.Б. Аневризма аорты: диагностика и лечение // Терапевтический архив. 2010. Т. 82, № 9. С. 59–63.

**2.** Баженова Ю.В., Драntусова Н.С., Шантуров В.А., Подашев Б.И. Компьютерная томография в диагностике аневризм аорты // Сибирский медицинский журнал (Иркутск). 2014. Т. 130, № 7. С. 37–41.

**3.** Белов Ю.В., Рыбаков К.Н., Губарев И.А., и др. Хирургическое лечение больных пороком аортального клапана в сочетании с расширением восходящей аорты менее 5 см // Московский хирургический журнал. 2019. № 5. С. 38–45. DOI: 10.17238/issn2072-3180.2019.5.38-45

**4.** van Puijvelde G.H.M., Foks A.C., van Bochove R.E., et al. CD1d deficiency inhibits the development of abdominal aortic aneurysms in LDL receptor deficient mice // PLoS One. 2018. Vol. 13, No. 1. ID e0190962. DOI: 10.1371/journal.pone.0190962

**5.** Лисина Е.В., Волкова С.Ю. Аневризма аорты как случайная находка // Университетская медицина Урала. 2019. Т. 5, № 2. С. 62–63.

**6.** Кузьмичев Д.Е., Скребов Р.В., Шакиров И.И., Вильцев И.М. Постмортальная диагностика аневризмы аорты // Здравоохранение Югры: опыт и инновации. 2019. № 1. С. 42–44.

**7.** Yegemberdiyev T.Zh., Baubekov A.A., Matkherimov A.Zh., et al. Preventive "before and after" surgical treatment of aortic aneurysms and peripheral arteries (literature review) // Bulletin of surgery in Kazakhstan. 2018. No. 2. P. 25–30.
**8.** Гапонов Д.П., Чернов И.И., Горбунов М.Г., и др. Гибридное хирургическое лечение расслаивающей торакоабдоминальной аневризмы аорты // Астраханский медицинский журнал. 2014. Т. 9, № 3. С. 130–134.
**9.** Чупин А.В., Дерябин С.В., Чигасов В.А. Эмболизация внутренней подвздошной артерии при эндопротезировании аневризмы брюшной аорты // Ангиология и сосудистая хирургия. 2019. Т. 25, № 4. С. 82–89.
**10.** Timaran D.E., Knowles M., Ali T., Timaran C.H. Fenestrated endovascular aneurysm repair among octogenarians at high and standard risk for open repair // J Vasc Surg. 2017. Vol. 66, No. 2. P. 354–359. DOI: 10.1016/j.jvs.2016.11.064
**11.** Manunga J., Sullivan T., Garberich R., et al. Single-center experience with complex abdominal aortic aneurysms treated by open or endovascular repair using fenestrated/branched endografts // J Vasc Surg. 2018. Vol. 68, No. 2. P. 337–347. DOI: 10.1016/j.jvs.2017.11.093
**12.** Аракелян В.С., Папиташвили В.Г. Аневризмы нисходящего грудного и торакоабдоминального отделов аорты: результаты открытых вмешательств // Анналы хирургии. 2016. Т. 21, № 5. С. 300–305. DOI: 10.18821/1560-9502-2016-21-5-300305
**13.** Kawatou M., Minakata K., Sakamoto K., et al. Comparison of endovascular repair with branched stent graft and open repair for aortic arch aneurysm // Interact Cardiovasc Thorac Surg. 2017. Vol. 25, No. 2. P. 246–253. DOI:10.1093/icvts/ivx111
**14.** Белов Ю.В., Чарчян Э.Р., Степаненко А.Б., и др. Хирургическое лечение больных с торакоабдоминальными аневризмами аорты // Хирургия. Журнал им. НИ Пирогова. 2015. № 12. С. 33–38. DOI: 10.17116/hirurgia20151233-38
**15.** Светликов А.В., Галкин П.А. Эндопротезирование аневризм аорты — новая парадигма в истории сосудистой хирургии или тупиковый путь: прошлое, настоящее и будущее // Клиническая больница. 2014. № 1. С. 33–40.
**16.** Shin S.H., Starnes B.W. Bifurcated-bifurcated aneurysm repair is a novel technique to repair infrarenal aortic aneurysms in the setting of iliac aneurysms // J Vasc Surg. 2017. Vol. 66, No. 5. P. 1398–1405. DOI: 10.1016/j.jvs.2017.02.044
**17.** Gallitto E., Gargiulo M., Faggioli G., et al. Impact of iliac artery anatomy on the outcome of fenestrated and branched endovascular aortic repair // J Vasc Surg. 2017. Vol. 66, No. 6. P. 1659–1667. DOI: 10.1016/j.jvs.2017.04.063
**18.** Lee M.J., Daniels S.L., Drake T.M., Adam I.J. Risk factors for ischaemic colitis after surgery for abdominal aortic aneurysm: a systematic review and observational meta-analysis // Int J Colorectal Dis. 2016. Vol. 31, No. 7. P. 1273–1281. DOI: 10.1007/s00384-016-2606-6
**19.** Shutze Sr W.P., Shutze R., Dhot P., et al. Sex as an independent risk factor for long-term survival after endovascular aneurysm repair // J Vasc Surg. 2019. Vol. 69, No. 4. P. 1080–1089. DOI: 10.1016/j.jvs.2018.07.057

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