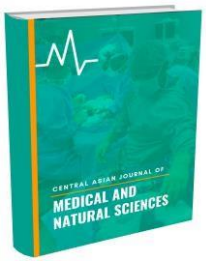

CENTRAL ASIAN JOURNAL OF MEDICAL AND NATURAL SCIENCES
https://cajmns.centralasianstudies.org/index.php/CAJMNS
Volume: 05 Issue: 02 | Mar 2024 ISSN: 2660-4159

Article

Physico-Chemical Properties of the New Domestic Mesh Implant "Niprocel"

Sapaev Duschan Shukhratovich[1], Sadikov Rustam Abrarovich[2], Ruzibaev Rashid Yusupovich[1], Kuryazov Bakhtiyor Nunyazovich[1], Yakubov Farkhod Radjabovich[1], Mardonov Jamshid Normurotovich[2], Khayitboeva Komila Khujayazovna[1]

1. Urgench branch of Tashkent Medical Academy, Republic of Uzbekistan, Urgench
* Correspondence: duschanboy.sapaev@mail.ru
2. Republican Specialized Scientific and Practical Medical Center for Surgery Named after Academician V. Vakhidov, Republic of Uzbekistan, Tashkent

Abstract: The article presents experimental studies on the evaluation of the physico-chemical properties of the new mesh implant "Niprocel". A mesh prosthesis with a composite coating was developed for use in herniology in allogernioplasty of ventral hernias. This series of experiments is a mandatory preclinical study. It has been established that the polypropylene mesh meets the requirements for medical implants in terms of: bioinertness, biocompatibility, adhesion, strength, hemostatic effect, as well as the possibility of sterilization without disturbing the structure and properties.

Keywords: new domestic mesh implant "Niprocel", Herniology, allogernioplasty of ventral hernias, the hemostatic effect

1. Introduction

In modern herniology, the issue of choosing the type of mesh implant remains relevant. The material used should provide both skeletal properties for the anterior abdominal wall and a low risk of developing specific prosthetic complications [1, 2, 3]. It is in this aspect that the development of new materials continues, which must meet the required physico-chemical and biological properties. Reaction to a foreign body is the main risk factor for the development and progression of prosthetic complications [4], [5]. The cascade of possible events may include the formation of long-term recurrent seromas in the area of the prosthesis, wound suppuration, the development of prosthetic fistulas, wrinkling or detachment of the mesh implant [6]. All these complications can lead to a recurrence of a ventral hernia with paraprosthetic hernial gates and (or) significantly reduce the quality of life of patients during the treatment of these problems with an increase in the cost of postoperative rehabilitation [7]. At the same time, the variant of the performed plastic surgery is not of little importance, namely the location of the mesh prosthesis relative to the aponeurosis.

Different schools have different views on this issue, since the choice of allogernoplasty option is influenced by the anatomical features of the hernial defect, the condition of the musculoaponeurotic skeleton of the anterior abdominal wall, and factors such as the type of mesh prosthesis used and the level of qualification of the surgeon. In this aspect,

Citation: Shukhratovich, S. D., Abrarovich, S. R., Yusupovich, R. R., Nunyazovich, K. B., Radjabovich, Y. F., Normurotovich, M. J., & Khujayazovna, K. K. Physico-Chemical Properties of the New Domestic Mesh Implant "Niprocel". Central Asian Journal of Medical and Natural Science 2024, 5(2), 51-59.

Received: 20th Feb 2024
Revised: 1st March 2024
Accepted: 14th March 2024
Published: 22th March 2024

the quality of the prosthesis plays an important role for herniology, and therefore work in terms of improving prosthetic materials continues and is actively discussed [8-12].

An indisputably fundamental point for practical healthcare in any country is the cost of treating patients with ventral hernias, including the cost of the mesh prosthesis itself, especially since the number of such patients does not tend to decrease. Accordingly, an urgent direction for domestic surgery is to optimize the choice of a mesh prosthesis and a type of plastic surgery in terms of reducing the risk of postoperative complications due to the development of a new implant that is not inferior in its properties to foreign analogues.

2. Materials and Methods

The study is based on the study of the physico-chemical properties of the first domestic mesh prosthesis for use in surgery of ventral hernias. According to modern requirements for the development of new medical devices, certain experimental studies are required to introduce them into clinical practice. Upon receipt of positive results of this analysis, the product can be recommended for production, sale and use in clinical surgery.

A group of scientists from the “Republic specialized scientific and practical medical center of surgery named after academician V.Vakhidov” and the Khorezm Regional Multidisciplinary Medical Center developed a new composite coating for a mesh prosthesis, which, with the support of Turon Silk Pharm LLC (Republic of Uzbekistan), was used to create the first domestic mesh implant "Niprocel" for use in herniology in allogernioplasty of ventral hernias.

Active ingredients of the Niprocel implant with composite coating:

- Polypropylene thread;
- Sodium carboxymethylcellulose (Sodium salt of cellulose glycolic acid, CMC, Sodium Carboxyl methyl cellulose) purified);
- Oxidized viscose;
- Calcium chloride "kh/ch";
- Mass obtained from a soluble fraction of collagen in distilled water according to GOST 6709;
- Medical glycerin;
- Methylene blue (blue).

According to the tasks set, the primary research is aimed at describing the characteristics, as well as studying the physico-chemical, biological and bacteriological properties of the new domestic mesh implant "Niprocel".

3. Results and Discussion

According to the developed technology, studies were conducted on the purification and production of highly purified Na-CMC samples from its technical grades. Viscose fiber is extracted by processing natural vegetable cellulose and is considered a modification of cellulose fiber called hydrate cellulose. In our study, the native state of both fibers was assessed using a stereomicroscope (MSP-2 LOMO).

At the same time, the viscose fiber is visually defect-free, smooth, transparent, and the fiber thickness is the same. Cotton cellulose fiber consists of many small fibers and is not smooth. The thickness varies along the length of the thread and varies unevenly.

Production of oxidized viscose by hydrolytic cleavage of viscose in a solution of sodium hypochlorite, powdered viscose with a yield of 50% was obtained. The resulting powdered viscose was further oxidized and bleached with a solution of 4% aqueous hydrogen peroxide solution at various temperatures for 30 minutes. Then the resulting mass was thoroughly washed with water, dehydrated with acetone and dried at a temperature of 80 °C for 2 hours.

When studying the effect of oxidants (oxidizer - 12% sodium hypochlorite solution) on the breakage of the fibers that make up the composite coating, it was found that the breakage of the viscose fiber increases over time, and the effort spent on breaking decreases. compared to cellulose fiber. The results are presented in the Table 1 and in Figure 1.

Under the influence of oxidants, both fibers changed in different ways. Cotton cellulose showed high resistance, the degree of fiber breakage decreased by only 1.5 times in 4 hours. The viscose fiber lost strength 3 times in 3 hours, completely disintegrated by 4 o'clock.

Table 1. The effect of oxidants (12% sodium hypochlorite solution) on fiber breakage

Fiber	Initial adhesion strength (Pa)	30 minutes	60 minutes	90 minutes	2 hours	3 hours	4 hours	5 hours	10 hours	15 hours	20 hours
Cellulose (gauze)	512	498	495	490	427	366	303	292	241	194	101
Viscose	114	97	85	74	52	28	complete breakdown of the fiber				

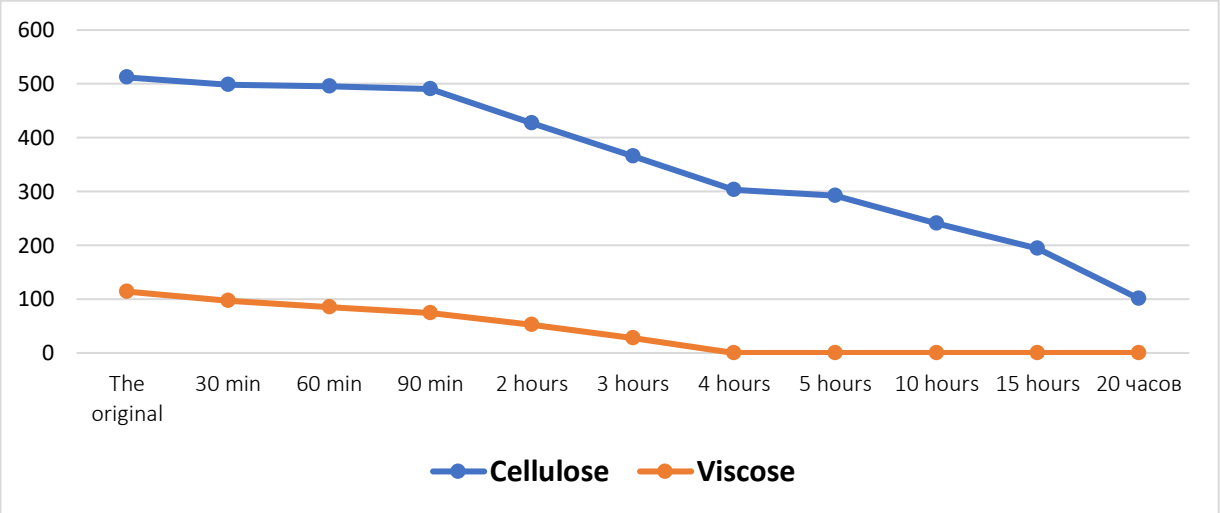

Figure 1. The change in the fiber rupture index over time under the action of an oxidizer (sodium hypochlorite 12%)

As a result of the tests, it was found that the adhesive ability of the viscose composite material is equal to 961 pascal (Pa). In the visual and stereomicroscopic evaluation of the new composite coating, as mentioned above, when examining the cross-section of a viscose composite film under a microscope, it can be seen that the fibers are located in the middle of the composite film and they form a single whole with other components. The process of preparing and constructing a viscose composite film took an average of 25 hours. A sample of the composite mesh is shown in Figure 2.

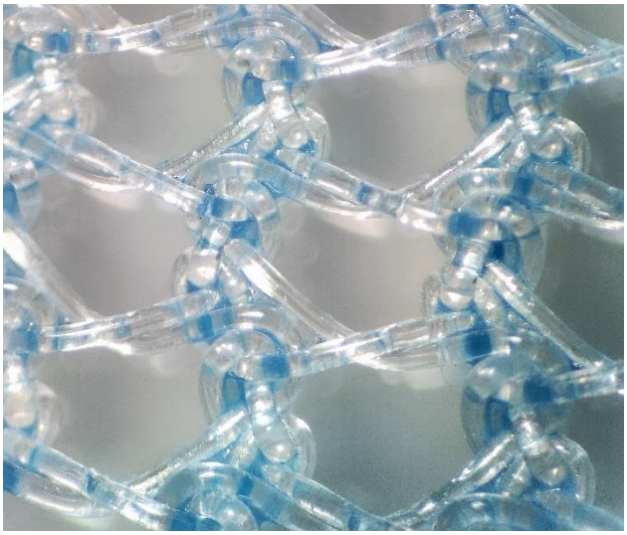

Figure 2. A sample of the Niprocel composite mesh. The mesh is composite with a multi-component polymer coating. StM 10x4

To create a composite coating, the physico-chemical characteristics of viscose fiber and cellulose fiber (medical gauze) were checked and an experimental and morphological assessment was given.

The main physico-chemical characteristics of the Niprocel composite mesh:

1) Physical examinations: The adhesion of the composite material. At the same time, the rules of practice for calculating the adhesive ability of a composite material were developed. The results obtained were calculated using the following formula: adhesive strength (F): F= mg. Here m is the mass, g is the acceleration of gravity of 9.8 m2/s. Then the stickiness was calculated: F/S. Ra (Pascal) was chosen as the unit of measurement.
2) Chemical Research: In this study, we analyzed the effect of oxidants on the rate of fiber rupture. The strength of fibers tested with oxidants was evaluated over time. A 12% solution of sodium hypochlorite was used for the study. Equal amounts of viscose and cellulose (gauze) fibers were taken, a solution of sodium hypochlorite was added to them and the degree of breakage was measured. The tensile strength was measured first every 30 minutes to 2 hours, then every 1 hour to 5 hours, and then every 5 hours. The results were studied in the form of a comparative table.

The main medical requirements for the polymer material were: adhesion strength, tensile strength, hemostatic activity. Studies have found that the adhesion required for medical purposes should ensure a tight fit to the wound surface, which ultimately provides an instant hemostatic effect. Comparative studies of the adhesion of the obtained Niprocel implant with analogues are shown in Figure 3. A comparative assessment of the adhesiveness of other polymer materials has shown that the adhesion of the Niprocel implant is comparable to No. aCMC, however, the latter is of little use for hemostasis purposes, since it dissolves quite quickly on a wet surface.

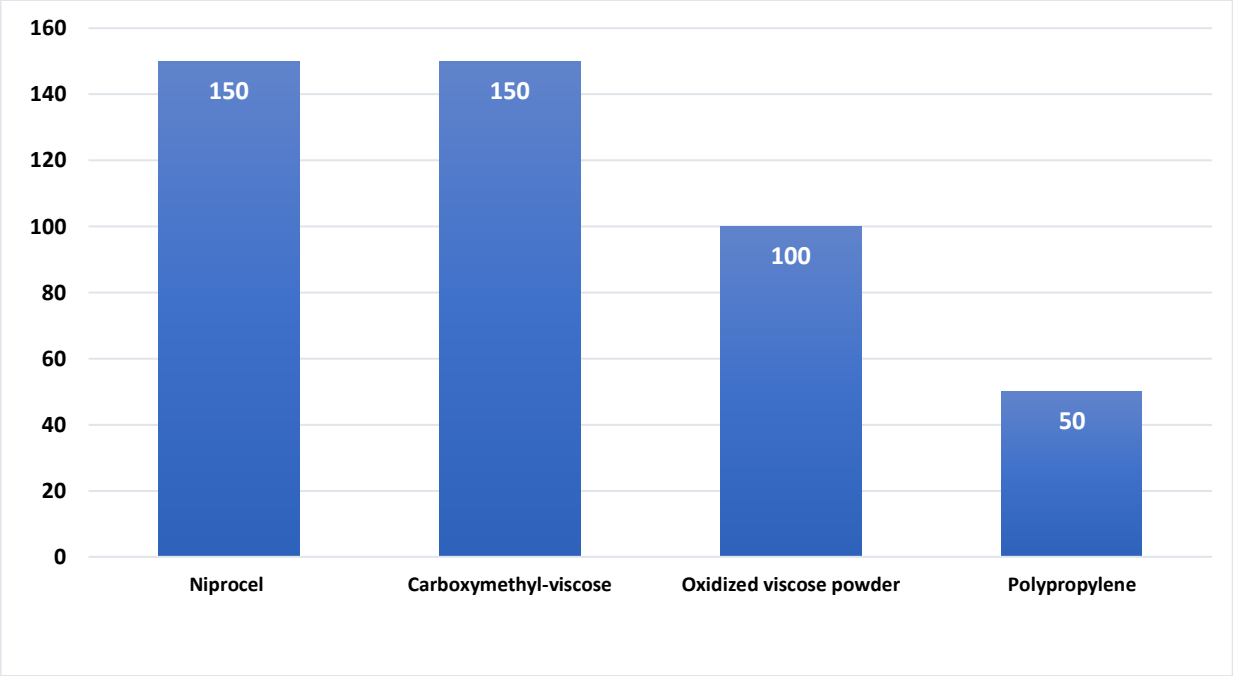

Figure 3. Investigation of the adhesion of the composite mesh. High adhesion of Niprocel in the range of 0.0076±0.00016 n/cm²

According to comparative studies, it has been established that Niprocel has a sufficiently high strength, which fully meets the requirements for implants of this kind. The study of the tensile strength of a composite mesh: Niprocel-tensile strength in the range of 290 – 480 kGf/cm².

Assessment of the hemostatic activity of the composite mesh in vitro. APTT (activated partial thromboplastin time) is a basic technique for studying hemostasis, gives an idea of the state of factors of the internal pathway of activation of X factor (YIII, IX, XI). In control plasma samples, the APTT was 38.3±2.3 seconds. In the presence of Na-Ca-CMC film, APTT shortened by 2.1 times; in the presence of oxidized cellulose, it did not significantly change ($p>0.05$), and in the presence of Niprocel, it shortened by 1.9 times compared with the control. The results indicate activation of factors of the internal mechanism of blood coagulation, adsorption and inactivation of factors in the presence of a film (Table 2).

Table 2. Evaluation of the hemostatic activity of the implant

No	Type of research	APTT, s	Prothrombin time, s	Fibrinogen, mg	Blood clotting time, min
1	Control, P1	38,3±2,3	14,2±0,8	3800±12	9,8± 0,6
2	Film, R2	18,2 ±1,7	4,5±0,2	3500±43	6,4±0,4
3	Niprocel, P3	20,1 ±0,8	6,1± 0,4	3700±32	2,4±0,6
4	P1:2	<0,05	<0,05	>0,05	<0,05
5	P1:3	<0,05	<0,05	>0,05	<0,05
6	P 2:3	>0,05	<0,05	>0,05	<0,05

Prothrombin time allows you to evaluate the factors of the prothrombin complex – II, Y, YII, X. In control plasma samples, the prothrombin time was 14.2±0.8s. In the presence

of the Na-Ca-CMC film, APTT shortened by 3.1 times, in the presence of Niprocel - by 2.8 times, in the presence of oxidized cellulose - it did not significantly change.

The fibrinogen content with the addition of film, oxidized cellulose and Niprocel did not significantly differ from that in the control plasma. The obtained results of ARTT shortening together with prothrombin time indicate activation of blood clotting in general, both by internal (with the participation of YIII IX XI factors) and by external mechanism (with the participation of YII factor) with activation of the entire prothrombinase complex (II, V, X). The effect of the film may be due to the presence of calcium ions – IV plasma factor involved in all phases of coagulation hemostasis. Niprocel also contains bound calcium, which causes the effect of increased blood clotting.

In the presence of a polymer, the blood clotting time according to Lee-White was shortened by 2.1 times relative to the control, which was 2.4 ± 0.6 minutes; in the presence of a film, it was shortened. The results indicate the activation of blood clotting in the presence of oxidized cellulose due to the transition of plasma to a gel-like state, which is probably due to the physico-chemical properties of oxidized cellulose. At the same time, oxidized cellulose does not have an activating effect on plasma coagulation factors.

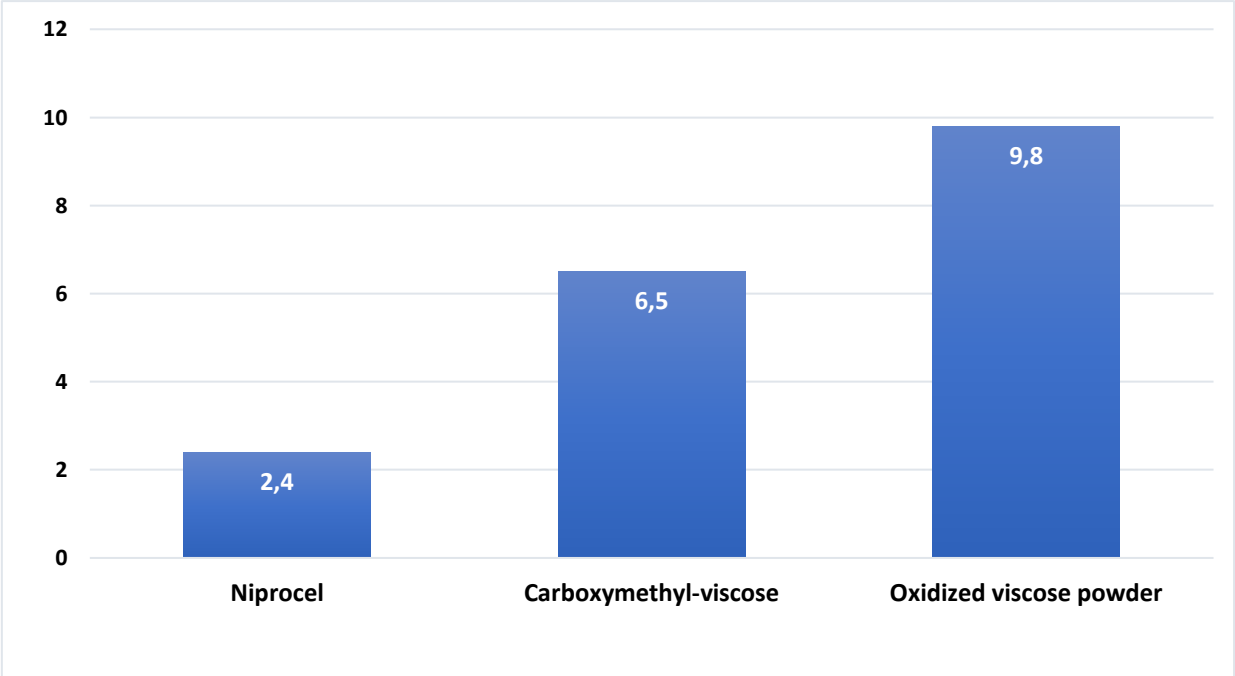

Figure 4. Evaluation of hemostasis of the implant. High hemostatic activity of the Niprocel mesh (2.4±0.6 min)

The results obtained indicate an increase in the coagulation process of donor blood in vitro in the presence of a polycompositional polymer based on cellulose derivatives, possibly due to the activation of factors involved in both the external and internal pathways of coagulation hemostasis. The presence of similar properties in the Niprocel polymer opens up the prospect of its use as a hemostatic implant in surgery.

Thus, the conducted studies have shown that in the presence of a polycompositional polymer based on Niprocel cellulose derivatives, the total coagulation activity of whole blood in vitro increases, which indicates the presence of hemostatic properties in this implant.

4. Conclusion

Taking into account the experience of creating mesh implants, it can be concluded that the most effective of them are represented by polypropylene filaments. Their main disadvantage is the lack of adhesion to the tissues of the body, the high risk of infection between the nodes of the grid. Broad-spectrum antibiotics are added to such implants to impart antimicrobial properties, however, the growth of resistance of microorganisms significantly limits the effectiveness of such antimicrobial coatings.

To solve the tasks set: to enhance the adhesion of the mesh to tissues, to provide a hemostatic effect, as well as to impart antimicrobial activity, we have developed a composite coating on a polypropylene mesh. Studies of the physico-chemical composition have shown the compatibility of these ingredients, the simplicity of the method of applying the composite coating, as well as the possibility of providing a multifunctional effect on surrounding tissues and microbes.

The coating created from a polycomposite polymer material has the ability to biodegradate in a certain period of time, gives the mesh implant new properties: it enhances the adhesion of the mesh to tissues, which allows to significantly prevent corrugation and deformation of the implant on the surface of tissues. Hemostatic properties make it possible to prevent the accumulation of hematomas and seromas in the area of mesh implantation. The inclusion of methylene blue in the coating, in addition to its own antimicrobial effect, will allow for photodynamic effects, which significantly increases antimicrobial activity, even against antibiotic-resistant strains of microorganisms. The neutral pH of the composite coating reduces the risk of increased aseptic inflammation in the wound.

According to research data, the developed implant has characteristics comparable to foreign analogues in terms of bioinertness, shelf life, and is characterized by greater hemostatic activity, adhesion, and relative cheapness of the technological process. The above allows us to start “in vivo” research to evaluate the effectiveness of the implant.

Polypropylene mesh meets the requirements for medical implants in terms of: bioinertness, biocompatibility, adhesion, strength, hemostatic effect, as well as the possibility of sterilization without disturbing the structure and properties. The commercial availability of products is due to the fact that local raw materials are used in production.

REFERENCES

[1] Белоусов А.М., Армашов В.П., Шкарупа Д.Д. Безопасность сетки с фторполимерным покрытием при интраабдоминальном размещении у крупных животных: результаты пилотного исследования. Хирургия (Москва). 2023;(2):43-58.

[2] Деговцев Е.Н., Колядко П.В. Диагностика и лечение сером после герниопластики передней брюшной стенки с использованием сетчатого импланта. Ж. Хирургия (Москва). 2018;(1):99-102.

[3] Сажин А.В., Ивахов Г.Б., Андрияшкин А.В., Мадумаров В.А., Никишков А.С. Эндоскопическая ретромускулярная аллопластика при первичных и послеоперационных вентральных грыжах: наш первоначальный опыт. Ж. Хирургия (Москва). 2018;(6):62-65. Russian. doi: 10.17116/hirurgia2018662-65.

[4] C. D. Brandi, S. Roche, S. Bertone, and M. E. Fratantoni, “No enterocutaneous fistula development in a cohort of 695 patients after incisional hernia repair using intraperitoneal uncoated polyproylene mesh,” *Hernia*, 2017, doi: 10.1007/s10029-016-1530-6.

[5] H. Hoffmann, F. Köckerling, D. Adolf, F. Mayer, D. Weyhe, and ..., “Analysis of 4,015 recurrent incisional hernia repairs from the Herniamed registry: risk factors and outcomes,” *Hernia*, 2021, doi: 10.1007/s10029-020-02263-x.

[6] M. O. Jakob, D. Spari, J. Zindel, T. Pinworasarn, and ..., "Prophylactic, synthetic intraperitoneal mesh versus no mesh implantation in patients with fascial dehiscence," *Journal of …*, 2018, doi: 10.1007/s11605-018-3873-z.

[7] A. Kohler, J. L. Lavanchy, U. Lenoir, A. Kurmann, and ..., "Effectiveness of prophylactic intraperitoneal mesh implantation for prevention of incisional hernia in patients undergoing open abdominal surgery: a randomized …," *JAMA …*, 2019, [Online]. Available: https://jamanetwork.com/journals/jamasurgery/article-abstract/2714605

[8] J. Ahmed, N. Hasnain, I. Fatima, F. Malik, M. A. Chaudhary, and ..., "Prophylactic mesh placement for the prevention of incisional hernia in high-risk patients after abdominal surgery: a systematic review and meta-analysis," *Cureus*, 2020, [Online]. Available: https://www.cureus.com/articles/40157-prophylactic-mesh-placement-for-the-prevention-of-incisional-hernia-in-high-risk-patients-after-abdominal-surgery-a-systematic-review-and-meta-analysis.pdf

[9] Y. F. Radjabovich, S. D. Shukhratovich, and ..., "Modern Aspects of Prevention of Hernias of the Linea Alba of the Abdomen After Laparotomy," *… Journal of Trauma …*, 2023, [Online]. Available: http://journals.academiczone.net/index.php/rjtds/article/view/702

[10] F. R. Yakubov, D. S. Sapaev, and ..., "Modern Approach to Effective Drainage of Postoperative Injury in Large and Complex Ventral Hernias," *Journal of …*, 2023, [Online]. Available: http://journals.academiczone.net/index.php/jiphr/article/view/797

[11] F. R. Yakubov, D. S. Sapaev, K. B. Allaberganov, and ..., "Results of effective postoperative wound drainage in large and complex ventral hernia," *European journal of …*, 2023, [Online]. Available: http://www.inovatus.es/index.php/ejmmp/article/view/1632

[12] F. R. Yakubov and D. S. Sapaev, "Surgical treatment of liver echinococcosis," *J Med Life*, 2022, [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9762364/

[13] S. Gallinetti, "Titanium reinforced calcium phosphate improves bone formation and osteointegration in ovine calvaria defects: A comparative 52 weeks study," *Biomedical Materials (Bristol)*, vol. 16, no. 3, 2021, doi: 10.1088/1748-605X/abca12.

[14] M. Blumer, "Customized Titanium Reconstruction of Orbital Fractures Using a Mirroring Technique for Virtual Reconstruction and 3D Model Printing," *Journal of Oral and Maxillofacial Surgery*, vol. 79, no. 1, p. 200, 2021, doi: 10.1016/j.joms.2020.09.001.

[15] F. Zhang, "Expert consensus on the bone augmentation surgery for alveolar bone defects," *Journal of Prevention and Treatment for Stomatological Diseases*, vol. 30, no. 4, pp. 229–236, 2022, doi: 10.12016/j.issn.2096-1456.2022.04.001.

[16] S. N. Eiger, "Congenital sternal defect repair in an adult cat with incomplete pentalogy of Cantrell," *J Am Vet Med Assoc*, vol. 254, no. 9, pp. 1099–1104, 2019, doi: 10.2460/javma.254.9.1099.

[17] K. A. Akilov, "evAluAtion of the effectiveness of A new method of suRgicAl tReAtment of RectAl pRolApse," *Grekov's Bulletin of Surgery*, vol. 182, no. 3, pp. 47–53, 2023, doi: 10.24884/0042-4625-2023-182-3-47-53.

[18] S. A. Makarov, "The place of laparoscopic IPOM in the surgical treatment of median ventral hernias: lessons from seven years of prospective experience. Long-term results," *Endoscopic Surgery*, vol. 28, no. 3, pp. 22–31, 2022, doi: 10.17116/endoskop20222803122.

[19] V. Parshikov, "Inflammatory complications of the abdominal wall prosthetic repair: Diagnostics, treatment, and prevention (review)," *Sovremennye Tehnologii v Medicine*, vol. 11, no. 3, pp. 158–178, 2019, doi: 10.17691/stm2019.11.3.19.

[20] Y. Liang, "Adhesive Hemostatic Conducting Injectable Composite Hydrogels with Sustained Drug Release and Photothermal Antibacterial Activity to Promote Full-Thickness Skin Regeneration During Wound Healing," *Small*, vol. 15, no. 12, 2019, doi: 10.1002/smll.201900046.

[21] S. J. Connolly, "Full study report of andexanet alfa for bleeding associated with factor Xa inhibitors," *New England Journal of Medicine*, vol. 380, no. 14, pp. 1326–1335, 2019, doi: 10.1056/NEJMoa1814051.

[22] P. N. Romashchenko, "JUSTIFICATION AND DIRECT RESULTS OF ENDOSCOPIC GYNRYOPLASTICS WITH TAPP AND TEP TECHNIQUES," *Vestnik Rossijskoj Voenno-Medicinskoj Akademii*, vol. 21, no. 1, pp. 125–129, 2019, doi: 10.17816/brmma13064.

[23] H. Kulacoglu, "Most cited 100 articles in herniology: Bibliometric study," *International Journal of Abdominal Wall and Hernia Surgery*, vol. 2, no. 3, pp. 96–104, 2019, doi: 10.4103/ijawhs.ijawhs_18_19.

[24] Y. Liang, "Mussel-inspired, antibacterial, conductive, antioxidant, injectable composite hydrogel wound dressing to promote the regeneration of infected skin," *J Colloid Interface Sci*, vol. 556, pp. 514–528, 2019, doi: 10.1016/j.jcis.2019.08.083.

[25] I. A. Tarasova, "Enhanced recovery after surgery programs in herniology," *Russian Journal of Evidence-Based Gastroenterology*, vol. 10, no. 4, pp. 57–66, 2021, doi: 10.17116/dokgastro20211004157.

[26] A. V Sazhin, "Current concepts of ventral hernia surgery," *Novosti Khirurgii*, vol. 28, no. 6, pp. 714–729, 2020, doi: 10.18484/2305-0047.2020.6.714.

[27] R. K. Azimov, "Titanium mesh implants in herniology," *Khirurgiia (Sofiia)*, no. 12, pp. 126–131, 2019, doi: 10.17116/hirurgia2019121126.

[28] V. V Boyko, "Comorbid pathology in herniology," *Emergency Medicine (Ukraine)*, vol. 17, no. 1, pp. 14–20, 2021, doi: 10.22141/2224-0586.17.1.2021.225709.

[29] H. Kulaçoğlu, "Most cited 100 articles from Turkey on abdominal wall hernias: A bibliometric study," *Turk J Surg*, vol. 36, no. 2, pp. 180–191, 2020, doi: 10.5578/TURKJSURG.4536.

[30] J. Škach, "Current view on prostheses in herniology (hernia meshes) - classifications, indications, advantages and disadvantages of different implants, complications J. Skach, M. Slamborova, V. Blecher, P. Hromadka, R. Gurlich," *Rozhl Chir*, vol. 98, no. 3, pp. 85–99, 2019.