

Article

Summary of Results of the Allohernioplasty in Postoperative Ventral Hernias

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Abstract: The problem of selection the type of mesh implant is actual in herniology for today. The work is dedicated to clinical and experimental testing of the new domestically made mesh implant with complex emulsion covering Niprocel" taking into account the developed operations with using it – corrective allohernioplasty. A scientific team of Health Sciences, The Republic specialized scientific and practical medical center of surgery named after academician V.Vakhidov and Khorezm Regional Multidisciplinary Medical Center created a new composite cover for mesh prosthesis. The clinical trials involved 239 participants with postoperative ventral hernias. All patients were divided into 2 groups: the main group (n=97) was made up of those who underwent uneven allohernioplasty with a new type domestic mesh prosthesis. The control group consisted of 142 patients who underwent the allohernioplasty using conventional prostheses (Eafil, Prolen). The first clinical trials of the original domestic polypropylene endoprosthesis with a complex "Niprocel" membrane demonstrated full correlation of experimental and practical data. Comparative evaluation of the clinical efficacy of allohernioplasty with the use of the developed mesh prosthesis indicated that bioinertion, combined with hemostatic-lymphostatic effects and a reparative potential of the created composite coating, decreases probability (13.1%) development of local reactive changes against an implant which ensured higher indices in life quality after surgery and also more frequency good results.

Keywords: Niprocel, Herniology, Corrective Allohernioplasty, Quality of Life Analysis

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1. Introduction

Today the issue of the choice of type of mesh implant is still open in modern herniology. The ideal material is required to restore both skeleton properties of the anterior abdominal wall and mechanical prosthetic complications [1-2-3]. It is as such that new materials are still being developed, which have to present suitable physico-chemical and biological properties.

The following issues can be observed in the area of open questions: Despite the benefits of contemporary plastic surgery techniques, there is a high risk for postoperative complications following such operations which results in considerable physical and psychological trauma to patient and influences the quality of life [4]. An increasing diversity of unprecedented non-communicable and infectious complications related to the massive use of nets has posed several challenges to clinicians [5]-[7]. These complications include inflammation, wound healing issues, chronic pain, seromas and adhesions along with those of mesh migration and implant rejection [8-9-10]. Prosthesis

materials continue to be interpreted as a foreign body by the host, leading to an accumulation of inflammatory reactions [10]. Various prostheses have their limitations, which range from the frequency of prosthesis-complications to the pricing-policy of modern implants [11-12].

Thus it remains a critical issue to develop polymer whose architecture improve the biocompatibility and reduce the cost as soon as possible.

2. Methodology

A team of researchers at the center of the Republic's specialized scientific and practical medical center for surgery named after academician V.Vakhidov and Khorezm regional multidisciplinary medical center developed a new composite coating for mesh prosthesis, which with financial assistance of Turon Silk Pharm LLC (Republic of Uzbekistan) was used in creation of the first domestic mesh implant "Niprocel" designed to be applied in herniology as allohernioplasty when carrying out operative treatment for ventral hernias.

Active substances of Niprocel implant with composition coating: polypropylene thread; Carboxymethylcellulose sodium salt (CMC-Na) purified (sodium carboxy methyl cellulose or the Sodium salt of cellulose glycolic acid, CMC, Sodium Carboxyl methyl celluloses); oxidized viscose; Chloride Calcium "kh/ch"; Mass received from a soluble collagen fraction in the distilled water on GOST 6709; Medical glycerin; Methylene blue (blue).

Considering that modern herniology has not abandoned the active use of plastic surgical technique with fixation of the prosthesis in onlay position, which is associated with a greater frequency of paraprosthetic complications, clinical trials for the new implant were initially performed in this category. The patients also had improved combined alloplasty of the hernia of the anterior abdominal wall.

The method is performed as follows:

- mobilization and isolation of the hernial sac, as well as the hernial gates;
- then, longitudinally dissecting the hernial sac to expose the contents of it along a conditional longitudinal boundary line between 1/3 and 2/3 of wall walls of the hernial sac, after which material in the hernial sac is mobilized and placed in an abdominal cavity;
- on the side of the entire remaining portion (2/3) of the dissected hernial sac, anterior abdominal wall is mobilized by aponeurosis no less than 5 cm inwards from an edge of herniae gate;
- after that, the synthetic mesh prostheses (SMP) of proportions corresponding to the volume of planned plastics is superimposed on mentioned above free edge of wall dissected hernial bag, one side edges are brought under skin flap at selected area aponeurosis and other its edge from free leaf peritoneum divorcing from painted hepato biliary system raised up by prosthesis in positions so that it was possible to put a bend them into each other turnings of peritoneum (from 2/3rd parts) and latter stitches insertions along this two stuck-together turnings with continuous sutures vycril 3.0;
- then from the side of the formed duplication poluparitoea SMP, at a distance of 4-5 cm from the edge of hernial gate ellipse unravel the parietal peritoneum parallel to manhole priority, remove it from forming chord through hole with formation up on 1b wide area between dissection edge and SMP Polkovnikova grafting to pripriate vagina rectus abdominis the leaf (endow sublay method) treated intestinosuture material in a continuous continuos;

- the top edges of the hernial gate are sutured to each other with at least 3 cm length, zone of prosthesis fabric is in sewing process, the bottom edges of the gate are also sutured;
- after which the remaining free edge of the SMP is sutured onto the anterior aponeurosis wall surface (onlay method) with a 2/0 continuous suture;
- the residual peritoneal free flap on the side of reinforcement of prosthesis to the posterior vaginal sheet of rectus abdominis muscle is sutured over this SMP over latter with continuous 3/0 vicryl suture;
- After cleaning the wound, tap water is introduced into it; then rubbed through contrapperture (to outside): subcutaneous tissue and skin are sutured.

The trials involved 239 patients carrying a postoperative ventral hernia. All the patients were divided into two groups: basic (n=97) and comparison group underwent allohernioplasty with application of new domestic mesh in the first--group included. The comparison group consisted of 142 patients, in whom allohernioplasty was applied with the conventional prostheses (Esfil, Prolen). In the comparison group the number of patients with reconstructive plastic surgery with Onlay mesh fixation was 85, in the main group--48, Number of patients with Reconstructive Plastic Surgery on an Onlay mesh fixation-14 and 12 respectively and corrective plastic surgery--43 and 37 patients.

More than 75% of the patients were between 31 and 60 years old; in the comparison group, they constituted 66.9% women, and in the main one, 66%. The proportion of men accounted for respectively 33.1% and 34%. According to the distribution of patients by the Toskin and Zhebrovsky classification, average hernias were in 22.5% of cases among patients of comparison group vs 18.6% in the main group; extensive -in 50.7% vs 51.5%, giant – in 26.8 % and 29.9%.

There were 130 median hernias in the comparison group and 87 in the main group, lateral hernias in 12 and 10. The small caliber gates in only 4 (2.8%) and 3(3.1%) patients were also thinning, the average size was watched in 96 (67.6%) and 64 (66.0%), the large ones formed in 42(29.6%) and 30(30.9%). Primary postoperative hernia in the comparison and main groups was detected respectively, in 127 (89.4%) and 87 (89.7%) patients. The other patients experienced one to three relapses. Occurrence of postoperative ventral hernias was observed after surgical procedures on gastroin-testinal tract and pelvic organs.

3. Results and Discussion

In the first clinical studies of a new national mesh implant with composite "Niprocel" coating, full conformity to experimental data was demonstrated. Based on the mesh prosthesis properties, higher-grade of its engraftment and decrease in rate of certain prosthetic complications was observed. The hemostatic function of the composite coating was demonstrated, characterized by normalization of risk for development of hematoma (2.1% in comparison). Another significant feature of the implant was a decrease of reaction of surrounding tissues to the foreign body (mesh prosthesis) due to combined covering, and together with haemostatic and therefore lymphostatic action reduced occurrence of exudative manifestations from the wound (2.8% in comparison group) as well as fluid accumulation in serous cavity - seroma formation, from 30.3% to 11.3%, formation Inflammatory infiltration in subcutaneous fat layer from 10.6% up to 4.1%. These properties made it possible to reduce the overall incidence of local wound complications in the early period after allogernoplasty from 34.5% to 13.4% ($\chi^2=13.362$; Df=1; $p<0.001$). In turn, with regard to the clinical significance of serous accumulations in the wound, the developed domestic mesh implant allowed not only to reduce the risk of their formation, but also provided a reduction in the need for additional manipulations (in most cases repeated) for their evacuation from 16.2% to 3.1%, respectively, the frequency of seromas resolved independently was 14.1% in the group comparison and 8.2% in the main group,

which together with the proportion of patients without seroma (69.7% and 88.7%) significantly improved the immediate results of allohernioplasty due to the use of the proposed mesh prosthesis ($\chi^2=13.445$; Df=2; p=0.002)[13].

Considering the histological structure and clinical significance of proven prosthetic complications, extra-local conservative therapy was indicated in a part of patients from the compared series (1.4%) for its treatment, while minimally invasive intervention in 12.7% of patients by this group (in main one amounting to only 3.1%), that along with the rate independently resolved complications (20.4%, and respectively 10.3%) are evidence about higher quality engraftment in main group ($\chi^2=14.468$; Df=3; p=0.003). This conclusion was also confirmed by dynamic indicators for the regression of pain intensity from 7.7 ± 1.1 to 6.0 ± 1.0 points on the second day in the comparison group and in the main group from 7.4 ± 1.1 to 5.4 ± 1.1 points (t=4.29; p<0.05), and on the fifth day this indicator was 3.8 ± 0.8 vs. 2.3 ± 1.3 points (t=9.65; p<0.05). Another factor confirming the good biological properties of the proposed mesh implant was the achieved reduction in the average amount of drainage discharge, which was 105.7 ± 24.4 ml on day 1 in the comparison group and 71.9 ± 33.2 ml in the main group (t=7.86; p<0.05), 82.9 ± 19.6 vs. 52.0 ± 26.9 ml on day 3 (t=7.31; p<0.05) and on day 5 39.2 ± 17.9 versus 25.8 ± 9.5 ml (t=3.20; p<0.05), as well as a reduction in the drainage period from 4.0 ± 1.7 to 3.1 ± 1.2 days (t=4.94; p<0.05) and the duration of the postoperative hospital stage from 8.5 ± 2.2 to 6.8 ± 1.5 days (t=7.01; p<0.05)[14-15].

In reconstructive operations the application of the developed composite-coated implant enabled us to reduce wound complications overall rate, when fixing the mesh implant in Onlay position from 40.4% to 18.3% ($\chi^2=8.353$; Df=1; p=0.004), including levelling such their manifestations as effusion from the wound (3.0% in comparison group), hematomas, divergence of edges and suppurative ones (2.0% each in comparison group) and also decrease among them seromas frequency which required evacuation from 13.1% up to 5.0%, collections of serous fluid themselves—from 36.4% up to 16.7%, among which required evacuation 20.2%, whereas only in every fifth five percent in main group and on this background for handling respectively) ($\chi^2=8.530$; Df=2; p=0.015).

A new issue of the allohernioplasty technique, based on the application of a domestic implant "Niprocel" for allogeneic transplantation and additional technical solutions reduction concerning development without effect on the infectious aspect of endogenous reaction to a foreign body, provided to decrease frequency of prosthetic complications in near-perspective period from 20.9% up to 5.4% ($\chi^2=4.042$; Df=1; p=0.045), in the structure of which a decrease was achieved the proportion of seroma formation increased from 16.3% to 2.7% ($\chi^2=4.073$; Df=1; p=0.044), while in the comparison group in 7.0% of cases it was necessary to evacuate these clusters, in the main group the volumes of seroma did not require additional manipulations.

The analysis of long-term complications showed that the introduction into clinical practice of the new domestic mesh implant "Niprocel" allowed to reduce the frequency of specific complications from 22.5% to 6.2% ($\chi^2=11.521$; Df=1; p<0.001), in the structure of which the leveling of complications such as the formation of cutaneous prosthetic fistulas was noted (2.8% in the group comparison), wrinkling or displacement of the prosthesis (2.1%) and paraprosthetic hernia (1.4%), as well as a significant decrease in the proportion of seromas – from 18.3% to 4.1% ($\chi^2=11.761$; Df=5; p<0.05), and the distribution of serous clusters by clinical significance showed that in the comparison group the presence of fluid accumulations that do not require treatment (type 0b-IIb) were verified in 13.4% of cases, and in the main group - 4.1%, and seromas requiring minimally invasive treatment (type III-IV) occurred in 4.9% of cases in the comparison group ($\chi^2=11.239$; Df=2; p=0.004).

In general, by groups, complications requiring follow-up in dynamics were detected in 14.1% of patients in the comparison group and 5.2% in the main group, requiring local conservative treatment in 1.4% and 1.0% of patients, while in the comparison group complications developed that required minimally invasive treatment - 5.6% or repeated

surgery - 1.4%, In total, 77.5% of patients in the comparison group and 93.8% in the main group were without long-term complications ($\chi^2=13,122$; Df=4; p=0.011).

In the structure of long-term complications after allogernoplasty with mesh fixation in the Onlay position, the proposed mesh implant allowed to reduce the incidence of prolonged wound exudation from 7.1% to 3.3%, gray from 22.2% to 5.0%, as well as to level the probability of formation of cutaneous prosthetic fistulas (3.0%), wrinkling or displacement of the prosthesis (2.0%) and the risk of recurrence with the formation of a paraprosthetic hernia (2.0%), which in general provided a reduction in the total proportion of complications from 25.3% to 8.3% ($\chi^2=6.986$; Df=1; p=0.009).

An analysis of the long-term results of the proposed technique, corrective allohernioplasty, showed that the use of improved technical aspects of the operation allowed to reduce the frequency of various complications from 16.3% to 2.7% ($\chi^2=4.073$; Df=1; p=0.044), while in the main group there was no development of complications such as prolonged wound exudation (in the comparison group 4.7%), cutaneous prosthetic fistulas (2.3%) and prosthetic displacement (2.3%).

Id] The main problem in the process of rehabilitation of patients after the made allogenoplasty, isn't presence as such operation (elimination of defect and non-recurrence crawling) and quality, but also terms of a recovery phase. This factor also depends on the quality of ingrowth of the mesh prosthesis, which directly polyspecific risk-related to complications. In this sense, the engineered implant, owing to the inherent characteristics of the composite coating, can promote an improved physical and emotional recovery in patients. The early period was characterized by the fact that pain syndrome regressed more rapidly, the frequency of complications (wound suppurating, formations of seroma, infiltration, etc.) was less expressed. For the remote period after allohernioplasty starting from time of discharge of patients, too, such issues matter as well that influence on quality and duration of rehabilitation phase.

To study this factor, the quality of life of patients was analyzed with reference to a SF-36 questionnaire and determining its level for not less than 30 but not more than 90 days after intervention in our study. As the quality of life study was not conducted for patients operated before 2021 as part of a comparison group, we could only analyze it in 44 patients whose surgery time did not exceed recommended and accepted time period within this group, receiving thus a SF-36 questionnaire in 67 respondents.

The QOL analysis was performed at long-term only, hence healthy subjects from 18 to 70 years of age were evaluated as a comparison group. By all the aspects of physical and psychoemotional status on this group, quality of life was above 80 points.

In the studied groups of patients, according to all 8 criteria, a significant difference was obtained with higher values in the main group (Table 1).

Table 1. Assessment of the quality of life of patients within 30 to 90 days after allohernioplasty.

Criteria	Control		Comparison Group		The main group		Reliability	
	M	δ	M	δ	M	δ	t	p
Physical functioning (PF)	85,5	6,0	61,4	8,8	70,8	8,8	5,54	<0,05
Role-Physical Functioning (RP)	82,5	6,3	62,5	6,1	70,3	6,7	6,35	<0,05
Bodily pain (BP)	81,0	3,9	60,2	8,2	78,9	7,6	12,04	<0,05
General Health (GH)	83,5	5,8	63,0	9,2	67,6	9,0	2,63	<0,05
Vitality (VT)	84,0	5,7	57,4	6,9	70,1	10,6	7,71	<0,05
Social Functioning (SF)	80,5	3,7	64,1	8,9	68,7	7,4	2,87	<0,05
Role-Emotional (RF)	83,5	5,8	57,6	8,1	70,4	8,2	8,14	<0,05
Mental Health (MH)	82,5	6,3	60,1	9,4	69,2	9,9	4,88	<0,05

Based on the data obtained according to the criteria for assessing the quality of life, the index of the total value for the domain of physical condition (PF, RP, BP, GH) was 61.8 ± 4.5 in the comparison group, and 71.9 ± 5.0 in the main group ($t=11.11$; $p<0.05$) (control – 83.1 ± 3.1). According to the domain of the psychoemotional state (VT, SF, RF, MH), these indicators also significantly differed and amounted to 59.8 ± 4.0 in the comparison group, and 69.6 ± 4.8 in the main group ($t=11.76$; $p<0.05$) (control – 82.6 ± 3.0) (Figure 1).

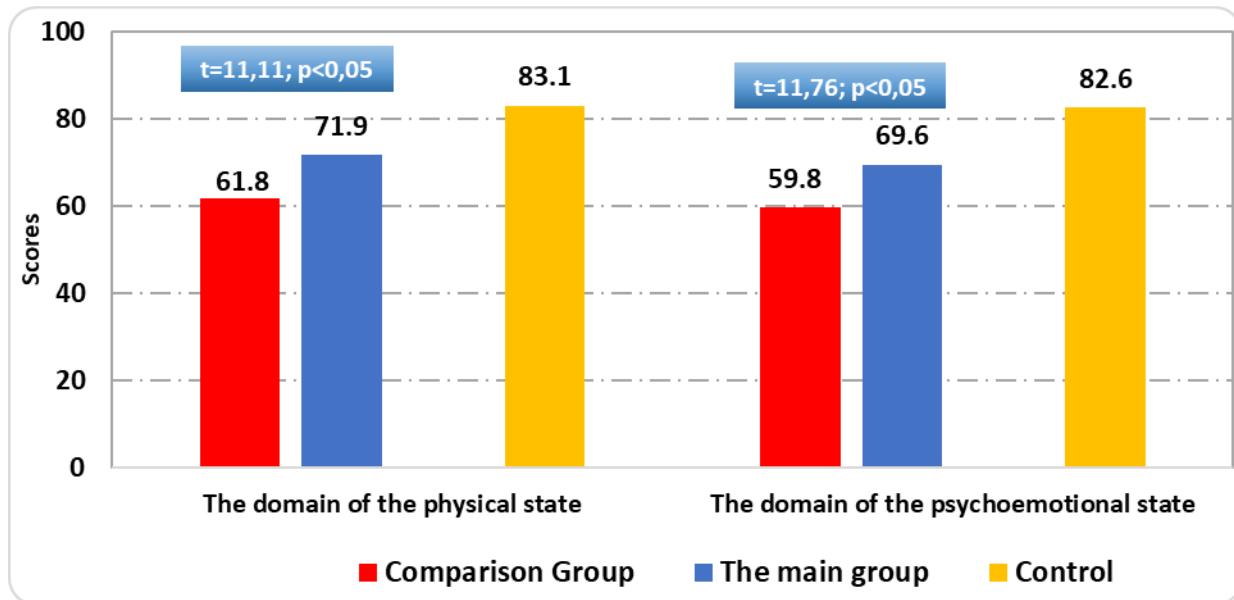


Figure 1. Summary assessment of the quality of life by main domains (points; $M \pm \delta$).

The obtained indicators on the level of quality of life were reflected in the overall results of allogenioplasty in the comparison groups. In particular, a good result was assigned if patients had no complaints from the area of surgery, as well as complications that were either resolved independently or through conservative therapy or minimally invasive interventions. The result was considered satisfactory when verifying any complications in patients, which were either resolved independently or through conservative therapy or minimally invasive interventions, provided there was no recurrence of the disease. The result was considered unsatisfactory with the development of a recurrence of a ventral postoperative hernia.

In our study, a good result was achieved in 110 (77.5%) patients in the comparison group, and in 91 (93.8%) patients in the main group. A satisfactory result was noted in 30 (21.1%) and 6 (6.2%) cases, and an unsatisfactory result in 2 (1.4%) patients in the comparison group ($\chi^2=11.739$; $Df=2$; $p=0.003$) (Figure 2).

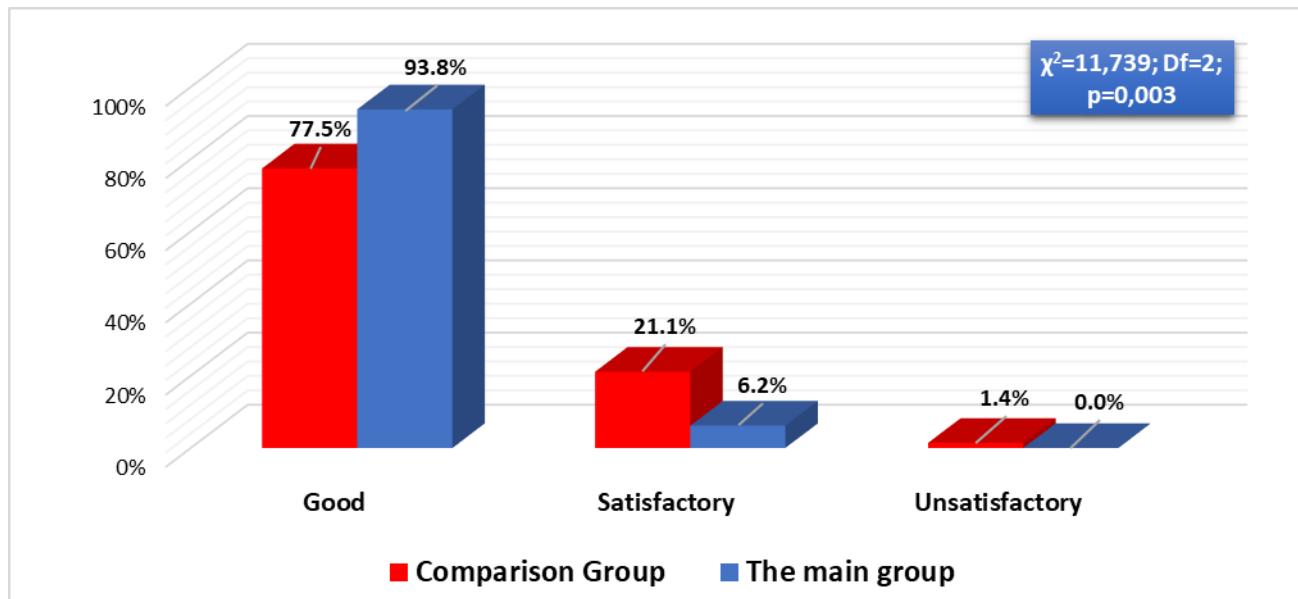


Figure 2. Distribution of patients according to the variant of resolution of complications after corrective allohernioplasty.

The data obtained undoubtedly state the advantages of using a new domestic mesh implant with a composite coating in ventral hernia surgery.

4. Conclusion

Summarizing the study, the following can be noted: a comparative analysis of the clinical effectiveness of allohernioplasty using the proposed mesh prosthesis showed that bioinertness, combined with hemo- and lymphostatic, as well as reparative properties of the developed composite coating, reduces the risk of developing local reactive manifestations on the implant, which provided higher indicators of the quality of life after surgery as a domain of physical state (in the comparison group - 61.8 ± 4.5 vs. 71.9 ± 5.0 points in the main group ($t=11.11$; $p<0.05$), and in the domain of psychoemotional status (59.8 ± 4.0 vs. 69.6 ± 4.8 points; $t=11.76$; $p<0.05$), and also allowed to increase the frequency of good results with 77.5% to 93.8% (satisfactory – 21.1% and 6.2%; unsatisfactory – 1.4% in the comparison group) ($\chi^2=11.739$; Df=2; p=0.003).

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