Wiadomości Lekarskie
Medical Advances

VOLUME LXXVII, ISSUE 5, MAY 2024
Official journal of Polish Medical Association has been published since 1928

ISSN 0043-5147
E-ISSN 2719-342X

INDEXED IN PUBMED/MEDLINE, SCOPUS, EMBASE, EBSCO, INDEX COPERNICUS,
POLISH MINISTRY OF EDUCATION AND SCIENCE, POLISH MEDICAL BIBLIOGRAPHY

ORIGINAL ARTICLE

CONTENTS

Benefits of a combined surgical technique for patients with secondary neovascular glaucoma

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ABSTRACT
Aim: To assess the effectiveness and safety of the proposed surgical technique for treating secondary neovascular glaucoma.
Materials and Methods: We examined 28 eyes of 28 patients (16 women and 12 men), aged 46±7,2 years, with secondary neovascular glaucoma. All patients underwent a comprehensive ophthalmological examination before and during treatment. Two-stage treatment was applied to all patients. At the first stage – performed an advanced technique of non-penetrating deep sclerectomy while administering anti-VEGF (anti-vascular endothelial growth factor) intravitreal or intracameral injections. At the second – we performed externalization of Schlemm's canal followed by YAG laser trabeculectomy. Statistical analysis of the results was used the SPSS v. 11.0, MedStat v.15.1 software package for medical and biological research.
Results: The proposed surgical technique, leads to a gradual decrease in intraocular pressure (IOP) and regression of the iris and anterior chamber angle neovascularization. The postoperative course was uneventful for all the patients. In the early postoperative period, the IOP was observed to be normalized in all the eyes. The IOP ranged from 12 to 16 mm Hg. The neovascularization regression occurred (in 100 % of cases) within 5-7 days.
Conclusions: Gradual reduction of IOP reduces intraoperative complications. Intravitreal or intracameral injections of anti-proliferative agents contribute to the regression of neovascularization and further gradual reduction of IOP. Performing a laser trabeculectomy in the area where a non-penetrating deep sclerectomy was previously performed creates new pathways for the outflow of intraocular fluid from the anterior chamber and reduces the risks of reintervention.

KEY WORDS: surgery for neovascular glaucoma, neovascularization, anti-VEGF therapy, inflammatory process, ultrasound, cavitation

Wiad Lek. 2024;77(5):1011-1017. doi: 10.36740/WLek202405121 DOI

INTRODUCTION

Over the past decades, there has been a rise in vascular diseases worldwide. One of the most severe manifestations and complications of vascular ophthalmological pathology, causing a rapid visual deterioration and subsequent blindness, is secondary neovascular glaucoma.

Ischemic central retinal vein thrombosis and branch retinal vein thrombosis are underlying factors for the disease in 30-40 % of cases. In recent years, the trend has been toward an increase in the number of working-age individuals affected by the disease [1, 2].

The inner retinal layers hypoxia, resulting in the production of vascular endothelial growth factors (VEGF), is basic to the development of secondary neovascular glaucoma.

The new vessels have incomplete endothelial coverage, and therefore, they have thin serous membranes that are prone to bleed. Iris neovascularization and vessel extension into the structures of the anterior chamber angle cause gradual blockage, which results in the angle closure and intraocular pressure (IOP) decompensation [1]. Moreover, this localization of neovascularization entails the high risk of intraoperative hemorrhagic complications, and as a consequence, it leads to IOP fluctuation, significantly reducing a desirable surgical hypotensive effect.

Existing neovascular glaucoma fistulizing surgery is usually highly traumatic and followed by intra- and postoperative hemorrhagic complications, which reach up to 50-55 % of cases [3-5].

The speed and extent of neovascularization are influenced by the concentration of angiogenic factors in the vitreous body and the aqueous humor of the anterior chamber.

To reduce intra- and postoperative hemorrhagic complications and achieve the regression of neovascularization there are used intravitreal and intracameral VEGF inhibitor injections [6, 7].

As an independent treatment, intravitreal anti-VEGF injections lead to a slight decrease in IOP when the angle

Table 1. Demographics and clinical features of patients with secondary neovascular glaucoma according to the stages of neovascularization and the state of the anterior chamber angle (N=28)

Index		n/N (%±m%)
Glaucoma Stage	II	9 (32±7.1)
	III	19 (68±7.2)
Neovascularization (stage)	II	12 (43±8.2)
	III	16 (57±7.5)
Gonioscopy: open angle /partially open angle	open	10 (36±7.9)
	partially open	18 (64±7.1)

Note: m% — percentage error.

of the anterior chamber is open due to neovascularization regression in this area.

However, the achieved clinical lowering of IOP is not long-lasting, so glaucoma surgery becomes necessary to drain fluid from the anterior chamber.

To stop progressive vision loss caused by neovascular glaucoma, it is necessary to influence the process of neovascularization and compensate IOP.

Searching new pathogenesis-based methods of surgical treatment for secondary neovascular glaucoma and preventing intra- and postoperative hemorrhagic complications are of importance for modern ophthalmology [8-10].

In our opinion, using anti-VEGF therapy in conjunction with lowering IOP in the treatment of neovascular glaucoma may produce a synergistic effect and be more effective than conventional glaucoma surgery with the prior administration of anti-VEGF injections [11].

AIM

To assess the effectiveness of the proposed surgical technique for treating secondary neovascular glaucoma, which involves a stepwise reduction of IOP used in combination with anti-VEGF therapy, as well as to evaluate its safety.

MATERIALS AND METHODS

We have developed a surgical technique for treating patients with secondary neovascular glaucoma, which involves performing a non-penetrating deep sclerectomy while administering anti-VEGF intravitreal or intracameral injections [12].

At the second stage we conducted the externalization of Schlemm's canal, then performed YAG laser trabeculectomy in combination with a non-penetrating deep sclerectomy.

We examined 28 eyes of 28 patients (16 women and 12 men), aged (mean [M] ± standard deviation [SD]) 46 ± 7,2 years, with secondary neovascular glaucoma.

In 10 patients, the neovascular glaucoma developed as a result of central retinal vein thrombosis, and in 18 patients, it occurred due to branch retinal vein thrombosis. The disease duration ranged from 6 to 8 months. All the patients (28 eyes) were treated by the proposed technique: a non-penetrating deep sclerectomy used in combination with administering anti-VEGF intravitreal injections for 16 patients and administering anti-VEGF intracameral injections for 12 patients.

Most patients had severe comorbidities: 71.4% of patients suffered from stage II/III hypertension, and 42.8% of patients had severe cerebral and coronary artery atherosclerosis.

The patients underwent standard examinations, which included visual acuity assessment, perimetry, tonometry, gonioscopy, biomicroscopy, and the optical coherence tomography of the optic nerve head.

Against the background of ocular hypotensive therapy (2-3 medications), the IOP ranged from 28 to 42 mm Hg and averaged out (M±SD) 34.2 ± 1.2 mm Hg. The optic nerve changes in 9 eyes (32.1%) were indicative of stage 2 glaucoma and those in 19 eyes (67.9%) corresponded to stage 3 glaucoma. The iris and anterior chamber angle neovascularization corresponded to grade 2 and grade 3 as per Weiss classification. The anterior chamber angle was open in 10 eyes, and it was partially open in 18 eyes (Table 1). The majority of patients had changes in the optic nerve, respectively, stage 3 glaucoma and neovascularization of the angle of the anterior chamber of grade 3 (Table 1).

Non-penetrating deep sclerectomy was performed for the open angle of the anterior chamber [11, 12]. During the postoperative period, the patients received instillations of antibacterial, steroid, and non-steroidal anti-inflammatory drugs.

Upon achieving regression of the iris and anterior chamber angle neovascularization, to create new pathways for the outflow of intraocular fluid from the anterior chamber, within 2-4 weeks we undertook the YAG laser trabeculectomy in the area where the non-penetrating deep sclerectomy was previously performed [12].

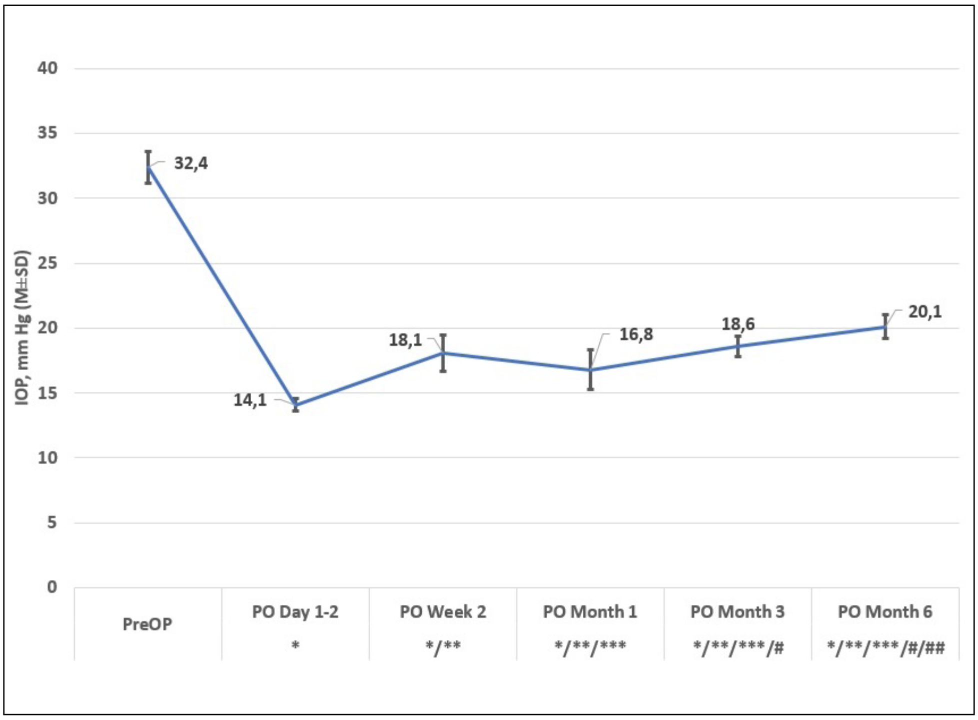

Fig. 1. Preoperative (PreOP) value and postoperative (PO) IOP dynamics. across the observation time series (mm Hg). * – p<0.05 vs. preOP; ** – p<0.05 vs. PO day 1-2; *** – p<0.05 vs. PO week 2; # – p<0.05 vs. PO month 1; ## – p<0.05 vs. PO month 3.

We assessed the outcomes 1, 2 weeks, and 1, 3, 6 months following surgery.

The researchers followed all protocols and procedures required by the Biomedical Research Ethics Committee and conform to the directive of the Ukrainian Legislation on health care, Helsinki Declaration 2000 and European Society Directive 86/609 on human participation in biomedical research to ensure adherence to all standards for adequate protection and well-being of participants. Informed consent was received from all respondents who took part in this research.

Statistical analysis of the results was performed using the SPSS v. 11.0, MedStat v. 5.2, MedCalc v.15.1 software package (MedCalc Software bvba) for medical and biological research. The quantitative variables were presented as M ± SD, qualitative – as absolute and relative (%) frequency (with percentage error [±m%]). The significance of difference in IOP between different postoperative follow-up periods was assessed by means of the Friedman test, with post hoc comparisons by the use of the Wilcoxon signed-rank test. The statistical difference was considered as $p<0.05$ (considering the Bonferroni correction).

RESULTS

The research has shown that the proposed surgical technique, which includes performing a standard non-penetrating deep sclerectomy while administering intravitreal or intracameral injections of antiproliferative agents for secondary neovascular glaucoma, leads to a gradual decrease in IOP and regression of the iris and anterior chamber angle neovascularization.

The analysis of the proposed combined technique and the postoperative results has shown that performing a non-penetrating deep sclerectomy (Stage I) reduces IOP. Moreover, lowering pressure by means of a non-penetrating deep sclerectomy compensates for a potential elevation in the IOP in response to administering anti-VEGF intravitreal or intracameral injections.

Having achieved the regression of neovascularization, we could perform the YAG laser trabeculectomy (Stage II) to create new pathways for the outflow of intraocular fluid from the anterior chamber. 28 patients (28 eyes) with secondary neovascular glaucoma underwent the surgical procedures.

The proposed combined technique included the following stages:

– retrobulbar anesthesia;
– the limbus-based incision of the conjunctiva and Tenon's capsule (it lasts from 11 to 13 hours).
– fashioning the superficial limbus-based scleral flap (3×4 mm; 1/3 scleral thickness), and then dissecting the scleral flap 1.5 mm into the clear cornea.
– excising the middle scleral flap with underlying Schlemm's canal exterior wall and corneal stroma behind the Descemet's membrane.
– juxtacanalicular trabecular tissue removal;
– excising the deep scleral flap behind the ciliary body, measuring 2 x 1 mm and 3-4 mm near the limbus;
– administering aflibercept 2 mg/0.05 mL anti-VEGF injections into the vitreous cavity or anterior chamber using a standard technique;

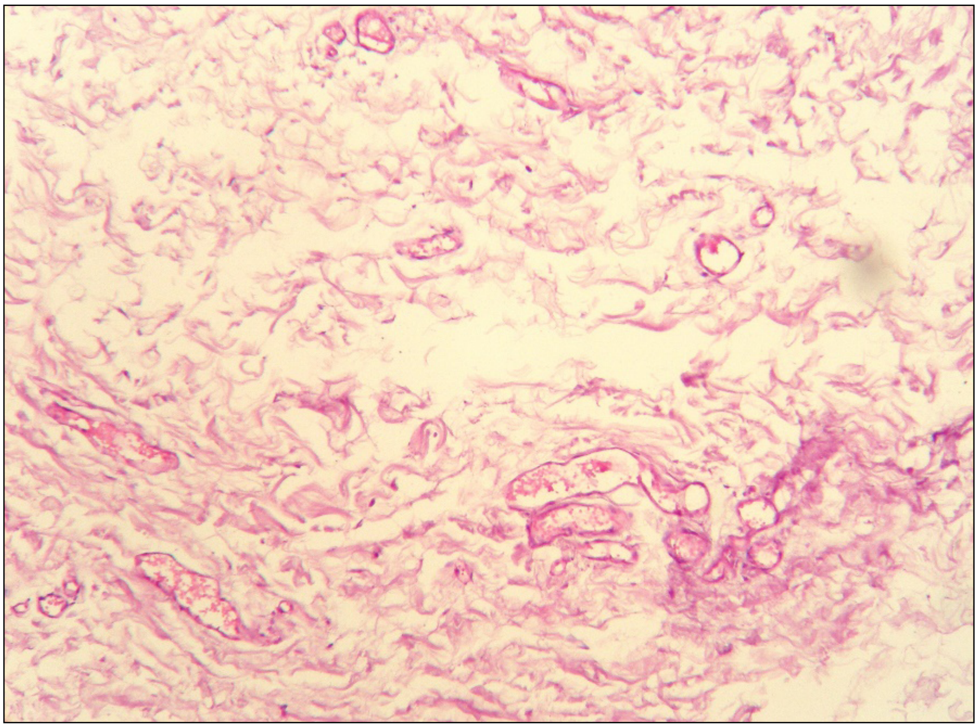

Fig. 2. Scleral flaps. Histological preparation.
Section stained with H&E, x400.

– closing the conjunctiva with two interrupted sutures; no sutures were inserted into the scleral flap;
– applying an aseptic dressing.

Hemorrhagic complications (minor hyphema) were observed in 3 eyes (10.7%). The hyphema resolved on its own within 4-5 days, no additional interventions were required.

The postoperative course was uneventful for all the patients. In the early postoperative period, the IOP was observed to be normalized in all the eyes that was accompanied by an evident filtering bleb. The IOP ranged from 12 to 16 mm Hg. The neovascularization regression occurred (in 100 % of cases) within 5-7 days.

To create new pathways for the outflow of intraocular fluid from the anterior chamber, within 2-4 weeks we undertook the YAG laser trabeculectomy in the area where the non-penetrating deep sclerectomy was previously performed.

Once the trabeculectomy was done we noted the filtering bleb enlargement. The IOP ranged from 16 to 18 mm Hg (with an average of 16.8±1.5 mm Hg), antihypertensive medications were not used. We did not observe any difference in the neovascularization regression at administering anti-VEGF intravitreal and intracameral injections.

The first 3 months monitoring has found that the IOP stayed within normal limits in 24 patients (86%), while in 4 patients (14%) it was normal in response to the antihypertensive treatment (Fig. 1).

The first 6 months monitoring has found that the IOP stayed within normal limits in 20 patients (71 %), while in 8 patients (29 %) it was normal in response to the antihypertensive treatment. There was no vision impairment (visual acuity and visual field decrease) during the monitoring period.

The normalized IOP made it possible to preserve visual functions in patients with secondary neovascular glaucoma.

Minor response to the surgical trauma, absent acute-phase response following surgery, few minor intraoperative complications (partial hyphema was in 10.7 % of cases), a sustained reduction of elevated IOP (71 %), feasible surgical techniques were reported.

In addition, this method of combined surgical treatment is appropriate, since our previous studies have shown that in glaucoma, in the area where anti-glaucoma intervention is usually performed, processes peculiar to chronic progressive inflammation occur.

This is evidenced by the results of histological examination of tissue (parts of scleral flaps) removed during anti-glaucoma surgery. When conducting microscopy, thickening of all layers of the sclera, the signs of neovascularization with endotheliocytes proliferation were determined in our study group (28 patients); it may point to chronic inflammatory process occurrence. The slightly changed cell nuclei of fibrous tissue (increased in size and more intensely colored, are located alone or form unstructured clusters) were established to indicate alteration in the examined tissue cells, and therefore, they may affect the postoperative scarring (Fig. 2).

The significant swelling of the surrounding tissue, which pathologically changed the structure of the tissue itself was also observed that could lead to an increase in outflow resistance and IOP (Fig. 2).

Therefore, the additional administration of anti-VEGF injections during surgery in patients with secondary neovascular glaucoma is pathogenetically justified.

DISCUSSION

Treating patients with secondary neovascular glaucoma is an unsolvable problem in modern ophthalmology. Despite the advances in the development of the improved diagnostic and treatment technologies for eye diseases, there is no consistent treatment approach to this pathology. Long-term efforts aimed at improving secondary neovascular glaucoma management have not reduced the urgency of the problem [1, 3, 13].

Due to the drug therapeutic failure, surgical treatment is a focus area for normalizing IOP and stabilizing visual functions in patients with secondary neovascular glaucoma, in particular after central retinal vein occlusion [3, 13].

The spectrum of surgical modalities used in patients with secondary neovascular glaucoma is rather wide: it includes as traditional filtering procedures for glaucoma so cryosurgical, drainage, and laser techniques [3, 6, 14].

The literature review analysis focused on surgery for secondary neovascular glaucoma has shown that this problem remains to be done as of today [8, 9]. Pathogenetic surgical approaches to secondary neovascular glaucoma have always been of ophthalmologists' particular emphasis. They are based on the understanding of the pathogenesis of intraocular fluid outflow disorder onset and development [10, 13]. In the case of secondary neovascular glaucoma, the intraocular fluid outflow disorder is localized in the filtration angle: trabeculae, Schlemm's canal, the anterior chamber angle [1, 2].

The majority of researchers agree that the main cause of outflow disorder is the anterior chamber angle and trabeculae areas. The cause of neovascular glaucoma is known to be a pathological neoplasm of blood vessels in the iris and the anterior chamber angle. The trigger for progressive neovascularization of the anterior vascular tract is ischemia of the retina, caused by its circulation disorder [6, 14].

Neovascular proliferation is induced by angiogenic factors (VEGF, etc.), which are produced by the inner layers of the retina in a state of hypoxia. The neovascularization factor is defined as a substance that provokes the uncontrollable growth of newly formed pathological vessels; their conglomerates lead to various hemorrhages with subsequent tissue destruction [4, 5]. The speed and spread of neovascularization are influenced by the concentration of angiogenic factors in the vitreous body and the aqueous humour of the anterior chamber [4, 5].

In its further development a newly formed fibrovascular tissue tends to retraction, which results in goniosynechiae formation. The process spreading over the perimeter of the anterior chamber angle leads to its closure. The oversaturation of intraocular tissues with newly formed vessels, their close location to the filtration area block the outflow of intraocular fluid, which impedes IOP normalization, increases the risk of intraocular hemorrhages [6-8]. Our evidence suggests that the inflammatory processes occur not only in the anterior chamber angle, which subsequently worsen the hydrodynamics of the intraocular fluid. The chronic inflammatory process occurs both in the Tenon's capsule and in the scleral capsule, that affects anti-glaucoma surgery outcomes.

Recently, secondary neovascular glaucoma surgery tends to combined interventions which influence various components of the disease pathogenesis, but an optimal treatment strategy is still absent.

Most of the existing surgical interventions are associated with a high risk of hemorrhagic intra- and postoperative complications, which is a consequence of both high IOP and the presence of newly formed vessels of the iris and the anterior chamber angle. Hemorrhagic complications and increased proliferation of connective tissue in the area of surgery reduce the hypotensive effect of surgery and limit their use in secondary neovascular glaucoma. Non-penetrating surgery, which is so widely used in the treatment of primary glaucoma, is characterized by the least number of complications, in secondary neovascular glaucoma it has a restricted effect due to the rapid scarring of the bleb [5, 7, 13].

There are few effective methods for treating progressive rubeosis iridis. The argon-laser coagulation of ischemic areas of the retina, newly formed vessels of the iris and the anterior chamber angle are widely used. The disadvantages of this method are the short-term occlusion of newly formed vessels, reactive hypertension, and a high risk of inflammatory complications [3].

The existing interventional trials of such glaucoma, both by means of antimetabolites and without them, have no expected hypotensive effect. Using a variety of drainage and valve systems provides somewhat greater efficiency, but also has great deal of surgical implications [3].

Recently, intravitreal and intracameral VEGF-injections have been used as a step in treating neovascular glaucoma to achieve regression of newly formed vessels of the iris and the anterior chamber angle as well as to reduce the frequency of surgical and postsurgical hemorrhagic complications [3-5, 14].

As an independent treatment, anti-VEGF therapy facilitates the regression of the newly formed vessels of the iris and the anterior chamber angle, reduces vascular permeability, and partially decreases IOP. But the achieved hypotensive result is not long-lasting (4-6 weeks), so glaucoma surgery is necessary to create a filtration fistula [4, 6].

However, neither the isolated use of anti-VEGF drugs, nor the use of their combination with traditional surgical interventions gives the expected result. In addition, even the combined interventions cannot influence all pathogenetic components of the secondary neovascular glaucoma development [3, 4].

The treatment of such a significant abnormality requires a treatment landscape aimed at reducing IOP, reducing neovascularization, as well as affecting the foci of retinal ischemia and VEGF production [3, 4, 6, 14].

Today, the phenomenon of ultrasonic cavitation, which occurs when high-intensity ultrasonic vibrations are introduced into a liquid, is widely used in technology [15]. In addition to other possibilities, ultrasonic cavitation provides high-quality removal of contaminants from surfaces and disinfection. It should be noted that one of the most used bioeffects of ultrasound for therapeutic purposes is cavitation. The phenomenon of the formation of bubbles from gases that exist in living tissue is used. Irradiation of a liquid containing a gas bubble with an acoustic field can lead to the transformation of a low-energy density of acoustic waves into a high-energy pulsating bubble. When a bubble is located near a rigid boundary, a liquid jet is formed in the final stage of bubble collapse. The jet stream concentrates a large amount of the bubble's energy in a small area, quite far from the initial location of the bubble. The pressure created by the jet shock generated by the collapse of the bubble near the border can lead to the fragmentation of fragile objects such as kidney stones, etc., [15] and, in our opinion, to restore the elasticity of the trabecular meshwork, the main component of the drainage system of the human eye.

The treatment of such a serious pathology requires a complex of methods aimed at reducing IOP, reducing neovascularization, as well as affecting the foci of retinal ischemia and VEGF production [3, 4].

Thus, the proposed combined surgical technique for secondary neovascular glaucoma includes performing a non-penetrating deep sclerectomy while administering intravitreal or intracameral injections of angiogenesis inhibitors, reducing IOP gradually through performing a YAG-laser trabeculectomy, that makes it possible to effectively lower IOP and minimize intra- and postoperative complications, thereby it ensures a sustained normalization of IOP.

Due to the mentioned characteristics this technique can be used as the surgery of choice for secondary neovascular glaucoma. The results obtained in the course of this experimental research are the basis for a more detailed study of the problem of glaucoma treatment.

CONCLUSIONS

1. Applying the surgical technique for treating neovascular glaucoma is instrumental for a gradual decrease in IOP, that thereby reduces intraoperative complications.
2. The iris and anterior chamber angle neovascularization regression achieved through administering the intravitreal or intracameral injections of anti-proliferative agents leads to a further gradual lowering of IOP. Performing the YAG laser trabeculectomy in the area where the non-penetrating deep sclerectomy was previously performed creates new pathways for the outflow of intraocular fluid from the anterior chamber.
3. This combined technique lowers the risks of reintervention and emotional stress for the patients.
4. The further study of the neovascular glaucoma pathogenesis may make the treatment more effective and reduce the frequency and severity of surgical complications.

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The work was carried out at the Department of Postgraduate Ophthalmology and Optometry of the Institute of Postgraduate Education of Bogomolets National Medical University and is a fragment of the initiative-research NDR «Theoretical and practical aspects of improving clinical and experimental methods of diagnosis, treatment and prevention of diseases and injuries of the organ of vision and their complications» (state registration number 0123U104207; 2023-2026).

CONFLICT OF INTEREST

The Authors declare no conflict of interest

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RECEIVED: 10.12.2023
ACCEPTED: 11.04.2024