

COMPARATIVE EVALUATION OF THE RESULTS OF SURGICAL TREATMENT OF OPEN-ANGLE GLAUCOMA USING AN EX-PRESS® P-200 FILTRATION DEVICE AND DRAINAGE DEVICE “ANTI-GLAUCOMA IMPLANT A3”

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For citation: Grineva MK, Astakhov SYu, Turgel VA. Comparative evaluation of the results of surgical treatment of open-angle glaucoma using an Ex-Press P-200® filtration device and drainage device “Anti-glaucoma implant A3”. *Ophthalmology Journal*. 2020;13(3):29-36. <https://doi.org/10.17816/OV42464>

Received: 17.08.2020

Revised: 16.09.2020

Accepted: 23.09.2020

✧ **Purpose.** The article presents the results of a comparative analysis of the effectiveness of surgical treatment of open-angle glaucoma using the Ex-Press® P-200 filtering device and the “Anti-glaucoma A3 implant”.

Materials and methods. Using simple sequential sampling, 52 patients (59 eyes) were divided into 2 groups. The first group was implanted with Ex-Press® P-200, the second — with “Anti-glaucoma implant A3”. The follow-up period for patients ranged from 6 months to three years. At each visit, a standard ophthalmic examination was performed. For tonometry, the ICare TA01i portable non-contact tonometer was used. To assess the stabilization of the glaucoma process, we performed static (threshold) automatic perimetry using the Pericom perimeter and optical coherence tomography (OCT) of the optic nerve heads using a Spectralis HRA-OCT tomograph (Heidelberg Engineering).

Conclusions. The implantation of devices of both types led to a persistent decrease in intraocular pressure, maintenance of visual functions, and stabilization of the glaucoma process. Intra- and postoperative complications corresponded to the nature of filtering procedures and did not have significant differences in the groups. However, cases of shunt erosion were noted only in the group with implanted Ex-Press® devices.

✧ **Keywords:** glaucoma; drainage; ophthalmic surgery; intraocular pressure; surgical treatment; IOP-lowering procedures; glaucoma drainage devices.

СРАВНИТЕЛЬНАЯ ОЦЕНКА РЕЗУЛЬТАТОВ ХИРУРГИЧЕСКОГО ЛЕЧЕНИЯ ОТКРЫТОУГОЛЬНОЙ ГЛАУКОМЫ С ПРИМЕНЕНИЕМ ФИЛЬТРУЮЩЕГО УСТРОЙСТВА EX-PRESS® P-200 И ДРЕНАЖА «ИМПЛАНТ АНТИГЛАУКОМНЫЙ АЗ»

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Для цитирования: Гринева М.К., Астахов С.Ю., Тургель В.А. Сравнительная оценка результатов хирургического лечения открытоугольной глаукомы с применением фильтрующего устройства Ex-Press® P-200 и дренажа «Имплант антиглаукомный АЗ» // Офтальмологические ведомости. — 2020. — Т. 13. — № 3. — С. 29–36. <https://doi.org/10.17816/OV42464>

Поступила: 17.08.2020

Одобрена: 16.09.2020

Принята: 23.09.2020

✧ **Цель работы.** В статье представлены результаты сравнительного анализа эффективности хирургического лечения открытоугольной глаукомы с применением фильтрующего устройства Ex-Press® P-200 и «Импланта антиглаукомного АЗ». **Материалы и методы.** Методом простой последовательной выборки 52 пациента (59 глаз) были разделены на 2 группы. Первой группе было имплантировано устройство Ex-Press® P-200, второй — «Имплант антиглаукомный АЗ». Срок наблюдения за пациентами составил от 6 мес. до 3 лет. При каждом посещении проводили стандартное офтальмологическое обследование. Для тонометрии использовали портативный бесконтактный тонометр ICare TA01i. Для оценки стабилизации глаукомного процесса выполняли статическую (пороговую) компьютерную периметрию на периметре «Периком» и оптическую когерентную томографию дисков зрительных нервов с помощью томографа Spectralis HRA-OCT (Heidelberg Engineering). **Выводы.** Имплантация устройств обоих типов привела к стойкому снижению внутриглазного давления, поддержанию зрительных функций

и стабилизации глаукомного процесса. Интра- и послеоперационные осложнения соответствовали характеру фистулизирующих вмешательств и не имели существенных различий в группах. Однако случаи прорезывания шунта отмечались лишь в группе с имплантированными устройствами Ex-Press®.

✧ **Ключевые слова:** глаукома; дренаж; офтальмохирургия; внутриглазное давление; оперативное лечение; гипотензивные вмешательства; шунтирующие устройства.

INTRODUCTION

Glaucoma still is one of the leading causes of irreversible vision loss worldwide [8]. Herewith, the share of primary open-angle glaucoma (POAG) is about 75% of cases [9]. As of 2015, the number of people suffering from this form of the disease reached about 58 million, with expected increase up to 65 million people by 2020, and up to 111 million by 2040 [10]. About 8.4 million people are bilaterally blind because of glaucoma [11].

Over the last years, in open-angle glaucoma (OAG) treatment, medical IOP-lowering therapy and different varieties of laser surgery got great development. Currently, a specific group of glaucoma procedures is highlighted – Minimally Invasive Glaucoma Surgery (MIGS).

Nevertheless, classic trabeculectomy and its multiple modifications still are the procedures of choice for moderate and advanced disease stages. This group of surgeries is designated as filtration surgeries, and aims to create additional aqueous humor (AH) outflow pathways, predominantly under the conjunctiva. With that, a so-called filtration bleb forms.

Unfortunately, it is not always possible to achieve a long-lasting optimal IOP-lowering effect after surgery. According to the data from different authors, a decrease of the IOP-lowering effect after filtration surgery is observed in 15–45% of cases [1] reaching up to 37–70% of cases [2]. The main cause of a recurrent intraocular pressure (IOP) rise is a development of proliferative process leading to the scarring of new aqueous humor outflow pathways. The severity of the proliferative process is directly correlated to the intensity of exudative and inflammatory manifestations arising in response to surgical trauma [3].

The filtration bleb scarring is a terminal stage of an aseptic inflammatory process, arising in affected tissues of the eye after surgery. On the average, scar reorganization begins in 10–14 days postoperatively, and ends to the 21 day [4].

In view of this, an important objective in glaucoma surgery is a slowdown of the regeneration process – to preserve the permeability of formed aqueous humor outflow pathways. For this pur-

pose, in global ophthalmic practice, several methods are used to suspend ocular tissue regeneration in the operation area, and this is performed according to two main focus areas: therapeutic action on reparation processes in the scarring area (use of cytostatics, e.g. anti-metabolite 5-fluorouracil [5]), and use of drainage devices (implants, shunts, valves) [6].

Concerning the first area, the off-label use of anti-metabolites and cytostatics (widely used abroad in filtration surgical procedures) is not allowed in the Russian Federation.

Over the course of glaucoma surgery development, many authors proposed different variants of devices implanted into the anterior chamber and aiming to enhance the aqueous humor outflow. In foreign countries, a widespread use gained the implantation of a filtering device Ex-Press® (Excessive Pressure Regulating Shunt System), manufactured in several modifications and believed to be an alternative to traditional trabeculectomy. In our country, Ex-Press® filtration device did not get any wide use due to its relatively high cost.

However there is an alternative variant of the tube shunt – Russian-made “Anti-glaucoma implant A3” produced by ООО “Reper NN” (Nizhny Novgorod). According to design and to internal lumen diameter this device is similar to the P-200 model of filtration device Ex-Press®.

In present article, we present a comparative evaluation of surgical treatment results of OAG patients using Ex-Press® P-200 filtration device and drainage device “Anti-glaucoma implant A3”.

MATERIALS AND METHODS

52 patients (59 eyes) with different OAG stages were included into the study. They were divided into 2 groups using simple sequential sampling. Into the group I, 28 patients (32 eyes) were included, in whom Ex-Press® P-200 filtration device was implanted. Group II consisted of 24 patients (27 eyes). They were subjects to surgery with “Antiglaucoma implant A3” implantation.

The diagnosis was established on the basis of history data and objective instrumental examination results.

Standard ophthalmic examination included automatic refractometry, visual acuity testing, biomicroscopy of the anterior segment, gonioscopy of the irido-corneal angle, indirect ophthalmoscopy.

For objective assessment of glaucoma stabilization, in all patients, we performed static (threshold) automated perimetry using Pericom perimeter, and optical coherence tomography (OCT) (Heidelberg Spectralis HRA-OCT) of the optic nerve heads to measure the thickness of the nerve fiber layer.

For IOP measurement, the ICare TA01i non-contact tonometer was used, having a high degree of result correlation with Goldman tonometer, which is an international clinical standard of intraocular pressure measurement.


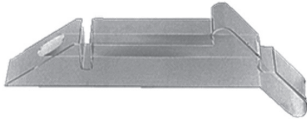
Ex-Press® filtration device is used from 2002 on. It represents a tube of medical stainless steel with 200 micron internal lumen diameter and 2.64 mm length. On the sharpened distal end, there is an additional port and a “beard” to fix the shunt in the anterior chamber. On the other end, there is a plate for fixation on the scleral bed. The device implantation is not a contraindication for magnetic resonance imaging.

Drainage device “Anti-glaucoma implant A3” in current modification is used from 2014 on. As described above, the device is produced in Nizhny

Novgorod at the enterprise ООО “Reper NN”. The device was designed by Tambov branch of S. Fyodorov Eye Microsurgery Federal State Institution and the Ophthalmology Chair of the Privolzhsky Research Medical University. It represents a tube shunt from transparent acrylic polymer with square cross section, and has a 3.2 mm length. The shunt’s distal end is cut at an angle of 45° and has an auxiliary port of 0.1 mm diameter. On the proximal end, there is a support element for implant’s fixation under a scleral flap (Tabl. 1).

Techniques of surgical procedures using these types of filtration devices do not differ significantly from each other. Implantation was performed in upper parts of the eye on 12 hours or in areas free of previous procedures. After dissection of the conjunctiva and excision of the Tenon’s capsule, a superficial limbal-based scleral flap is formed up to so-called grey zone. Meridional intrascleral canal is formed in intermediate scleral layers, which reached beyond the superficial flap. A paracentesis is done using 22G or 23G needle for “Anti-glaucoma implant A3” and Ex-Press® P-200, respectively. Filtration device Ex-Press® P-200 is implanted with disposable injector enclosed. The drainage of the Reper Company is positioned with special reusable forceps, jaws of which have notches repeating the form of the device’s supporting element [7].

Table 1 / Таблица 1

| Comparison of the main technical characteristics of Ex-Press® P-200 shunt devices and drainage “Anti-glaucoma implant A3” Сопоставление основных технических характеристик шунтирующих устройств Ex-Press® P-200 и «Имплантат антиглаукомный А3» | | |
|---|--|---|
| Technical characteristics | Ex-Press® P-200 (Alcon, USA)  | Anti-glaucoma implant A3 (ООО “Reper-NN”, Russia)  |
| Material | Stainless medical steel | Hydrophobic acryl |
| Length | 2.64 mm | 3.20 mm |
| Cross section | Round, diameter 400 microns | Square, side length 400 microns |
| Lumen diameter | 200 microns | 200 microns |
| End bevel | 45° | 45° |
| Additional port | Present | Present, 100 microns |
| Fixation furrow | Present | Present |
| Fixation spur | Present | Not present |
| Installational features | Paracentesis with 22G needle. Implantation with an injector | Paracentesis with 23G needle. Implantation with a forceps |

The evaluation of surgical procedure results was done at discharge from the hospital, it is, on the 3rd–5th day after surgery, and further on every 6 months, with maximal follow-up of more than three years.

RESULTS

Despite the undertaken IOP-lowering therapy, at the time of admission, the average intraocular pressure's level was above the normal level in both groups, and was 26.87 ± 6.11 and 25.85 ± 7.75 mm Hg, respectively. 17 (53.12%) of patients from the group I and 20 (74.07%) patients from the group II were had a maximum regimen of instillations (3 medications). In 20 (62.5%) patients from the group I and 18 (66.67%) patients from the group II, IOP-lowering procedures had been carried out, which did neither lead to glaucomatous process stabilization, nor to "target" pressure achievement.

The dynamic follow-up of the IOP level in the early post-op period showed that after 3–5 days after surgery in the group I in 27 (84.38%) patients, hypotony was present, normal IOP was found in 4 (12.5%) cases, and in one patient (3.13%), in the early post-op period, ophthalmic hypertension was revealed. In the group II, low IOP was found in 25 (92.59%) eyes, and normal IOP level in 2 (7.41%) cases. There were no ophthalmic hypertension cases.

6 months after surgery, in the group I in 26 (81.25%) patients out of 32 the IOP was normalized without any IOP-lowering medication. In 6 (18.75%) cases, the target IOP level was reached using one medication. In the group II, 20 (74.07%) patients did not need any IOP-lowering therapy, as target IOP level was reached. In 7 (25.93%) cases, to normalize the IOP level one medication was prescribed.

In one after surgery, in the group II, 15 (57.69%) patients did not need any therapy. In 8 (30.77%) cases, IOP was stabilized by instillation of 1 medication. To reach the target level, for 2 (7.69%) patients, two medications were prescribed. In 1 case (3.85%), IOP was normalized at a maximal instillation regimen (3 medications). In 1 case (3.85%), a diode-laser transscleral cyclocoagulation (TSCPC) was performed. In the group II, in 11 cases (44.0%), pressure was stabilized without drops, for 11 (44.0%) patients 1 IOP-lowering medication was prescribed, for 2 (8%) – 2 preparations to stabilize the IOP level were given, and 1 patient (4.0%) received 3 medications. In 1 case (4.0%), a diode-laser TSCPC was performed.

In 1.5 years after surgery, in the group I, in 5 patients (25.0%), a stable IOP normalization was preserved. In 13 cases (65.0%), one medication was prescribed. In 2 patients (10.0%), the IOP level was stabilized using two medications. In the group II, 8 patients (33.33%) stayed without any therapy. In 10 cases (41.67%), to stabilize the IOP level, one medication was prescribed. In 6 eyes (25.0%), the target IOP level was reached using two medications. In 1 case (4.17%), to stabilize intraocular pressure figures, a diode-laser TSCPC was performed.

In 2 years after the implantation of drainage devices, in the group I, pressure stayed normal without IOP-lowering medications in 3 cases (16.67%). One medication was prescribed in 12 cases (66.66%), 2 preparations – in 3 cases (16.67%). In 2 cases (11.11%), a diode-laser TSCPC was performed. In the group II, in 6 cases (26.09%), the IOP level stayed in the limits of target figures without prescription of IOP-lowering medications. One medication was prescribed to 11 patients (47.82%), in 6 cases (26.09%), – two medications. A diode-laser TSCPC to stabilize the IOP level was performed in one patient (4.34%).

After 2.5 years of follow-up, in group I, in 4 people (33.33%), IOP stayed normal without instillations of IOP-lowering medications. The target IOP level was reached with one medication in 4 cases (33.33%). 4 patients (33.33%) were in need of three medications. In the group II, 2 patients (14.28%) preserved stabilized IOP without therapy. In 4 cases (28.57%), to maintain target IOP, one medication was prescribed, in 6 (42.87%) – two, and in 2 cases (14.28%) – 3 medications. In two patients of the group, to stabilize IOP, a diode-laser TSCPC was performed.

In 3 years after surgery, in group I, 1 patient (14.28%) did not instill any IOP-lowering medication to maintain target IOP level. Two and three medications were prescribed to 3 (42.86%) and 3 (42.86%) patients, respectively. In the group II, 1 patient (14.28%) preserved the target IOP level without drop instillation. To five patients (71.44%), 2 medications were prescribed, and to one patient (14.28%) – 3 medications (Table. 2).

At the time of admission, mean best corrected visual acuity in the group I was 0.48 ± 0.29 , and in the second one – 0.44 ± 0.28 . Data on visual acuity changes depending on follow-up terms are presented in the Tabl. 4.

Table 2 / Таблица 2

Mean intraocular pressure values (mm Hg) depending on the follow-up time ($M \pm SD$)Средние значения внутриглазного давления (мм рт. ст.) в зависимости от срока наблюдения ($M \pm SD$)

| Group | Follow-up period | | | | | | | |
|----------|------------------|-----------------|------------------|------------------|------------------|------------------|------------------|------------------|
| | Before surgery | 3–5 days | 6 months | 1 year | 1.5 years | 2 years | 2.5 years | 3 years |
| Group I | 26.87 \pm 6.11 | 5.39 \pm 2.91 | 12.68 \pm 2.61 | 14.16 \pm 2.57 | 13.97 \pm 2.21 | 13.83 \pm 1.6 | 15.00 \pm 3.33 | 13.46 \pm 2.21 |
| Group II | 25.85 \pm 7.75 | 4.30 \pm 2.88 | 13.11 \pm 3.5 | 13.04 \pm 4.34 | 13.00 \pm 2.09 | 12.83 \pm 2.42 | 14.29 \pm 4.75 | 14.43 \pm 4.79 |

Table 3 / Таблица 3

Intraocular pressure level depending on follow-up time, n Зависимость уровня внутриглазного давления от срока наблюдения, n

| Follow-up period | Intraocular pressure level (mm Hg) | | | | | | | |
|------------------|------------------------------------|-------|-------|-------|-------|-------|-----------|-------|
| | 2–10 | | 11–20 | | 21–30 | | ≥ 31 | |
| | I | II | I | II | I | II | I | II |
| At admission | – | – | 5 | 3 | 20 | 21 | 6 | 3 |
| | | | 16.1% | 11.1% | 64.5% | 77.8% | 19.4% | 11.1% |
| 3–5 days | 30 | 25 | 1 | 2 | – | – | – | – |
| | 96.8% | 92.6% | 3.2% | 7.4% | – | – | – | – |
| 6 months | 6 | 7 | 25 | 18 | 0 | 2 | – | – |
| | 19.4% | 25.9% | 80.6% | 66.7% | 0.0% | 7.4% | – | – |
| 1 year | 1 | 6 | 30 | 17 | 0 | 2 | – | – |
| | 3.2% | 22.2% | 96.8% | 63.0% | 0.0% | 7.4% | – | – |
| 1.5 years | 2 | 2 | 28 | 22 | 1 | 0 | – | – |
| | 6.5% | 7.4% | 90.3% | 81.5% | 3.2% | 0.0% | – | – |
| 2 years | 1 | 3 | 29 | 20 | 0 | 0 | – | – |
| | 3.2% | 11.1% | 93.5% | 74.1% | 0.0% | 0.0% | – | – |
| 2.5 years | 0 | 2 | 26 | 10 | 1 | 2 | – | – |
| | 0.0% | 7.4% | 83.9% | 37.0% | 3.2% | 7.4% | – | – |
| 3 years | 1 | 1 | 23 | 5 | 0 | 1 | – | – |
| | – | 3.7% | 74.2% | 18.5% | 0.0% | 3.7% | – | – |

Note. n – number of patients.

Table 4 / Таблица 4

Mean best corrected visual acuity according to follow-up time ($M \pm SD$)Средняя максимально скорректированная острота зрения в зависимости от срока наблюдения ($M \pm SD$)

| Group | Follow-up period | | | | | | | |
|----------|------------------|-----------------|----------------|----------------|-----------------|-----------------|-----------------|-----------------|
| | Before surgery | 3–5 days | 6 months | 1 year | 1.5 years | 2 years | 2.5 years | 3 years |
| Group I | 0.48 \pm 0.29 | 0.52 \pm 0.3 | 0.5 \pm 0.34 | 0.5 \pm 0.35 | 0.5 \pm 0.32 | 0.41 \pm 0.28 | 0.37 \pm 0.29 | 0.47 \pm 0.32 |
| Group II | 0.44 \pm 0.28 | 0.44 \pm 0.29 | 0.47 \pm 0.3 | 0.46 \pm 0.3 | 0.43 \pm 0.32 | 0.5 \pm 0.37 | 0.26 \pm 0.19 | 0.35 \pm 0.26 |

Table 5 / Таблица 5

Optical coherence tomography data of patients, *n***Значения данных оптической когерентной томографии пациентов, *n***

| Follow-up period | Dynamics of the RNFL thickness | | | | | | | | Total number of patients | |
|------------------|--------------------------------|----------|-----------------|----------|-----------------------|----------|------------------------|----------|--------------------------|----------|
| | 0 – negative dynamics | | 1 – no dynamics | | 2 – positive dynamics | | 3 – cannot be assessed | | | |
| | Group I | Group II | Group I | Group II | Group I | Group II | Group I | Group II | Group I | Group II |
| 6 months | – | – | 29 | 23 | 0 | 2 | 3 | 2 | 32 | 27 |
| | – | – | 90.6% | 85.2% | 0.0% | 7.4% | 9.4% | 7.4% | 100.0% | 100.0% |
| 1 year | 1 | 1 | 22 | 22 | – | – | 3 | 2 | 26 | 25 |
| | 3.8% | 4.0% | 84.6% | 88.0% | – | – | 11.5% | 8.0% | 100.0% | 100.0% |
| 1.5 years | 0 | 2 | 19 | 20 | – | – | 1 | 2 | 20 | 24 |
| | 0.0% | 8.3% | 95.0% | 83.3% | – | – | 5.0% | 8.3% | 100.0% | 100.0% |
| 2 years | 4 | 4 | 14 | 19 | – | – | | | 18 | 23 |
| | 22.2% | 17.4% | 77.8% | 82.6% | – | – | | | 100.0% | 100.0% |
| 2.5 years | 0 | 1 | 11 | 12 | – | – | 1 | 1 | 12 | 14 |
| | 0.0% | 7.1% | 91.7% | 85.7% | – | – | 8.3% | 7.1% | 100.0% | 100.0% |
| 3 years | 0 | 1 | 8 | 5 | – | – | 0 | 1 | 8 | 7 |
| | | 14.3% | 100.0% | 71.4% | – | – | 0.0% | 14.3% | 100.0% | 100.0% |

Note. *n* – number of patients. RNFL – retinal nerve fiber layer. Dynamics (Friedman's criterion): for group I $p = 0.221$; for group II $p = 0.543$.

Table 6 / Таблица 6

Changes in patients' visual fields by automated perimetry, *n***Данные изменения компьютерной периметрии КПЗ пациентов, *n***

| Follow-up period | Dynamics of automated perimetry data | | | | | | Total number of patients | |
|------------------|--------------------------------------|-------|-----------------|-------|-----------------------|------|--------------------------|--------|
| | 0 – negative dynamics | | 1 – no dynamics | | 2 – positive dynamics | | | |
| | I | II | I | II | I | II | I | II |
| 6 months | – | – | 32 | 25 | 0 | 2 | 32 | 27 |
| | – | – | 100.0% | 92.6% | 0.0% | 7.4% | 100.0% | 100.0% |
| 1 year | 1 | 1 | 25 | 24 | – | – | 26 | 25 |
| | 3.8% | 4.0% | 96.2% | 96.0% | – | – | 100.0% | 100.0% |
| 1.5 years | 0 | 2 | 20 | 22 | – | – | 20 | 24 |
| | 0.0% | 8.3% | 100.0% | 91.7% | – | – | 100.0% | 100.0% |
| 2 years | 3 | 3 | 15 | 20 | – | – | 18 | 23 |
| | 16.7% | 13.0% | 83.3% | 87.0% | – | – | 100.0% | 100.0% |
| 2.5 years | 0 | 2 | 12 | 12 | – | – | 12 | 14 |
| | 0.0% | 14.3% | 100.0% | 85.7% | – | – | 100.0% | 100.0% |
| 3 years | 0 | 1 | 8 | 6 | – | – | 8 | 7 |
| | 0.0% | 14.3% | 100.0% | 85.7% | – | – | 100.0% | 100.0% |

Note. *n* – number of patients.

Table 7 / Таблица 7

Post-operative complications, *n*Осложнения в послеоперационном периоде, *n*

| Group | Post-operative complications | | | | | | | | In total |
|----------|------------------------------|-----------------------------------|---------|----------|-------------------|----------------------|--------|----------|----------|
| | No compli- cations | Cilio- choroidal detachment | Hyphema | Cataract | Shunt eruption | Corneal dystrophy | Fibrin | Hypotony | |
| Group I | 22 | 1 | 3 | 1 | 2 | 0 | 1 | 2 | 32 |
| | 68.8% | 3.1% | 9.4% | 3.1% | 6.3% | 0.0% | 3.1% | 6.3% | 100.0% |
| Group II | 18 | 1 | 4 | 3 | 0 | 1 | 0 | 0 | 27 |
| | 66.7% | 3.7% | 14.8% | 11.1% | 0.0% | 3.7% | 0.0% | 0.0% | 100.0% |

Note. *n* – number of patients.

CONCLUSIONS

1. Both variants of filtration devices have similar construction and implantation technique.

2. The target IOP level was reached in all patients, but much of them needed an additional prescription of therapy. In the present study with patients' follow-up, within three years after implantation, there was no statistically significant difference in IOP level revealed.

3. Best corrected visual acuity within the 2 years follow-up time stayed on the level close to the initial one. But in 3 years, visual acuity was just above in patients, to whom filtration device Ex-Press® P-200 has been implanted

4. According to the OCT data, negative dynamics was registered only in one patient in the "Implant A3" group after a follow-up of more than two years. According to remaining dynamic indicators, during all the follow-up time, there was no statistically significant difference between groups revealed. A similar pattern was observed in functional visual field testing of patients. Statistically significant differences involved only the follow-up terms of more than two years, and negative dynamics was recorded only in a patient of the group II.

Thus, the clinical efficacy of both devices appeared comparable.

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