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Aligadgyeva L.G., Makkayeva S.M.*, Omarova E.D.

BİRİNCİLİ AÇIQ BUCAQLI QLAUKOMADA "PRESERFLO" MİKROŞUNT İMPLANTASİYASI ÜZRƏ TƏCRÜBƏMİZ

H.O.Bulaç adına Respublika Oftalmoloji Xəstəxanası, Mahaçqala

Korrespondensiya üçün:
Aligadgyeva Leyla Qambulatovna, t.ü.f.d., H.O.Bulaç adına Respublika Oftalmoloji Xəstəxanası, Mahaçqala, Dağıstan
E-mail: leylarob@yandex.ru
https://orcid.org/0009-0001-5829-5759

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XÜLASƏ

Qlaukomanın drenaj cərrahiyyəsi sahəsində mühüm nailiyyətlərdən biri minimal invaziv drenaj sistemləridir. Bu üsullar cərrahi travmanı və əməliyyatdan sonrakı ağırlaşmaları azaltmaqla yanaşı, gözdaxili təzyiqin (GDT) effektiv şəkildə aşağı salınmasını təmin edir. "PRESERFLO™ MicroShunt" göz daxili mayesinin axınını yaxşılaşdırmaq üçün hazırlanmış minimal invaziv drenaj vasitəsidir. Qısa müddətli nəticələr ümidverici olsa da, onun klassik cərrahi üsullarla müqayisəli effektivliyi barədə məlumatlar məhduddur.

Məqsəd – mikroşunt implantasiyasının müstəqil GDT-i azaldan üsul kimi effektivliyini Fedorov–Kozlov metoduna əsasən icra edilən standart nüfuz etməyən dərin sklerektomiya (NEDS) ilə müqayisəli qiymətləndirmək.

Material və metodlar

Bu açıq prospektiv tədqiqata, refrakter hallar da daxil olmaqla, birincili açıq bucaqlı qlaukoması olan 16 xəstə daxil edilmişdir. Xəstələr iki qrupa bölünmüşdür: I qrupda (n = 8) – "Mitomisin C" tətbiqi ilə "PreserFlo" microşunt implantasiyası, II qrupda isə (n = 8) – NEDS əməliyyatı icra edilmişdir. Qruplar arasında ilkin klinik göstəricilər müqayisə edilə bilən səviyyədə idi ($p > 0,05$). Xəstələr 12 ay ərzində müşahidə edilmişdir. Əməliyyat sonrası qiymətləndirməyə maksimal korreksiya olunmuş görmə itiliyi, perimetriya, GDT təyini, biomikroskopiya, gonioskopiya, göz dibinin müayinəsi, ön seqmentin optik koherens tomoqrafiyası və ultrasəs biomikroskopiyası daxil edilmişdir.

Nəticələr

I qrupda orta GDT əməliyyatdan əvvəl 31,0 ± 3,7 mmHg-dən əməliyyatdan sonrakı 1-ci gündə 9,4 ± 1,8 mmHg-ə enmiş və 1 il sonra 16,3 ± 4,1 mmHg səviyyəsində stabilləşmişdir. II qrupda isə GDT 29,0 ± 4,1 mmHg-dən 1-ci gündə 16,5 ± 2,8 mmHg-ə düşmüş və 1 il sonra 19,6 mmHg-ə yüksəlmişdir. Müşahidə dövründə heç bir xəstədə əlavə hipotenziv dərmanlara ehtiyac yaranmamışdır. II qrupda 25% hallarda əlavə lazer müdaxiləsi tələb olunmuşdur. Hər iki qrupda görmə funksiyaları və optik sinir diski göstəriciləri stabil qalmış, heç bir əməliyyatdaxili və ya əməliyyatdan sonrası ağırlaşma müşahidə edilməmişdir.

Yekun

Bir illik müşahidə dövründə "PreserFlo" microşunt implantasiyası NEDS ilə müqayisədə GDT-ə daha effektiv nəzarət, təhlükəsizlik və əlavə müdaxilələrə daha az ehtiyac olması ilə qiymətləndirilə bilər. Bu cərrahiyyə üsulu refrakter birincili açıq bucaqlı qlaukoma hallarında tövsiyə edilə bilər. Bununla belə, uzunmüddətli effektivlik və iqtisadi səmərəliliyin qiymətləndirilməsi üçün daha geniş və uzunmüddətli tədqiqatlara ehtiyac vardır..

Açar sözlər: *PRESERFLO™ mikroşunt, birincili açıq bucaqlı qlaukoma, gözdaxili təzyiq, minimal invaziv qlaukoma cərrahiyyəsi*

**Dağıstan Dövlət Tibb Universiteti, Mahaçqala*

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Aligadjyeva L.G., Makkaeva S.M.*, Omarova E.D.

OUR EXPERIENCE WITH PRESERFLO MICROSHUNT IMPLANTATION SURGERY FOR PRIMARY OPEN-ANGLE GLAUCOMA

Republican Ophthalmological Hospital after H.O. Bulach, Makhachkala

For correspondence:
Aligadgyeva Leyla Gambulatovna, PhD, Republican Ophthalmological Hospital after H.O.Bulach, Makhachkala, Dagestan
E-mail: leylarob@yandex.ru
https://orcid.org/0009-0001-5829-5759

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Authors participation:
Concept and design of investigation: Aligadjyeva L.G., Makkaeva S.M.
Material collection and processing: Aligadjyeva L.G.
Statistical data processing: Aligadjyeva L.G., Makkaeva S.M.
Spelling text: Aligadjyeva L.G., Makkaeva S.M.
Editing: Aligadjyeva L.G., Makkaeva S.M., Omarova E.D.

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SUMMARY

Drainage devices represent an important advancement in glaucoma surgery, offering effective intraocular pressure (IOP) reduction with reduced surgical trauma and fewer postoperative complications. The PRESERFLO™ MicroShunt is a minimally invasive drainage device designed to enhance aqueous humor outflow. Although short-term outcomes are promising, data on its comparative efficacy with conventional surgical techniques remain limited.

Purpose – to evaluate the efficacy of microshunt implantation as a standalone IOP-lowering procedure in comparison with the standard non-penetrating deep sclerectomy (NPDS) technique performed according to the Fedorov-Kozlov method.

Material and methods

This open-label prospective study included 16 patients with primary open-angle glaucoma (POAG), including refractory cases, who underwent primary glaucoma surgery. Patients were divided into two groups: Group I (n = 8) underwent PRESERFLO™ MicroShunt implantation with Mitomycin C, and Group II (n = 8) underwent NPDS. Baseline demographic and clinical characteristics were comparable between groups ($p > 0.05$). Patients were followed for 12 months. Postoperative evaluation included best-corrected visual acuity (BCVA), perimetry, IOP measurement, slit-lamp examination, gonioscopy, fundus examination, anterior segment Optical Coherence Tomography (OCT), and ultrasound biomicroscopy (UBM).

Results

In Group I, mean IOP decreased from 31.0 ± 3.7 mmHg preoperatively to 9.4 ± 1.8 mmHg on day 1, stabilizing at 16.3 ± 4.1 mmHg after 1 year. In Group II, IOP decreased from 29.0 ± 4.1 mmHg to 16.5 ± 2.8 mmHg on day 1 and increased to 19.6 mmHg at 1 year. No patients required hypotensive medication during follow-up. Two NPDS patients (25%) required additional laser intervention. Visual acuity, perimetric indices, and optic nerve head parameters remained stable in both groups. No intraoperative or postoperative complications were observed.

Conclusion

PRESERFLO™ MicroShunt implantation demonstrated superior IOP control, a favorable safety profile, and reduced need for additional interventions compared with NPDS over a 1-year follow-up. This method may be recommended for patients with refractory POAG; however, larger studies with longer follow-up are required to confirm long-term efficacy and cost-effectiveness.

Key words: *PRESERFLO™ MicroShunt, primary open-angle glaucoma, intraocular pressure, minimally invasive glaucoma surgery*

**Dagestan state medical university, Makhachkala*

The use of drainage devices in surgery is one of the most common methods of glaucoma treatment. They can be employed as a primary surgical intervention POAG, as the implantation of micro-stents is considered a less traumatic type of glaucoma surgery. This rationale supports the expanding indications for the use of drainage devices in glaucoma surgery [1 - 3].

New surgical devices have been developed to minimize the invasiveness of interventions and reduce the incidence of postoperative complications.

The PreserFlo MicroShunt (Santen Pharmaceutical Co. Ltd.) is a drainage device with the following dimensions: length – 8.5 mm, outer diameter – 350 μm, inner diameter – 70 μm. The device is made from a biocompatible material known as SIBS (styrene-isobutylene-styrene). It is designed to drain aqueous humor from the anterior chamber into a subconjunctival filtering bleb. According to study results, this shunt is associated with a lower risk of postoperative complications [4 - 7].

The risk of postoperative hypotony is reduced due to the internal design that restricts aqueous humor flow. The material of the drainage device contributes to a lower incidence of postoperative inflammation and a reduced risk of bleb fibrosis [8 - 11].

The PreserFlo MicroShunt lowers IOP by facilitating the outflow of aqueous humor into the sub-Tenon's space with the formation of a filtering bleb. Published study results indicate advantages of the PreserFlo MicroShunt over trabeculectomy, including a lower frequency of postoperative complications such as transient postoperative hypotony and hyphema, as well as a reduced need for additional surgical interventions [12, 13].

Current data also demonstrate effective IOP reduction following PreserFlo implantation, both as a standalone procedure and in combination with phacoemulsification cataract surgery [14].

However, despite positive short-term outcomes, data on the long-term efficacy of the PreserFlo MicroShunt are lacking.

Our experience with PreserFlo MicroShunt implantation involves performing the surgery with the use of Mitomycin C and conducting prospective postoperative follow-up of patients with POAG. The follow-up period was 1 year.

Purpose – to evaluate the efficacy of microshunt implantation as a standalone IOP-lowering procedure in comparison with the standard NPDS technique according to the Fedorov-Kozlov method.

Material and methods

A total of 16 patients with POAG, including refractory cases, participated in this open-label prospective study. These patients underwent either PreserFlo MicroShunt implantation or NPDS. Under a donation agreement, the initial samples were received by the Glaucoma Center at the "Republican Ophthalmology Hospital after H.O. Bulach" State Budgetary Institution of the Republic of Dagestan.

The patients were divided into two groups: Group I comprised 8 patients with POAG who underwent PreserFlo MicroShunt implantation. Group II also consisted of 8 patients with POAG who underwent NPDS.

Baseline characteristics (duration of illness, age, gender, IOP, number of IOP-lowering medications, retinal nerve fiber layer thickness) were comparable between the two groups ($p > 0.05$).

In all 8 cases of group I, target IOP was not achieved on combined hypotensive therapy.

Postoperative assessment criteria included: BCVA, perimetry, IOP measurement using Maklakov tonometry, slit-lamp examination, fundus examination (optic nerve head and retina), gonioscopy, anterior segment OCT for shunt positioning, anterior chamber angle assessment, and UBM.

Surgical Technique: The surgery was performed under topical instillation anesthesia. A 7-0 silk traction suture was placed 1 mm from the limbus. A conjunctival and Tenon's capsule incision was made at the

3-4 o'clock limbal position. When necessary, diathermy coagulation of the scleral bed was performed.

Mitomycin C was diluted in saline solution (0.2-0.4 mg/ml). Three round sponges soaked in Mitomycin C were applied to the scleral bed for 2 minutes, after which the area was copiously irrigated with 20 ml of saline solution.

A mark was then made 3 mm posterior to the limbus, and a scleral tunnel matching the curvature of the globe was created, extending into the anterior chamber. Upon passing through the trabecular meshwork, the tunnel was directed to become parallel to the plane of the iris.

The PreserFlo device was introduced into the tunnel using smooth, non-toothed forceps. The microshunt was advanced with its bevel facing upwards until its fins were properly seated within the tunnel. Aqueous humor outflow was confirmed at the distal end of the device.

Finally, the conjunctiva and Tenon's capsule were secured to the episclera at the limbal level with a single 10-0 nylon interrupted suture. No subconjunctival injections of Mitomycin C were administered in the postoperative period.

Results

No complications were identified in either the early or late postoperative periods. No statistically significant difference in complication rates was found between the two groups ($p > 0.05$).

In Group I (PreserFlo), IOP decreased to 9.4 ± 1.8 mmHg on postoperative day 1, compared to a preoperative value of 31.0 ± 3.7 mmHg. Subsequently, an increase in IOP to 16.3 ± 4.1 mmHg was observed over the 1-year follow-up period.

In Group II (NPDS), the reduction in IOP in the early postoperative period was less pronounced, measuring 16.5 ± 2.8 mmHg on the first day after surgery, with a further increase to 19.6 mmHg at the 1-year follow-up (compared to a preoperative value of 29.0 ± 4.1 mmHg). At the 1-year follow-up, no patients in either group required antihypertensive medication. In Group II, two patients with IOP = 22 mmHg underwent needling revision (gonipuncture) one month after surgery.

No significant differences in BCVA were noted in the postoperative period for patients following PreserFlo MicroShunt implantation.

Perimetry performed at various time points after surgery showed that the mean values of the mean deviation (MD) index did not differ significantly from preoperative levels.

According to perimetry and assessment of the optic nerve head (ONH) status, the same stage of glaucoma was maintained in the majority of patients: 87.5% in the PreserFlo group and 75% in the NPDS group, compared to their preoperative status.

Optic nerve head assessment was performed based on OCT data.

Differences from baseline in the area and volume of the neuroretinal rim, as well as in the cup-to-disc ratio, were statistically insignificant in all cases for both groups.

According to perimetry and ONH assessment, all patients in both groups maintained the same stage of glaucoma as before PreserFlo MicroShunt implantation.

Based on UBM and anterior segment OCT findings, the PreserFlo MicroShunt maintained a stable position within the eye. UBM data were as follows: mean thickness of the trabeculo-descemet's membrane (TDM) was 0.15 ± 0.005 mm (range 0.08 to 0.20 mm), mean height of the intrascleral space (ISS) was 0.29 ± 0.03 mm (range 0.13 to 0.4 mm), and mean height of the filtering bleb (FB) was 0.38 ± 0.07 mm (range 0.2 to 1.30 mm).

This study presents a comparative analysis of the efficacy of PreserFlo drainage device implantation versus NPDS in patients with refractory primary open-angle glaucoma. PreserFlo drainage implantation demonstrated efficacy and safety based on clinical and functional data obtained over a 1-year

observation period. This method achieved sustained and long-term normalization of IOP in 100% of patients without the need for additional hypotensive medication for 1 year and resulted in stabilization of the glaucomatous process.

In Group II (NPDS), 25% of patients required an additional laser intervention - descemetogoniopuncture (DGP).

Discussion

Thus, surgical treatment of POAG with PreserFlo MicroShunt implantation demonstrated high efficacy, characterized by a sustained hypotensive effect and stabilization of visual function. Based on perimetry and OCT data, it can be concluded that the vast majority of patients exhibited stabilization of the glaucomatous process throughout the 1-year follow-up period after microshunt implantation. The absence of complications in both early and late postoperative periods confirms the safety of this treatment method for patients with refractory glaucoma [4 - 7]. A comparative analysis of the efficacy of PreserFlo MicroShunt implantation versus NPDS in patients undergoing primary surgery for open-angle glaucoma demonstrated the advantage of the microshunt in achieving the target hypotensive effect. Implantation of the PreserFlo MicroShunt provides effective IOP reduction with a favorable safety profile [8 - 11].

This procedure can be considered highly successful, as it is performed as a standalone intervention even in cases with high baseline IOP (≥ 31 mmHg) by antihypertensive therapy and maintains postoperative IOP within the 16-17 mmHg range throughout the observation period after operation. PreserFlo MicroShunt implantation has proven to be an effective and safe intervention for patients with POAG for up to one year postoperatively. Therefore, it can be recommended in refractory cases.

Hypotensive surgery using the PRESERFLO™ microshunt is easy to perform, with an operation time of 7-10 minutes, and is non-traumatic to the eye. Postoperative management takes less time, requires fewer check-ups and additional interventions, which improves the quality of life. Although the high cost of the PRESERFLO™ microshunt significantly increases the overall cost of the surgery, the smooth postoperative course does not require frequent follow-up visits, descemetogoniopuncture, or needling of the filtering bleb, which may offset the total treatment costs . As proof, new studies on the cost-effectiveness of microshunt use are needed.

Our clinical experience is still at an initial stage. It is necessary to wait for longer-term results to definitively judge the efficacy and safety of PRESERFLO™ microshunt implantation.

To evaluate long-term outcomes, further studies with larger patient cohorts are required.

Conclusion

PRESERFLO™ MicroShunt implantation demonstrated superior IOP control, a favorable safety profile, and reduced need for additional interventions compared with NPDS over a 1-year follow-up. This method may be recommended for patients with refractory POAG; however, larger studies with longer follow-up are required to confirm long-term efficacy and cost-effectiveness

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