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ORIGINAL PAPER

Comparison of the 1-year postoperative results of phacoemulsification–trabeculectomy and phacoemulsification–ExPRESS miniature shunt combined surgeries

Kemal Turgay Özbilen · Şerife Bayraktar · Emre Altınkurt · Mehmet Cemil Yılmazlı · Muhammed Talha Sadık · Ali Üstüner

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Abstract

Background and objective This study aimed to compare the 1-year postoperative phacoemulsification–trabeculectomy (P-Trab) and phacoemulsification–ExPRESS® (P-200 model) miniature shunt (P-ExPRESS) combined surgeries.

Materials and methods This retrospective, comparative clinical study investigated 41 eyes of 41 patients diagnosed with open-angle glaucoma and cataract. Of these, 21 eyes underwent P-Trab surgery and 20 eyes underwent P-ExPRESS surgery. The 1-year follow-up results, including intraocular pressure (IOP), visual acuity (VA), medications, and complications, were reviewed and compared. A $5 \leq$ IOP ≤ 18 mmHg or 30% reduction from baseline was defined as Qualified Success (QS-1), and target IOP without medication was defined as Complete Success (CS-1). A $5 \leq$ IOP ≤ 15 mmHg or 40% reduction from baseline was defined as Qualified Success (QS-2), and target IOP without medication was defined as Complete Success (CS-2).

Results The mean follow-up time was 16 months (12–26 months). Results after the twelfth month for P-Trab versus P-ExPRESS are: CS-1: 42.8% versus 60.0% ($P = 0.354$); QS-1: 86.7% versus 95% ($P = 0.606$); CS-2:33.3% versus 40% ($P = 0.751$); QS-2: 66.6% versus 75% ($P = 0.733$). Kaplan–Meier survival analysis was not statistically significant between two groups for both QS-1, CS-1 and QS-2, CS-2 ($P = 0.329$ vs $P = 0.365$, $P = 0.765$ vs $P = 0.789$, respectively). Pre-op mean IOP was: 33.19 ± 8.7 versus 34.55 ± 11.3 mmHg; post-op mean IOP was: 15.19 ± 3.07 versus 15.30 ± 3.32 mmHg ($P = 0.913$); pre-op mean VA was: 1.17 ± 1.04 versus 1.15 ± 1.07 logMAR; and post-op mean VA was: 0.61 ± 0.80 versus 0.66 ± 0.99 logMAR ($P = 0.869$). The pre-op mean number of antiglaucomatous medications was 3.76 ± 0.53 versus 3.30 ± 1.45, and the post-op results were 1.52 ± 1.53 versus 0.85 ± 1.26 ($P = 0.135$). Comparing the pre-op and post-op values, both types of surgeries were equally effective ($P = 0.00$). Surgical failure was 14.2% (3/21) versus 5% (1/20), and the incidence ratios of significant complications were: 47% (10/21) versus 10% (2/20) and P-Trab versus P-ExPRESS, respectively ($P = 0.015$).

Conclusion The 1-year postoperative results suggest that P-ExPRESS is as effective as P-Trab, with fewer complications.

K. T. Özbilen (✉) · Ş. Bayraktar · E. Altınkurt · M. T. Sadık
Department of Ophthalmology, Istanbul Faculty of Medicine, Istanbul University, 34093 Capa, Istanbul, Turkey
e-mail: turgay.ozbilen@istanbul.edu.tr

M. C. Yılmazlı · A. Üstüner
Glaucoma Department, Istanbul Eye Hospital, Bahcelievler, Istanbul, Turkey

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Introduction

Glaucoma is a multifactorial, chronic, progressive optic neuropathy characterized by a loss of ganglion cells and nerve fibers. The only controllable factor is intraocular pressure (IOP), which is also the most important one to consider [1]. Topical antiglaucomatous medication is the first choice for treating patients with open-angle glaucoma (OAG). However, if the glaucoma cannot be controlled after either administering the maximum tolerable amount of medication or using laser treatment, filtration surgery may be inevitable to prevent irreversible damage [2–4]. If the patient's vision is affected by cataracts, then cataract removal surgery can be performed simultaneously with the glaucoma filtration procedure.

Trabeculectomy has been the gold standard of penetrative glaucoma surgery since Cairns [5] introduced the procedure. The ExPRESS® miniature glaucoma shunt (Alcon, Fort Worth, Texas, USA) was introduced as a safer alternative for trabeculectomy. This device is made of medical grade 316L stainless steel. The P 200 model has an internal diameter of 200 microns, an external lumen diameter of 400 microns, and a length of 2.64 mm. The procedure does not require iridectomy or sclerectomy, and a standard lumen diameter is used. Combining this shunt with trabeculectomy has several advantages, such as reduced inflammation, increased potential for fast visual recovery, and decreased probability of hypotony, hyphema, and other complications [2, 6–8]. When the device was first described, clinical implantation was subconjunctival, and it was done by insertion into the anterior chamber through full-thickness sclera, thereby providing direct aqueous humor shunting of the non-valved lumen from the anterior chamber to the subconjunctiva. This caused two major problems: over-filtration and exposure of the device. Dahan and Carmichael [9] solved these problems by implanting the device under a partial-thickness scleral flap. This technique was also used in the surgeries performed in the present study.

Surgical procedure

All the surgeries were performed by two experienced surgeons (MCY and AÜ) at the Istanbul Eye Hospital. Two types of anesthesia were used: (1) local anesthesia (1% lidocaine + 0.5% bupivacaine) with intravenous sedatives and (2) general anesthesia. The procedure consisted of three consecutive stages. The same standard method was used for the first two stages, whereas two different alternatives were used for the final stage. These alternatives are trabeculectomy (P-Trab group) and the use of the ExPRESS miniature glaucoma shunt device (P-ExPRESS group).

The first stage began with the preparation of the fornix-based conjunctival flap ($\sim 6 \times 6$ mm), ~ 6 mm limbal incision was done by using Wescott scissors, blunt dissection was applied tenon and subconjunctival tissues followed by wet mild cauterization for hemostasis, and harvesting of a square-shaped, 4×4 mm, partial-thickness scleral flap (~ 300 µ) dissection was created by using blade (no: 15) and crescent knife. Then, 0.2 mg/ml mitomycin C (MMC) was applied subconjunctivally by avoiding the edge of the incision for three minutes using a soaked sponge. Next, irrigation was done using 50 ml balanced salt solution (BSS).

The second stage began with temporal clear corneal 2.4-mm microincisional phacoemulsification using the Phaco-Chop technique (WhiteStar Signature Pro Phacoemulsification System, Johnson & Johnson Vision CA, USA) and intraocular lens (IOL) implantation (monofocal IOL, Tecnis iTec Preloaded delivery system, Johnson & Johnson Vision).

As previously mentioned, two alternative methods were employed for the third and last stage. A corneal superior traction suture was passed when needed, and eye was rotated to inferiorly. In the P-Trab group, trabeculectomy was performed with 2×2 mm ostium by using 15° knife and then peripheral iridectomy by using Vannas scissors. Anterior chamber (AC) was maintained by BSS or viscoelastic device, if needed. In the P-ExPRESS group, implantation of the ExPRESS miniature shunt (P 200) was performed using a 25-G needle without sclerotmoy and iridectomy. Entry of the needle was parallel to the iris, passing the blue line into the anterior chamber, and confirmed that the tip of the implant does not touch the corneal endothelium or iris, and not obstructed by iris.

Finally, the scleral flap was closed with four, 10.0 nylon sutures. Sutures were as tightened to maintaining anterior chamber well. In both trabeculectomy and ExPRESS shunt implantation, filtration was checked by AC irrigation with BSS from side port, and then, the conjunctiva was closed with 8.0 polyglactin sutures.

Postoperative care was administered by the surgeon discretion, and topical moxifloxacin 0.5% and topical prednisolone acetate 1% were administered. Moxifloxacin was administered four times a day for the first week and then stopped. Prednisolone acetate was prescribed six times a day for the first 2 weeks, and later tapered off and stopped by the surgeon's discretion usually after 1 month. When needed, topical treatment of prednisolone was prolonged to 6–8 weeks if inflammation is persist. Laser suturolysis was applied to only 1 suture each time when filtration was insufficient by using Nd:YAG laser and suture lysis lenses to facilitate the outflow. Needling was performed to slow down wound healing when the blep was encapsulated or in cases of vascularized blep. 0.1 ml–5 mg of undiluted 5-fluorouracil (5-FU) was injected by 30-G needle into the subconjunctival area from the upper edge of the bleb, avoiding reflux and administration into bleb.

Patients and method

This study is a retrospective study based on reviewing patient files. The study was approved by the institutional research ethics committee of the Istanbul Faculty of Medicine, Turkey. Informed written consent was obtained from all the patients. The trial conformed to the tenets of the Declaration of Helsinki. Data were collected from 41 eyes of 41 consecutive patients diagnosed with OAG (only primary OAG [POAG] and pseudoexfoliation glaucoma [PEXG]) who underwent combined penetrating glaucoma filtration and cataract surgery at Istanbul Eye Hospital from January 2015 to January 2018. The decision to perform combined glaucoma filtration and cataract surgery was made by two experienced glaucoma specialists (MCY and AÜ). The decision to operate was made in cases where the patient's vision was significantly affected by cataracts, and either of the following mentioned below conditions were satisfied:

- Deterioration of visual field (VF) and structural values [1–34]: if reliable standard automated perimetric test results and OCT RNFL measurements are available;
- Abnormal glaucoma hemifield test in two consecutive examinations. Mean deviation (MD) > 3.5 dB and in two consecutive examinations, three or more non-margins in areas typical for glaucoma, $P < 5\%$ loss at one point and one of them is $P < \%$ 1. In two consecutive examinations, if the corrected pattern had a 5% probability of the pattern standard deviation (PSD) value.

Glaucoma severity staging was performed following the Hodapp classification.

Early glaucomatous loss: (a) MD $< -$ 6 dB, (b) fewer than 18 points depressed below the 5% probability level and fewer than 10 points below the $P < 1\%$ level, and (c) no point in the central 5 degrees with a sensitivity of less than 15 dB.

Moderate glaucomatous loss: (a) MD $< -$ 12 dB, (b) fewer than 37 points depressed below the 5% probability level and fewer than 20 points below the $P < 1\%$ level, (c) no absolute deficit (0 dB) in the 5 central degrees, and d) only one hemifield with sensitivity of < 15 dB in the 5 central degrees.

Advanced glaucomatous loss: (a) MD $> -$ 12 dB, (b) more than 37 points depressed below the 5% probability level or more than 20 points below the $P < 1\%$ level, (c) absolute deficit (0 dB) in the 5 central degrees and (d) sensitivity < 15 dB in the 5 central degrees in both hemifields.

- Assessing progression: Eyes that show deterioration of at least three test point locations are flagged as possibly progressing, if the finding is repeated in two consecutive tests and likely progressing if existing in three consecutive tests. MD index or the newer VFI index over time. If generalized reduction in visual field sensitivity alone, or focal loss alone, or a combination of both. If trend analysis indicates a change in VFI, MD, or mean defect, media opacity due to cataract was borne in mind
- Detecting progressive glaucomatous RNFL thinning and neuroretinal rim narrowing. But disease-related damage was differentiated according to normative data of age and ethnicity. Pitfalls of OCT such as artifacts and false segmentation were considered when using OCT

- IOP > 21 mm Hg, despite having administered the maximum tolerable amount of antiglaucomatous medication (possibly in addition to laser treatment).

Once the surgeon made the decision to perform a combined surgery, the patients were given the choice of whether to use the ExPRESS miniature shunt or the trabeculectomy technique. A complete ophthalmologic examination was performed on all patients, preoperatively. Visual activity (VA) was measured using the Snellen chart (uncorrected–corrected distance vision) and then converted to LogMAR. Three consecutive IOP measurements were taken using Goldman applanation tonometry (GAT) (Haag-Streit, Bern, Switzerland). The anterior segment was evaluated using slit lamp biomicroscopy. Angle evaluation was done using gonioscopy (Goldman 3 mirror gonioscopy lens and Schaffer classification). Central corneal thickness (CCT) measurements were done with ultrasonic pachymetry (Ocuscan® RxP, Alcon Inc, Irvine, CA, USA). VF analysis was done with automatic perimetry (full threshold program 30-2, Humphrey Field Analyzer; Carl Zeiss Meditec, Dublin, CA, USA). Structural values for the retina nerve fiber layer (RNFL) and the optic nerve head (ONH) were measured using optical coherence tomography (OCT) (3D OCT-2000 FA plus, Topcon, Tokyo, Japan). Fundus and ONH evaluation (rim thinning, excavation, RNFL defects) were evaluated using a 90-D lens. IOL was calculated using optical biometry (Lenstar® LS 9000, Haag-Streit AG, Switzerland); immersion biometry was used if optical biometry was not possible.

To be included in the study, patients had to meet the following criteria. They had to be at least 20 years old, have medically uncontrollable OAG (only the POAG or PEXG subtypes), and have vision that is significantly affected by cataracts. Patients that had other OAG subtypes (e.g., pigmentary, steroid induced, etc.), uveitis or uveitic glaucoma, primary or secondary angle-closure glaucoma, or those who had previously undergone incisional eye surgery, had significant eye disease (other than cataracts), or had conjunctival scarring were excluded from the study.

The minimum follow-up time for both the inclusion and exclusion criteria was 12 months.

Postoperatively, complete ophthalmologic examinations were performed on the first day, the first and second week, and at the first, third, sixth, and twelfth month follow-ups. The scope of this examination included Snellen chart results for best-corrected visual acuity (BCVA), IOP measurement with GAT, slit lamp biomicroscopy assessment of bleb morphology, the position of the implant and the anterior chamber, the Seidel test, the IOL position, the presence of inflammation and other complications, and fundus examination. All findings were recorded in the patient's file.

The postoperative success criterion 1 was: (a) $5 \leq$ IOP value ≤ 18 mm Hg and (b) if the postoperative IOP is > 18 mm Hg, then the IOP reduction should be at least 30% in comparison with the preoperative value. The postoperative success criterion 2 was: (a) $5 \leq$ IOP ≤ 15 mm Hg and (b) if the postoperative IOP is > 15 mm Hg, then the IOP reduction should be at least 40% in comparison with the preoperative value. Qualified Success (QS-1 for criterion 1 and QS-2 for criterion 2) was defined as satisfying these criteria without any additional surgical intervention. Complete Success (CS-1 for criterion 1 and CS-2 for criterion 2) was defined as satisfying these criteria without the use of antiglaucomatous medication. Criterion 1 was targeted for moderate glaucoma cases (-6 dB $<$ MD <-12 dB), and criterion 2 was targeted for advanced glaucoma cases (MD >-12 dB) [10]. The procedure was not considered to have failed in the event of laser suturoloysis or suture removal, or bleb needling to improve bleb function. The procedure was considered to have failed if re-filtration surgery or any other additional surgical intervention (e.g., bleb revision) was performed.

Hypotony was defined as IOP < 5 mm Hg. Three grades were defined for anterior chamber (AC) shallowing, as follows: grade 1: peripheral iridocorneal touch; grade 2: mid-peripheral iridocorneal apposition; and grade 3: IOL corneal touch.

Statistical analysis was performed using SPSS software version 17 (SPSS Inc. Chicago, IL, USA). The paired t test and t test were used for continuous univariate analysis, and the ANOVA test was used for repeated measurement of the independent variables between the treatment groups. Chi-square tests and Fisher's exact tests were used for the categorical variables. Kaplan–Meier survival function analysis was used. P value ≤ 0.05 was considered to be statistically significant.

Results

A total of 41 eyes of 41 patients were included in this study. These were partitioned into two groups: 21 eyes in the P-Trab group and 20 eyes in the P-ExPRESS group. There were four patients with PEXG in each group. Preoperative VF test results were available 14 of 20 patients in P-ExPRESS group and 16 of 21 patients in P-Trab groups. Patients who could not perform perimetry mostly had advanced glaucoma or low visual acuity. RNFL thickness was significantly lower in almost all patients according to age and ethnic normative data and was sectoral or total defective. The demographic information and characteristics of the groups are presented in Table 1. No statistically significant differences were found between the two groups, as shown by the *P* values.

The pre-op and post-op BCVA values, collected after the first, sixth, and twelfth months, are summarized in Table 2. Significant improvements were observed over time within each group; however, the difference in the improvement rate between the two groups was not statistically significant. In each group, there was one patient whose VA had worsened in comparison with baseline values. This was considered to be the result of surgical failure.

The IOP values, reduction amounts, and rates are summarized in Table 3 and Fig. 1. The reduction in IOP from the baseline values, observed in the first, sixth, and twelfth month visits, was statistically significant in each group ($P = 0.00$). The reduction was similar for both groups, and no statistically significant difference between them was found. The most significant reduction occurred in the first month. The reduction in mean IOP after 12 months was found to be 54% in the P-Trab group and 55% in the P-ExPRESS group. The two results are similar.

The changes in the mean amount of antiglaucomatous medications used preoperatively are summarized in Table 4. The reduction in the amount of medications used from baseline was statistically significant in each group (*P*: 0.00 for each). Postoperatively, the amount of medications used was slightly lower and the reduction in the medication use was slightly higher in the P-ExPRESS group than the P-Trab group, but the difference between the two groups was not statistically significant.

As stated in the Patients and Method section, the criteria were chosen as criteria determined by WGA [10, 11]. Criterion 1 was the target pressure for moderate glaucoma, and criterion 2 was the target pressure for advanced glaucoma cases. Criterion 1, $5 \leq \text{IOP} \leq 18$ mmHg or a 30% reduction in IOP from the baseline values, was defined as QS-1. Achieving the target IOP without medication was defined as CS-1. The CS-1 rate was 42.8% in the P-Trab group and 60% in the P-ExPRESS group. The QS-1 rate was 86.7% (P-Trab) and 95% (P-ExPRESS). For criterion 2, $5 \leq \text{IOP} \leq 15$ mm Hg and or a 40% reduction in IOP from the baseline, CS-2 rate was 33.3% in the P-Trab group and 40% in the P-ExPRESS group. The QS-2 rate was 66.6% (P-Trab) and 75% (P-ExPRESS). Laser suturolysis was performed once in seven patients and two times in two patients in the P-ExPRESS group. Suturolysis was performed once in five patients and two times in one patient in the P-Trab

Table 1 Characteristics of groups

Groups	Phaco-Trab	Phaco-ExPRESS	*P* values (*T* test)
Total no of patients (POAG-PEXG)	21 (17–4)	20 (16–4)	
Age, years	67.23 ± 10.12	71.15 ± 7.15	0.163
Males/females	7/14	12/8	0.091
Follow-up time (months)	15.6 ± 3.08	16.05 ± 3.56	0.723
Pre BCVA (logMAR)	1.17 ± 1.04	1.15 ± 1.01	0.944
Pre IOP (mmHg)	33.19 ± 8.7	34.55 ± 11.3	0.669
Amount of medications	3.76 ± 0.53	3.30 ± 1.45	0.133
RNFL thickness (μ)	59.09 ± 11.86	57.20 ± 12.31	0.796
Perimetry MD (dB)	13.44 ± 4.22 (16/21 available)	14.96 ± 3.67 (14/20 available)	0.244[a]
Glaucoma severity (moderate/advanced/no assessed[b])	6/10/5[b]	5/9/6[+]	

MD, mean deviation; dB, decibel

[a]Kruskal–Wallis test

[b]Could not be assessed because of perimetric values are not available

Table 2 Mean BCVA values (logMAR)

Groups	Phaco-Trab	Phaco-ExPRESS	*P* value between groups
Pre-op	1.17 ± 1.04	1.15 ± 1.07	$P = 0.94$
Post-op 1. month	0.68 ± 0.93 ($P < 0.05$)	0.63 ± 0.81 ($P < 0.05$)	$P = 0.84$
Post-op 6. month	0.79 ± 0.97 ($P < 0.05$)	0.68 ± 0.98 ($P < 0.05$)	$P = 0.73$
Post-op 12. month	0.61 ± 0.80 ($P < 0.05$)	0.66 ± 0.99 ($P < 0.05$)	$P = 0.85$

T test and ANOVA

Table 3 Mean IOP values and reduction in IOP from baseline (mm Hg)

Groups	Phaco-Trab	Phaco-ExPRESS	*P* value between groups
Pre-op IOP (mm Hg)	33.19 ± 8.7	34.55 ± 11.3	$P = 0.669$
Post-op 1. month	11.71 ± 4.3	13.95 ± 4.1	$P = 0.098$
Reduction in IOP	21.47 ± 8.61 $P = 0.00$	20.60 ± 10.8 $P = 0.00$	
Post-op 6. month	14.14 ± 4.36	14.50 ± 2.58	$P = 0.753$
Reduction in IOP	19.04 ± 9.45 $P = 0.00$	20.05 ± 11.3 $P = 0.00$	
Post-op 12. month	15.19 ± 3.07	15.30 ± 3.32	$P = 0.913$
Reduction in IOP	18.00 ± 9.0 $P = 0.00$	19.25 ± 10.61 $P = 0.00$	

T test and ANOVA

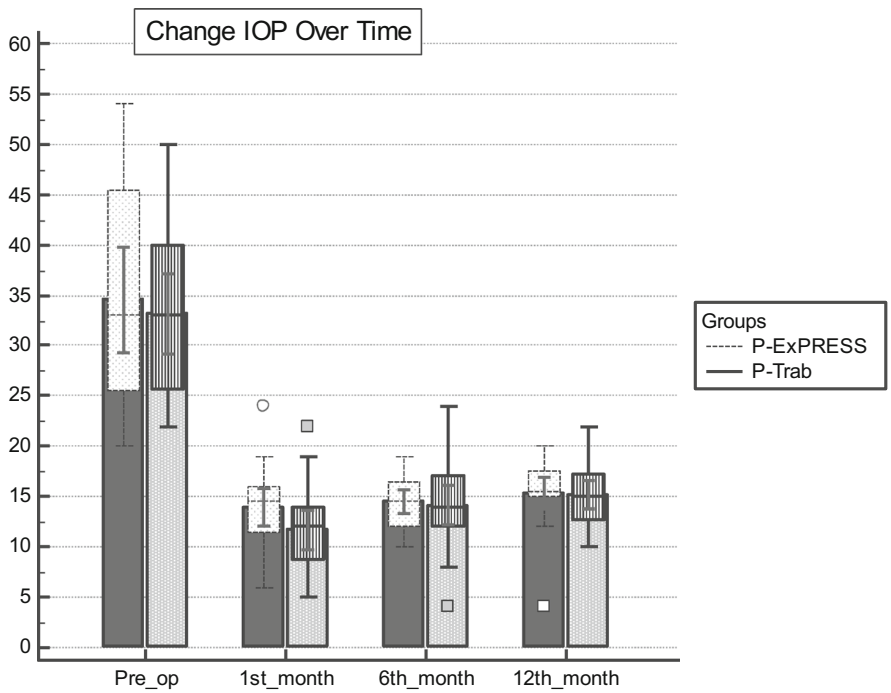

Fig. 1 Change of IOP over time

Table 4 The amount of antiglaucomatous medications

Groups	Phaco-Trab	Phaco-ExPRESS	*P* value between groups
Pre-op use	3.76 ± 0.53	3.30 ± 1.45	$P = 0.18$
Post-op 12th month use	1.52 ± 1.53	0.85 ± 1.26	$P = 0.13$
Reduction in medication	2.23 ± 1.44 ($P < 0.05$)	2.45 ± 1.49 ($P < 0.05$)	$P = 0.13$

Paired *T* test

group. In the P-ExPRESS group, needling was performed once in four patients and in two times in three patients. In the P-Trab group, needling was performed once in five patients and two times in two patients. Early transient hypotony was common in both groups: 28% (6/21) (P-Trab) and 30% (6/20) (P-ExPRESS). All such cases resolved within 2 weeks, except for one patient in each group for whom prolonged hypotony was detected. The patient with prolonged hypotony in the P-ExPRESS group progressed to hypotony maculopathy, resulting in vision deterioration, which prompted the need for bleb revision. Choroidal effusion was only seen in three patients (3/21, 14%) in the P-Trab group. Two of cases spontaneously regressed within 3 months, while the third case persisted and resulted in vision deterioration. AC shallowing was common in the P-Trab group at 19% (4/21); it was 5% (1/20) in the P-ExPRESS group. Apparent hyphema was only seen in a single patient in the P-Trab group, and it disappeared spontaneously. No blebitis or endophthalmitis was observed in either group. Bleb revision was applied to two patients in the P-Trab group due to failing to achieve the target IOP values, and one patient in the P-ExPRESS group due to prolonged hypotony and maculopathy. In the P-ExPRESS group, implant-related complications were not be observed as exposure, dislocation, corneal touch, and tip occlusion of the implant (Table 5).

Three out of 21 (14%) of the surgeries in the P-Trab group and 1 out of 20 (5%) of surgeries in the P-ExPRESS group were considered to be surgical failures. For two of the patients in the P-Trab group, the surgery was considered to be a failure because the patients failed to reach the target IOP and bleb revision was performed; visual deterioration due to prolonged choroidal effusion was the reason that the third surgery was considered to be a failure. For the P-ExPRESS group, the surgery was considered to be a failure because bleb revision was necessary due to prolonged hypotony, maculopathy, and visual deterioration, all in the same patient. Serious complication (microhyphema and transient early hypotony were not considered serious complications) rates were 47% (10/21) in the P-Trab group and 10% (2/20) in the P-ExPRESS group; this difference was statistically significant (Fisher's exact test; $P = 0.015$). Test of equality of survival distributions for the different levels of groups was not statistically significant. *P* values for CS-1 and QS-1 and CS-2 and QS-2 were 0.354 and 0.606 and 0.751 and 0.733, respectively. Kaplan–Meier survival analysis diagram for CS and QS is shown in Figs. 2, 3, 4 and 5.

Discussion

Currently, IOP reduction is the only controllable factor in the progression of glaucoma. Therefore, all treatment strategies aim to decrease IOP. Surgical intervention becomes inevitable if medication and laser treatment are insufficient in alleviating the progression of the disease, or in the event of poor patient compliance.

Despite high complication rates [7, 12, 13], trabeculectomy is still the gold standard procedure for treating glaucoma. Over the last 2 decades, the ExPRESS miniature shunt glaucoma device has become an alternative to trabeculectomy, with claims of lower complication rates [2, 4, 14]. The ExPRESS miniature shunt method has several advantages. The lumen diameter is fixed, and the method does not involve iridectomy or sclerectomy. It provides controlled filtration, and the surgical procedure is less traumatic. Due to these advantages, a large number of published prospective and retrospective studies have compared trabeculectomy and the ExPRESS miniature shunt. However, there are only several combined

Table 5 12-month results

Groups	Phaco-Trab	Phaco-ExPRESS
Complete Success-1	42.8%	60%
Qualified Success-1	86.7%	95%
Complete Success-2	33.3%	40%
Qualified Success-2	66.6%	75%
Failed	3 (14.2%)	1 (5%)
Blep revision	2 (9.5%)	1 (5%)
Laser suturolysis (times)	7 (6 cases)	11 (9 cases)
Needling (times)	10 (7 cases)	9 (6 cases)
Serious complications	10 (47%)	2 (10%)
Early hypotony	6/21(28%)	6/20 (30%)
Hyphema	1	No
AC shallow	4	1
Prolonged hypotony/maculopathy	1/1	1/1
Choroidal effusion	3	no
Vision loss	1	1
Blebitis or endophthalmitis	No	No

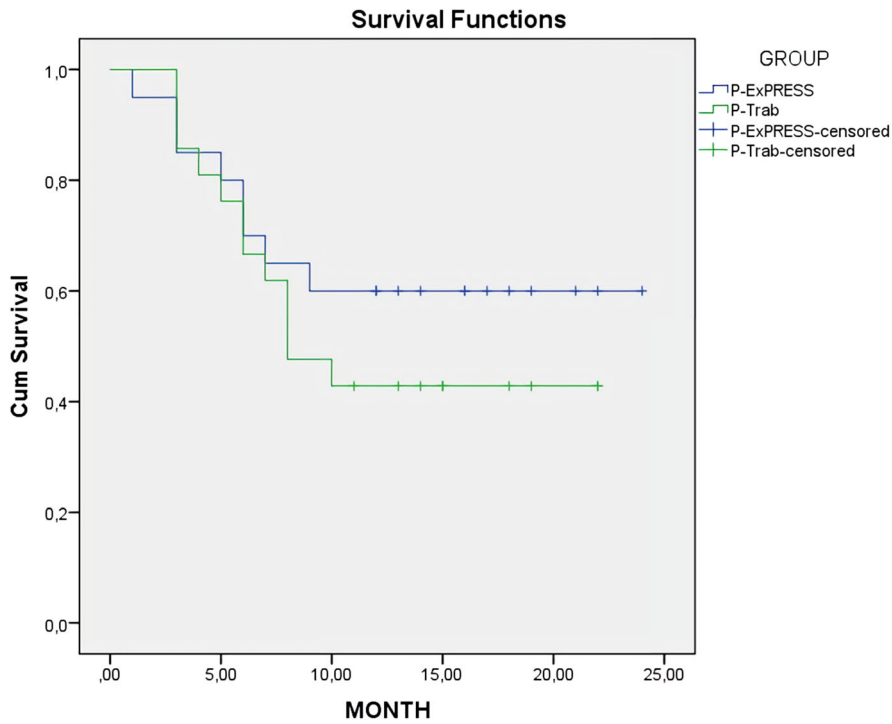

Fig. 2 Kaplan–Meier survival analysis curve diagram of Complete Success-1, comparing groups. (P = 0.365)

surgical glaucoma–cataract studies and only two studies on phacotrabeculectomy and phaco-ExPRESS, one conducted in 2015 in Poland by Konopinska et al. [15] and one conducted in 2008 in Spain by Gallego-Pınazo et al. [16]. However, these studies do not specify which ExPRESS miniature shunt model was used, making interpretation of the results more difficult. Most of the considered studies reported similar results, the consensus being that the outcome of the ExPRESS miniature glaucoma shunt procedure is equivalent to that of trabeculectomy [2, 4, 6, 7, 12–24].

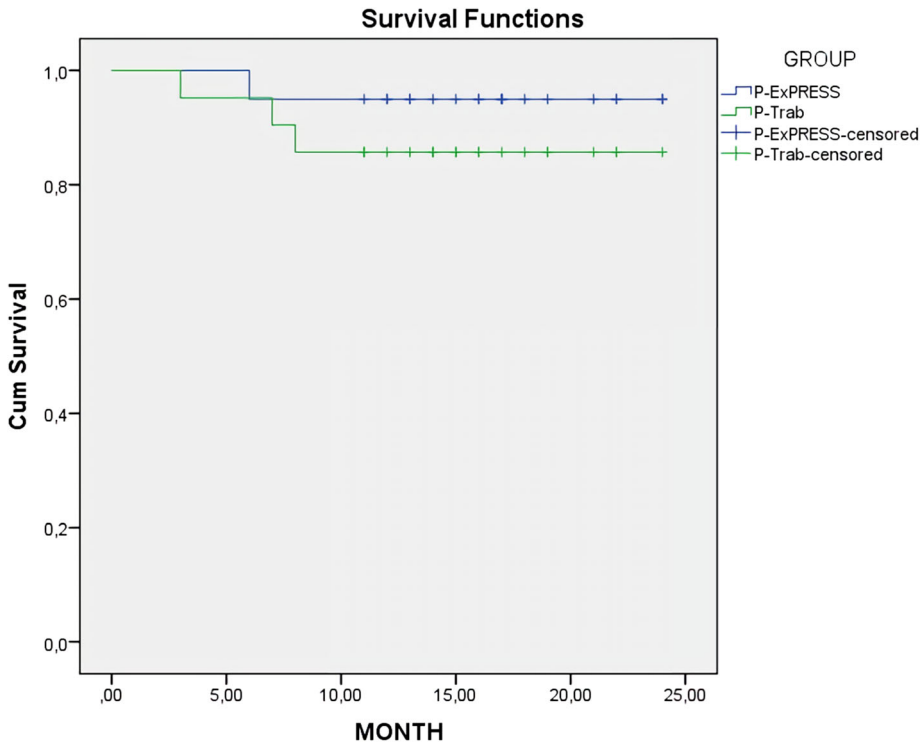

Fig. 3 Kaplan–Meier survival analysis curve diagram of Qualified Success-1, comparing groups. (P = 0.329)

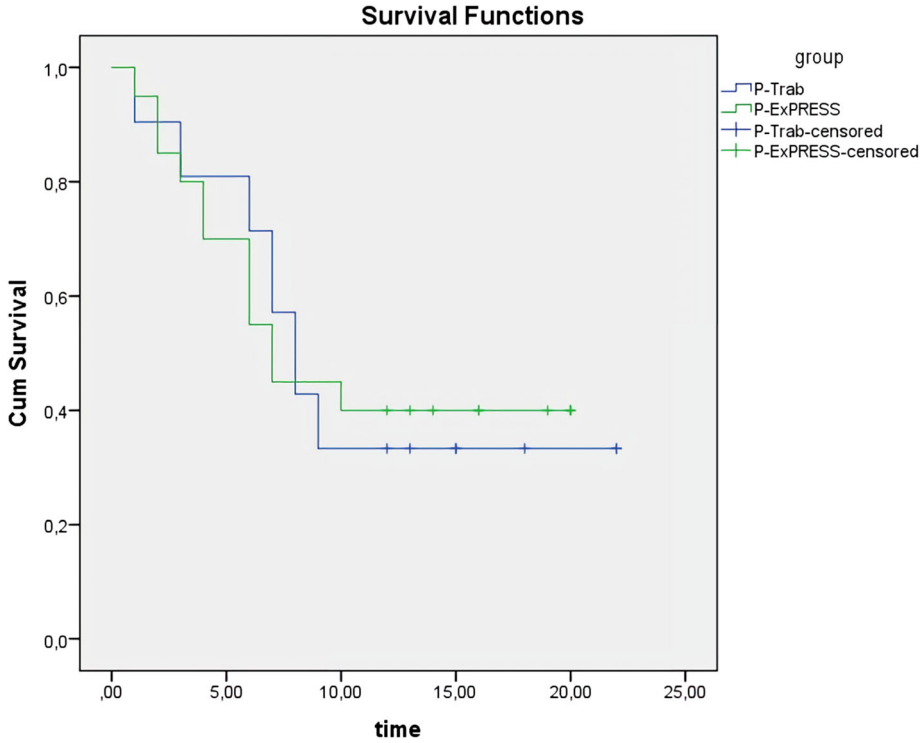

Fig. 4 Kaplan–Meier survival analysis curve diagram of Complete Success-2, comparing groups. (P = 0.789)

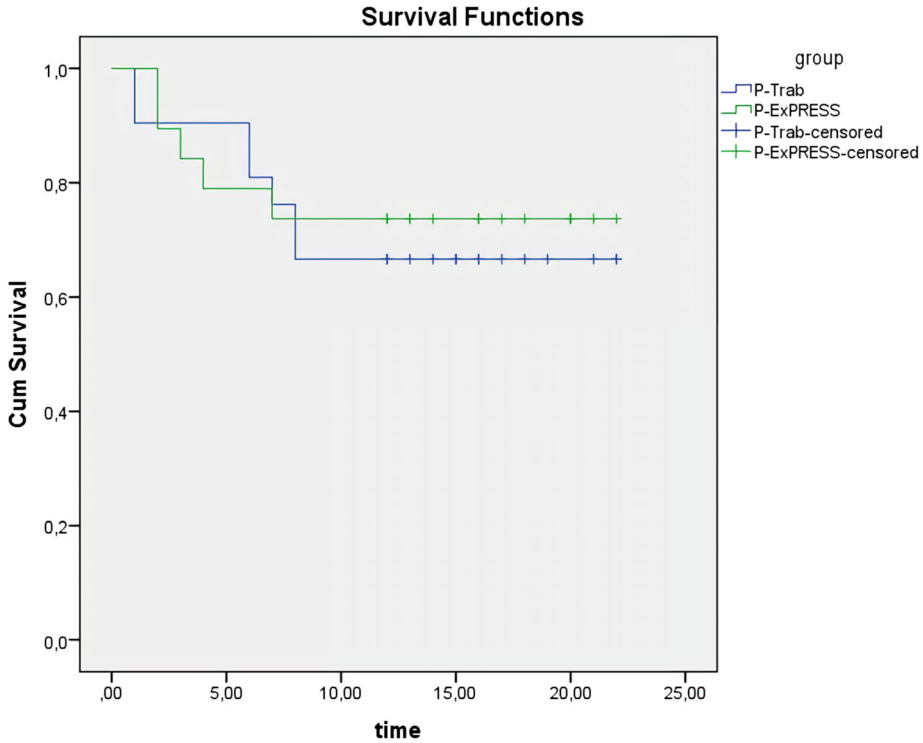

Fig. 5 Kaplan–Meier survival analysis curve diagram of Qualified Success-2, comparing groups. ($P = 0.765$)

The present study performed a comparative analysis of combined glaucoma–cataract surgery, focusing specifically on the P-200 ExPRESS miniature glaucoma shunt device. To the best of our knowledge, this is the first study to investigate the use of this ExPRESS miniature glaucoma shunt device model in the context of combined glaucoma–cataract surgery.

In the present study, most of the patients were older than 60. They all had OAG, and their vision was affected by cataracts. Therefore, it was decided to perform combined glaucoma and cataract surgery. While phacoemulsification, IOL implantation, and the use of intraoperative MMC can also contribute to decreased IOP in combined surgeries, the expectation is that this would affect both groups equally. Several studies have shown that phacoemulsification can cause a decrease in IOP on the order of 1.4–1.9 mm Hg to 4.9–5.3 mm Hg [25–27].

However, Jiang's meta-analysis [28] reported that trabeculectomy was more effective than combined phacotrabeculectomy for decreasing IOP and decreasing the use of antiglaucomatous medication, but the difference between CS and QS was not statistically significant. Combined phacotrabeculectomy could decrease visual recovery time; it could also reduce the number of surgical interventions and the cost. Combined surgery could also increase postoperative inflammation and decrease the effect on IOP reduction [29]. In a prospective study of 81 patients and 88 eyes, Stawowski et al. [30] compared the use of ExPRESS miniature shut implantation alone versus combined P-ExPRESS; they reported no difference in efficacy and complications between the two procedures.

Most of the studies comparing trabeculectomy and ExPRESS miniature shunt implantation surgeries used the ExPRESS models P 50, X 50, and X 200. Only one small retrospective study by Liu et al. [19] used the P 200 model exclusively. To the best of our knowledge, only two studies in the literature have compared the use of phacoemulsification combined with trabeculectomy and ExPRESS: Konopinska et al. [15] and Gallego-Pinazo et al. [16]. In the study conducted by Konopinska et al. [15], the IOP reduction rate was 35.2% in the P-Express group and 43% in the P-Trab group. The first-year reduction reported in Konopinska et al. [15] seems lower than the reduction reported in the present study; however, since Konopinska et al. [15] did not specify the ExPRESS model that was

used, the differences in the results could be due to the different type of models that were used. Moreover, the baseline IOP is lower in Konopinska et al. [15] than in the present study. In that study, the baseline IOP was 27.9 ± 12.9 mm Hg in the P-Trab group and 26.4 ± 9.3 mm Hg in the P-ExPRESS group. The values dropped to 15.9 ± 2.7 mm Hg and 17.1 ± 5 mm Hg, respectively. Gallego-Pinazo et al. [16] included 37 patients, 40 eyes, and short follow-up time series. In early postoperative period reported in that study, IOP reduction rate was lower in the P-ExPRESS group than in the P-Trab group, but complication rate was higher in the P-Trab group. Postoperative 1 month, that study reported similar IOP and success rates for both groups. This result is consistent with the findings reported in present the study.

De Jong et al. [2] included 78 patients and a 5-year follow-up series. The IOP reduction rate at the end of the first-year visit was 35% in the Trab group and 48% in the ExPRESS group; at the fifth-year visit, it was 47% in the Trab group and 50% in the ExPRESS group.

In the 15 patient and 30 eye prospective randomized studies conducted by Dahan et al. [17] comparing fellow eye trabeculectomy versus ExPRESS, the reduction rate over a period of 30 months was 48% in the Trab group and 44% in the ExPRESS group.

Netland et al. [6] conducted a study with a large number of samples (120 cases); the reduction rate at the end of the second year was 45% in the Trab Group and 41% in the ExPRESS group. In other studies, similar reduction rates were reported for the Trab (35–60%) and ExPRESS (35–59%) groups [4, 7, 12, 14, 18–20, 24, 31].

The present study's criteria for CS-1 and QS-1 are similar to the criteria used in many other published studies [2, 6, 14, 15, 19]. In the present study, CS-1 was 42.8% in the P-Trab group and 60% in the P-ExPRESS group. QS-1 was 86.7% in the P-Trab group and 95% in the P-ExPRESS group. In the study conducted by Konopinska et al. [15], CS was similar, but it was slightly in favor of the P-Trab group (52% for P-Trab, 46% for P-ExPRESS), and QS was slightly lower in both groups, although the QS in the P-Trab group was slightly better (72%) than the QS for the P-ExPRESS group (65%). The success rates were similar in the study conducted by Liu et al. [19], which compared trabeculectomy with the ExPRESS miniature shunt model P 200 (CS 47% for Trab, 43% for ExPRESS; QS 76.5% for Trab, 75% for ExPRESS). In other studies and meta-analyses, the reported CS values ranged from 45% to 74% for trabeculectomy and from 43 to 80% for the ExPRESS miniature shunt [2, 4, 7, 8, 14, 17, 31–33]. The reported QS values ranged from 72 to 90% for trabeculectomy and from 65 to 100% for ExPRESS [2, 4, 6–8, 12, 14, 17, 20, 31, 34].

In the present study, a statistically significant decrease in the use of antiglaucomatous medications was observed in both groups. The reduction was slightly greater in the P-ExPRESS group than the P-Trab group; however, the difference was not statistically significant. These results are consistent with the findings reported in the existing literature. In almost all the studies evaluating the use of antiglaucomatous medication, a reduction in the number of medications was reported from a mean value of 3–4 medications preoperatively to 0.5–1.5 medications postoperatively. Differences in the medication reduction between the two groups were not statistically significant in any of the studies [6, 7, 12, 15, 18, 19, 23, 24, 31].

In general, VA may decrease in the early postoperative period, especially due to hypotonia, AC shallowing, choroidal effusion, or hypotonia maculopathy. This usually improves within one to 3 months, returning its preoperative level [2, 6]. However, cataract progression can be accelerated due to surgical intervention—especially trabeculectomy—leading to permanent visual deterioration [14].

In the present study, significant VA improvement due to simultaneous cataract surgery was observed as expected, and the difference between the two groups was not statistically significant ($P = 0.85$). This result is consistent with the findings reported in Konopinska et al. [15], which is the published study with findings that are most similar to the findings reported in the present study. Konopinska et al. [15] found that the VA increased from 0.34 ± 0.43 to 0.14 ± 0.18 in the P-Trab group and from 0.54 ± 0.56 to 0.3 ± 0.49 in the P-ExPRESS group.

Both ExPRESS and trabeculectomy surgeries can lead to complications associated with penetrative glaucoma surgery, such as hypotonia, decompression maculopathy, choroidal effusion, AC shallowing, hyphema, aqueous misdirection, bleb failure, cystic bleb, bleb leakage, blebitis, and endophthalmitis.

However, since ExPRESS is a technique that can be standardized, it does not require iridectomy and sclerectomy, and because the fixed lumen diameter provides controlled filtration, the likelihood of such complications is expected to be lower [6, 7, 12, 13]. Still, combined surgery introduces the possibility of complications due to phacoemulsification surgery in addition to penetrative glaucoma surgery.

In the present study, no complications due to phacoemulsification were observed, but the proportion of complications due to glaucoma surgery was 47% in the P-Trab group and 10% in the P-ExPRESS group. This difference was statistically significant (P: 0.015). The most common complications were AC shallowing and choroidal effusion. In the literature, the ExPRESS shunt was reported to have fewer or similar complication rates. Netland et al. [6], Dahan et al. [17], Wang et al. [8], Wang et al. [33], and others [7, 12, 13, 19, 20, 23] reported that the complication rate of the ExPRESS miniature shunt was significantly lower; the findings from the present study are consistent with this result. In contrast, Seider et al. [31] reported more complications in the ExPRESS group, and other studies have reported similar complication rates [14, 21, 24, 32].

The present study has some limitations. The main limitations are its retrospective design, small sample size, and relatively short follow-up period. However, both study groups had similar demographic characteristics. Moreover, allowing patients to choose between the ExPRESS shunt and trabeculectomy increases the randomization of the samples. This study provides insight on the comparison of combined P-ExPRESS and P-Trab surgeries, showing that P-ExPRESS surgery can achieve success rates that are similar to P-Trab, despite leading to fewer complications. The study's results call for the need for prospective, randomized clinical trials with larger sample sizes and a longer follow-up period.

In conclusion, if a combined surgical approach is planned for uncontrollable OAG and cataract patients, P-ExPRESS combined surgery is as effective and safe as P-Trab, and it has a lower complication rate.

Compliance with ethical standards

Conflict of interest The authors have no financial or proprietary interest in any materials described in the article. The authors are responsible for the content and writing of the paper. Author Kemal Turgay Özbilen declares that he has no conflict of interest. Author Şerife Bayraktar declares that she has no conflict of interest. Author Emre Altınkurt declares that he has no conflict of interest. Author Mehmet Cemil Yılmazlı declares that he has no conflict of interest. Author Muhammed Talha Sadık declares that he has no conflict of interest. Author Ali Üstüner declares that he has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study. This article does not contain any studies with animals performed by any of the authors.

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