

# ExPress mini shunt device with trabeculectomy surgery in patients with uncontrolled glaucoma of Middle Eastern descent

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## Abstract:

**PURPOSE:** The aim of this study is to assess the efficacy and safety of ExPress mini shunt in glaucoma patients of Middle Eastern descent.

**METHODS:** This is a prospective cohort study. Uncontrolled glaucoma patients were subjected to ExPress mini-shunt implant. Pre- and post-operative glaucoma clinical indices were measured and compared. Both intra- and postoperative complications and surgical success rates were assessed. In addition to comparing a group of combined ExPress mini-shunt implant with cataract surgery versus ExPress mini-shunt implant alone.

**RESULTS:** A total of 35 eyes of 31 patients were involved. The most common type of glaucoma was primary open-angle glaucoma in 13 eyes (37.1%). Fourteen eyes (40.0%) were combined ExPress device with cataract surgery. The mean intraocular pressure (IOP) ( $\pm$ standard deviation) at the last visit dropped from 24.6 mmHg ( $\pm$ 8.3) to 13.9 mmHg ( $\pm$ 4.5). There was a significant reduction in the number of postoperative glaucoma medications from  $3.0 \pm 0.5$  to  $1.3 (\pm 0.7)$ . In cases combined with cataract extraction, the patients required fewer anti-glaucoma medications. Complete success was achieved in 22 eyes (63%) and qualified success was achieved in 9 eyes (26%), whereas 4 eyes (11%) were considered a failure. The two most common complications encountered were hypotony (28.6%) and hyphema (11.4%).

**CONCLUSION:** Among the studied population of patients, ExPress offers IOP reduction that is comparable to reported rates following standard trabeculectomy. Postoperative hyphema was encountered at a slightly higher rate.

## Keywords:

ExPress shunt, glaucoma, trabeculectomy

## INTRODUCTION

One of the leading causes of blindness worldwide is glaucoma and it continues to be a major challenge in public health.<sup>[1]</sup> Glaucoma filtration surgery is indicated to reduce intraocular pressure (IOP) when maximal medical therapy and/or laser fail to lower IOP sufficiently and/or fail to prevent optic nerve damage or visual field deterioration.<sup>[2]</sup> The most common procedure for glaucoma filtration surgery since 1968 has been trabeculectomy.<sup>[3]</sup> The success rate of trabeculectomy is variable among studies. In a study for 4 years after surgery on 797 eyes, complete success (IOP 18 mm Hg without IOP-lowering medications and >20%

IOP reduction) was reached in 53% of patients, and qualified success (IOP 18 mm Hg with or without IOP-lowering medications and 20% IOP reduction) was reached in 70% of patients.<sup>[4]</sup>

Postoperative complications are not uncommon following trabeculectomy. In a large study of more than 1200 cases, the early complication rate was 47%, with the most common complication being hyphema in 24.6%. Most complications resolved within a few weeks after surgery, but around 18.8% of patients lost visual acuity (>1 Snellen line) mainly from the development of cataract. In addition, the irreversible visual loss was found in 4.4% of patients.<sup>[5]</sup>

The placement of the ExPress glaucoma filtration device (Alcon, Fort Worth, TX) under a partial thickness scleral flap is one of the

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modifications of glaucoma filtration surgery. The ExPress glaucoma filtration device is a stainless steel biocompatible, magnetic resonance imaging-compatible, nonvalved device that shifts aqueous humor from the anterior chamber to the subconjunctival space and forms a filtration bleb, as seen in standard trabeculectomy.<sup>[6]</sup> The ExPress device eliminates the need for both peripheral iridectomy and removal of a deep corneoscleral tissue block as compared with trabeculectomy, but these advantages are counterbalanced by the need to align the device properly to avoid contact with either the cornea or the iris. Evidence suggests that complementing trabeculectomy with the use of the ExPress device leads to a lower complication rate and a faster visual recovery.<sup>[7]</sup>

The majority of the previously published studies report the results of the ExPress device in primary open-angle glaucoma (POAG).<sup>[8]</sup> Moreover, the outcomes of the ExPress device have not been previously studied in patients of Middle Eastern ethnicity. Therefore, our aim in the study was to determine the outcomes of ExPress glaucoma filtration device in terms of demographic and clinical indicators, visual acuity, IOP, complications, and success rate of the surgery in a heterogeneous group of glaucoma patients of Middle Eastern ethnicity.

## METHODS

This was a single-center, prospective, cohort study. The Institutional Review Board at King Abdulaziz University Hospital approved the study protocol, and informed consent was obtained before the surgery. Consecutive patients with glaucoma uncontrolled on maximum tolerated medical therapy requiring trabeculectomy were included in the study. Pre-operative data included patient age, sex, race, glaucoma diagnosis, history of glaucoma surgery and laser, glaucoma medications, best-corrected Snellen visual acuity, slit-lamp biomicroscopy, IOP measured by Goldmann applanation tonometer, and optic nerve head evaluation.

Most of the cases were performed under local anesthesia, the surgery was started with a fornix-based conjunctival incision, then cautery was used if needed to control any bleeding episcleral vessels, sponges soaked with mitomycin C (0.2 mg/mL) were applied before the formation of the scleral flap for a duration of 2 min, after that, it was copiously irrigated by balanced salt solution after removal of the sponges. A partial-thickness triangular scleral flap was created, and then a needle (25G) was used to open the anterior chamber just posterior to the blue-gray zone under the scleral flap. In patients with a shallow chamber, a paracentesis was performed and the chamber was deepened with the use of a viscoelastic agent, especially at the area of device entry. The P-50 ExPress device using a disposable delivery system was then inserted into the anterior chamber through the needle track, following that the scleral flap was sutured, and tension was adjusted. At the end of the procedure, the conjunctiva was sutured, subconjunctival steroids and antibiotics were given, and the operated eye was covered with a light patch.

In the postoperative period, topical steroid drops were used in a tapering manner in addition to topical antibiotic drops. The patients were evaluated at fixed postoperative intervals as following: 1 week, 1 month, 3 months, 6 months, 12 months, and the last visit at 18–24 months. In each visit, the visual acuity, IOP, number of medications, and complications were recorded.

The primary outcome measure was IOP. Secondary outcome measures were visual acuity, rate and type of complications, the number of postoperative glaucoma medications, need for further interventions, for example, needling, laser suture lysis. Complete surgical success was defined as IOP of  $\geq 6$  mmHg and  $\leq 21$  mmHg without IOP-lowering medication, qualified success was defined as IOP  $\geq 6$  mmHg and  $\leq 21$  mmHg with IOP-lowering medication, and failure was defined as IOP  $> 21$  mmHg or cases requiring further surgical intervention to control IOP.

Demographic data and preoperative data for the patients involved were analyzed with a paired *t*-test or Chi-square test. Rates of postoperative change in visual acuity, surgical success and complications were analyzed using Chi-square test. IOP and medications comparisons were analyzed with a paired *t*-test. The probability of success was calculated by the Kaplan–Meier life-table analysis. Value of  $P < 0.05$  was considered statistically significant.

## RESULTS

A total of 35 eyes of 31 patients were involved in the study, 64.5% of patients were male and the most common cause of glaucoma was POAG in 13 eyes (37.1%). The mean follow-up period ( $\pm$ standard deviation [SD]) was  $6 \pm 4.8$  (3–24) months. The majority of patients were operated by one surgeon (25 eyes, 71.4%) and the remaining cases were done by two different surgeons, implementing the same surgical technique. Five patients (14.3%) had a previous history of glaucoma surgery. Detailed demographic and clinical characteristics at presentation are shown in Table 1.

Fourteen eyes (40.0%) were combined ExPress glaucoma filtration device with cataract surgery, in which 12 eyes had phacoemulsification and 2 eyes had lens aspiration. Intraoperative complications were encountered in two patients: the first case had an extension of the anterior lens capsule that was managed by carefully completing phacoemulsification and implanting the intraocular lens (IOL) in the sulcus, whereas the other patient had a posterior capsule rupture that was managed by anterior vitrectomy without placement of an IOL due to weak bag support.

The mean IOP ( $\pm$ SD) at the last visit dropped to 13.9 mmHg ( $\pm 4.5$ ), the postintervention visual acuity improved to 0.9 ( $\pm 0.6$ ) and there was a significant reduction in the number of postoperative glaucoma medications down to 1.3 ( $\pm 0.7$ ). Table 2 shows a comparison between different pre-postoperative outcome measures.

Looking at outcomes in each subgroup individually (ExPress alone vs. ExPress combined with cataract surgery), the combined group had a greater improvement in visual acuity that was close to, but did not reach, statistical significance. Both

**Table 1: Demographics and clinical characteristics at presentation**

Characteristic	n (%)
Gender	
Male	20 (64.5)
Female	11 (35.5)
Age (years), mean±SD (range)	57.8±19.7 (12-86)
Nationality	
Saudi	25 (80.6)
Non-Saudi	6 (19.4)
Systemic diseases	
Diabetes	17 (54.8)
Hypertension	18 (58.1)
Dyslipidemia	5 (16.1)
Ischemic heart disease	4 (12.9)
Others - asthma	2 (6.4)
Type of glaucoma	
POAG	13 (37.1)
CACG	6 (17.1)
NVG	6 (17.1)
Uveitic	3 (8.6)
Juvenile	2 (5.7)
PXG	1 (2.9)
Combined	1 (2.9)
Other	3 (8.6)
Angle recession glaucoma	1 (2.9)
Pigmentary glaucoma	2 (5.7)
Number of topical anti glaucoma medication	
1	0
2	4 (11.4)
3	27 (77.1)
>3	4 (11.4)
History of glaucoma surgery	5 (14.3)
Type of surgery	
Trabeculectomy	3 (8.6)
Deep sclerectomy	2 (5.7)
Eye involved	
Right	22 (62.9)
Left	13 (37.1)

POAG=Primary open angle glaucoma; CACG=Chronic angle closure glaucoma; NVG=Neovascular glaucoma; PXG=Pseudoexfoliation glaucoma

**Table 2: Comparing pre- and post-intervention glaucoma indices**

Characteristic	Mean±SD (range)		P
	Preoperative	Postoperative	
Visual acuity in LogMAR	1.1±0.7 (0.1-3.0)	0.9±0.6 (0-2)	0.036*
IOP (mmHg)	24.6±8.3 (16-50)	13.9±4.5 (8-30)	<0.001*
Number of medications	3.0±0.5 (2.0-4.0)	1.3±0.7 (1-3)	0.002*

\*Statistically significant at 5% level of significance. LogMAR=Logarithm minimum angle of resolution; SD=Standard deviation; IOP=Intraocular pressure

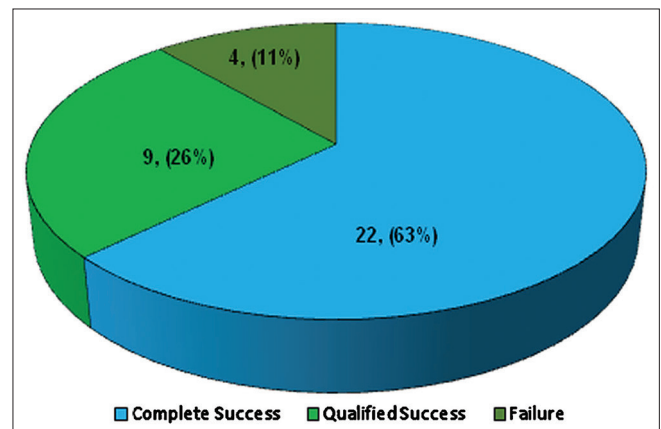
groups had a significant reduction of IOP from preoperative to postoperative. In cases combined with cataract extraction, the patients required fewer anti-glaucoma medications postoperatively as compared to stand-alone ExPress. A detailed comparison between both groups is shown in Table 3.

Complete success was achieved in 22 eyes (63%) and qualified success was achieved in 9 eyes (26%), while 4 eyes (11%) were considered a failure [Figure 1]. The first failed case was a patient with uveitic glaucoma and failure occurred at 12 months, and the patient underwent ultrasound cycloplasty. The second case was also a uveitis patient in which failure occurred 1 month after surgery and the patient underwent Ahmed glaucoma valve surgery. The third case had neovascular glaucoma and failure occurred at 6 months and the patient required endoscopic cyclophotocoagulation to further reduce IOP. The last failed case was an angle closure glaucoma patient with a recorded failure at 6 months and he also underwent endoscopic cyclophotocoagulation. Figure 2 shows a Kaplan–Meier curve illustrating the survival probability over the follow-up period. Univariate analysis of our cohort showed that a history of prior glaucoma surgery is the only statistically significant risk factor for failure [Table 4].

Hypotony was the most common postoperative complication encountered (28.6%) followed by hyphema in 4 eyes (11.4%), maculopathy in 3 eyes (8.6%), and early bleb leak in 2 eyes (5.7%). Other complications encountered were: choroidal effusion, blocked tube, and cystic bleb, all of which occurred in 1 eye each (2.9%).

**DISCUSSION**

Our findings demonstrate that performing trabeculectomy with ExPress is an effective method of lowering IOP in the studied population. The complete and qualified success rates in our cohort were 63% and 26%, respectively. Bissig *et al.* showed a complete success rate (IOP ≤18 mmHg with no anti-glaucoma medication) of 69% in 26 eyes with a mean follow-up of 18.6 ± 2.4 months,<sup>[9]</sup> while Gindroz *et al.* showed a lower success rate (46%) in a cohort that was followed for



**Figure 1: Success rate**

**Table 3: Comparing pre- and post-intervention glaucoma indices for different subgroups**

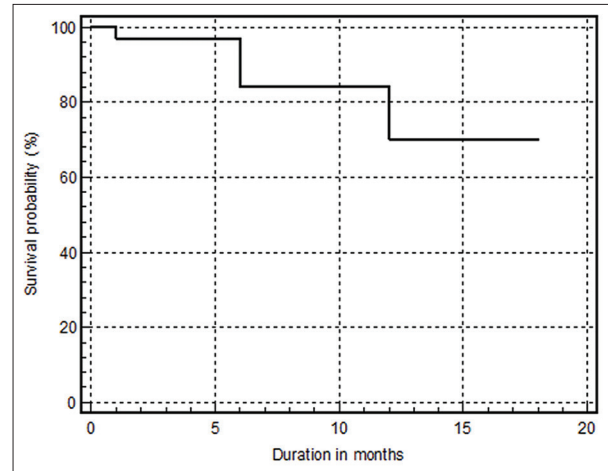
Characteristic	Express alone (n=21)		P	Express combined with cataract surgery (n=14)		P
	Mean±SD (range)			Mean±SD (range)		
	Preoperative	Postoperative		Preoperative	Postoperative	
Visual acuity in LogMAR	1.1±0.7 (0.1-3.0)	1.0±0.6 (0.0-2.0)	0.212	1.0±0.7 (0.2-2.0)	0.7±0.5 (0.2-2.0)	0.130
IOP (mmHg)	27.1±8.7 (18-50)	14.9±5.0 (8-30)	<0.001*	20.8±6.2 (16-36)	12.4±3.3 (8-17)	0.001*
Number of medications	3.2±0.4 (3-4)	1.8±0.8 (1-3)	0.059	2.7±0.5 (2-3)	1.0±0.0 (1-1)	0.014*

\*Statistically significant at 5% level of significance. LogMAR=Logarithm minimum angle of resolution; SD=Standard deviation; IOP=Intraocular pressure

**Table 4: Factors associated with failure**

Variable	Success (n=31), n (%)	Failure (n=4), n (%)	P
Diabetes			
Yes (n=20)	18 (90.0)	2 (10.0)	0.759
No (n=15)	13 (86.7)	2 (13.3)	
Hypertension			
Yes (n=22)	20 (90.9)	2 (9.1)	0.572
No (n=13)	11 (84.6)	2 (15.4)	
Dyslipidemia			
Yes (n=6)	6 (100)	0	0.334
No (n=29)	25 (86.2)	4 (13.8)	
Ischemic heart disease			
Yes (n=4)	4 (100)	0	0.445
No (n=31)	27 (87.1)	4 (12.9)	
Type of glaucoma			
POAG (n=13)	13 (100)	0	0.102
CACG (n=6)	5 (83.3)	1 (16.7)	
PXG (n=1)	1 (100)	0	
Uveitic (n=3)	1 (33.3)	2 (66.7)	
Combined (n=1)	1 (100)	0	
NVG (n=6)	5 (83.3)	1 (16.7)	
Juvenile (n=2)	2 (100)	0	
Other (n=3)	3 (100)	0	
Number of preoperative glaucoma medications			
2 (n=4)	4 (100)	0	0.536
3 (n=27)	24 (88.9)	3 (11.1)	
4 (n=4)	3 (75.0)	1 (25.0)	
History of glaucoma surgery			
Yes (n=5)	3 (60.0)	2 (40.0)	0.030*
No (n=30)	28 (93.3)	2 (6.7)	
Eye involved			
Right (n=22)	19 (86.4)	3 (13.6)	0.593
Left (n=13)	12 (92.3)	1 (7.7)	
Preoperative visual acuity			
≥20/40 (n=6)	6 (100)	0	0.334
<20/40 (n=29)	25 (86.2)	4 (13.8)	
Preoperative IOP			
≤21 (n=16)	16 (100)	0	0.051
>21 (n=19)	15 (78.9)	4 (21.1)	
Preoperative CDR			
≤0.5 (n=5)	4 (80.0)	1 (20.0)	0.515
>0.5 (n=30)	27 (90.0)	3 (10.0)	
Type of surgery			
Trab alone (n=21)	18 (85.7)	3 (14.3)	0.515
Combined (n=14)	13 (92.9)	1 (7.1)	

POAG=Primary open angle glaucoma; CACG=Chronic angle closure glaucoma; NVG=Neovascular glaucoma; PXG=Pseudoexfoliation glaucoma; IOP=Intraocular pressure; CDR=Cervical disc replacement



**Figure 2: Kaplan–Meier curve**

a longer duration (48 months).<sup>[10]</sup> The definition of success differs between our study and the cited groups, which makes a comparison between studies difficult; however, this does not invalidate the relevance of success rate within studies.

The mean reduction of IOP in our study was 43% and the reduction in the number of IOP lowering medications was 57%. IOP reduction in previous prospective studies was comparable to ours. Bissig *et al.* showed an IOP reduction of 42% and the reduction in the number of medications was 79% at 18 months.<sup>[9]</sup> Gavrić *et al.*, who followed 44 eyes for 1 year, showed a mean reduction of IOP by 53% and a reduction of medications by 77%.<sup>[11]</sup>

We found that the combined surgery group (ExPress combined with cataract surgery) had a statistically significant lower number of anti-glaucoma medications as compared to ExPress alone; a possible explanation for such finding is that removing the lens enhances aqueous outflow facility, especially in angle-closure patients, therefore providing further IOP lowering.

A statistically significant improvement in the logarithm of the minimum angle of resolution (logMAR) acuity was documented in our patients ( $P = 0.036$ ). This is explained by the fact that 40% of cases were combined with cataract extraction. Dahan *et al.* did not document a change in visual acuity between preoperative and postoperative values.<sup>[12]</sup> On the other hand, on comparing standard trabeculectomy with ExPress, Good and Kahook reported a statistically significant difference in logMAR acuity between both groups (0.09 logMAR in the ExPress group and 0.15 logMAR in the trabeculectomy group).<sup>[13]</sup>

Bissig *et al.* showed that encysted bleb was the most common postoperative complication (54%), followed by transient hypotony, hyphema, and bleb leak (15%).<sup>[9]</sup> Dahan *et al.* reported shallow anterior chamber in 13% and hypotony in 7% among the ExPress group compared to a shallow anterior chamber in 20% and hypotony in 33% among the standard trabeculectomy group.<sup>[12]</sup> In our study, transient hypotony was found in 28.6% and hyphema in 11.4%. Postoperative laser suture lysis was performed in three patients of our cohort (8.6%). The retrospective case–control study performed by Good and Kahook showed a higher rate of suture lysis in both arms. In the ExPress group, it was 51%, while in the trabeculectomy group, it was 20%.<sup>[13]</sup>

Relatively small sample size is considered a major limitation of the current study; however, this study is considered an initial pilot to demonstrate the short-term outcomes of ExPress among our population. Further studies with larger sample sizes and a longer duration of follow-up are needed to better define the role of ExPress in the glaucoma surgical management paradigm in patients with Middle Eastern ethnicity. Another limitation is that our study lacks data on the effect of ExPress on the corneal endothelium. We recommend that future studies looking into the outcomes of ExPress document preoperative endothelial cell count values and follow them postoperatively.

## CONCLUSION

The ExPress device leads to decrease in IOP, which is at least as good as trabeculectomy and may have some advantages in terms of a lower complication rate. Because of the technical differences between the procedures, some specific complications may differ from standard trabeculectomy (e.g., iris bleeding). The additional issue of interest is the cost-effectiveness of the device, in long-term ExPress may be more cost-effective given that patients require fewer postoperative interventions and fewer medications.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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