EX-PRESS shunt implantation in Chinese glaucoma patients: 1-year results

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Abstract

Aim: To report the safety and efficacy of EX-PRESS glaucoma filtration device implantation in Chinese glaucoma patients.

Methods: Records of 38 eyes from 38 Chinese glaucoma patients who underwent EX-PRESS shunt implantation between August 2012 and June 2014 with at least 1 year of follow-up were retrospectively reviewed. Main outcome measures included intraocular pressure (IOP), visual acuity, success rate, number of topical antiglaucoma medications applied, and postoperative complications.

Results: The mean IOP reduced significantly from 25.8 ± 12.4 mmHg before surgery to 15.1 ± 6.3 mmHg at 1 year after surgery ($p < 0.005$). Repeated measures ANOVA showed that IOP at all time points after surgery was significantly lower than IOP before surgery. 73.7% of patients achieved complete or qualified success.

Conclusions: EX-PRESS shunt implantation is safe and effective in Chinese patients.

stainless steel magnetic resonance imaging-compatible device.¹ With an external lumen of 400 μ m and internal lumen of 50 μ m, it facilitates minimally invasive surgery and promotes the postoperative consistency and predictability of trabeculectomy.²⁻⁴ The EX-PRESS shunt was originally intended for subconjunctival implantation. Although this implant achieves significant reduction in intraocular pressure (IOP), complications related to excess outflow such as hypotony, flat anterior chamber, and suprachoroidal hemorrhage are frequent.^{5,6} Therefore, subconjunctival implantation has been replaced by implantation under a scleral flap.²

The latest P50 model of the EX-PRESS shunt has a vertical channel in the back plate intended to direct aqueous flow more posteriorly to create a more diffuse posterior bleb. Compared with trabeculectomy, EX-PRESS shunt implantation demonstrates comparable IOP-lowering efficacy, faster visual recovery, and fewer postoperative complications,⁷ as well as lower risk of postoperative hypotony.⁸ In addition, EX-PRESS shunt negates the need for iridectomy, resulting in less inflammation and shorter operation time.⁹ To the best of our knowledge, the surgical outcomes of EX-PRESS shunt implantation in the Chinese population have not been reported. Therefore, we evaluated the safety and efficacy of P50 EX-PRESS shunt implantation in Chinese patients.

Methods

The study was approved by the Institutional Review Board of The University of Hong Kong and was conducted in accordance with the Declaration of Helsinki. Medical records

Key words: Filtering surgery; Glaucoma

Introduction

The EX-PRESS glaucoma filtration device (Alcon Laboratories, Fort Worth [TX], USA) is a non-valved

of Chinese glaucoma patients who underwent EX-PRESS shunt implantation between August 2012 and June 2014 at Queen Mary Hospital with at least 1 year of follow-up were retrospectively reviewed. For patients with bilateral EX-PRESS shunt implantation, only information on the first eye was collected. Patients with cataract surgery within 1 year after EX-PRESS shunt implantation were excluded to avoid confounding IOP results. Patients with glaucoma surgery within 6 months before EX-PRESS shunt implantation were excluded to avoid the effect of scarring. Indications for EX-PRESS shunt implantation included suboptimal IOP control, disease progression despite maximally tolerated topical antiglaucoma medications, and topical medication intolerance.

Main outcome measures were IOP (measured by Goldman applanation), number of topical antiglaucoma medications applied, visual acuity, and postoperative complications requiring intervention. Each type of medication was counted as a single unit, with fixed combination eyedrops counted as two medications. Complete success was defined as IOP of 5–21 mmHg in high-tension glaucoma or a >20% decrease from preoperative IOP in normal-tension glaucoma, without antiglaucoma medications. Qualified success was defined using the same criteria, with patients on antiglaucoma medications achieving the target IOP. Failure was defined as hypotony with IOP of <5 mmHg or IOP of >21 mmHg despite topical medications, complete loss of light perception, or any further glaucoma drainage surgeries, excluding bleb needling.

All P50 EX-PRESS shunt implantations were performed by surgeons specializing in glaucoma surgery. Topical anesthesia with 0.4% oxybuprocaine was applied with or without subtenon anesthesia with 1% lidocaine. All conjunctival flaps were fornix based. Most shunts were implanted in the superonasal quadrant. In cases where the superonasal quadrant was not viable owing to conjunctival scarring or previous drainage surgery, the shunt was placed in other viable quadrants in the following order: superotemporal, inferotemporal, and inferior quadrant. A partial-thickness scleral flap of 4 mm × 3 mm was created. Mitomycin C (0.4 mg/mL) was applied subconjunctivally and underneath the sclera flap for 2 minutes, followed by irrigation with 50 mL of balanced saline solution. A paracentesis wound was created with a 15° stab knife at the temporal clear cornea. A 25- or 27-gauge needle was used to enter the anterior chamber just anterior to the scleral spur, at the posterior aspect of the blue zone, creating a track parallel to the iris plane. The EX-PRESS shunt was implanted. The scleral flap was closed with two 10-0 nylon sutures, and the conjunctiva was closed with either 8-0 or 9-0 vicryl. Postoperative topical medications included 0.5% levofloxacin four times a day and 1% prednisolone acetate six to eight times a day. Patients were followed up at day 1, week 1, and months 1, 3, 6, and 12.

Normality of data was tested using Q-Q plots. Outcomes at 1 year after surgery were compared with preoperative values using the paired sample *t*-test for continuous variables and

Chi-squared test for categorical variables. Repeated measures ANOVA with Bonferroni post hoc test was used to compare continuous variables throughout the study period. Correlation between previous glaucoma surgery and the probability of success was determined using logistic regression analysis. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using SPSS (Windows version 20; IBM Corp, Armonk [NY], US).

Results

45 EX-PRESS shunt implantations were performed during the study period. Two of the patients were lost to follow-up. Five of the patients underwent bilateral implantations and data from the second surgery were excluded to avoid statistical overestimation secondary to inter-eye correlation. A total of 21 right eyes and 17 left eyes from 28 men and 10 women (mean age, 59 ± 17 years) were included for analysis (**Table 1**). The most common diagnosis was primary open angle glaucoma (44.7%), followed by uveitic glaucoma (28.9%). Previous ocular surgery was common, with 57.9% having had cataract surgery and 23.7% having had failed filtration surgery.

The mean IOP decreased from 25.8 ± 12.4 mmHg before surgery to 15.1 ± 6.3 mmHg at 1 year after surgery ($p < 0.005$, paired *t* test, **Table 2**). The lowest mean IOP (9.2 ± 6.0 mmHg) occurred approximately 1 week after surgery. The box and whisker plot revealed outliers that lay >1.5 times above the third quartile (**Figure**). Repeated measures ANOVA with and without outliers both showed that IOP at all time points after surgery was significantly lower than IOP before surgery

Table 1. Patient demographics

Variable	No. (%)
Sex	
Male	28 (73.7)
Female	10 (26.3)
Eye	
Right	21 (55.3)
Left	17 (44.7)
Diagnosis	
Primary open angle glaucoma	17 (44.7)
Uveitic glaucoma	11 (28.9)
Primary angle closure glaucoma	3 (7.9)
Congenital/childhood/juvenile glaucoma	3 (7.9)
Normal-tension glaucoma	2 (5.3)
Silicon oil-induced glaucoma	1 (2.6)
Neovascular glaucoma	1 (2.6)
Previous surgery	
Cataract surgery	22 (57.9)
Trabeculectomies	7 (18.4)
Pars plana vitrectomies	4 (10.5)
Ahmed valves	2 (5.3)

(Table 3). Patients who required a second glaucoma surgery within 1 year after of EX-PRESS shunt implantation were excluded from the ANOVA analysis.

The mean number of topical antiglaucoma medications applied was 3.3 ± 1.5 before surgery, 1.0 ± 1.4 at 6 months after

Table 2. Intraocular pressure (IOP) at different time points	
Time point	Mean $\pm$ SD (95% CI) IOP, mmHg
Before surgery	25.8 $\pm$ 12.4 (21.1-30.5)
After surgery	
1 day	10.1 $\pm$ 6.4 (7.7-12.6)
1 week	9.2 $\pm$ 6.0 (7.0-11.5)
1 month	10.6 $\pm$ 4.6 (8.8-12.3)
3 months	12.3 $\pm$ 4.6 (10.5-14.0)
6 months	13.7 $\pm$ 4.8 (12.0-15.6)
12 months	15.1 $\pm$ 6.3 (12.7-17.5)

Figure. Box and whisker plot showing intraocular pressure (IOP) before surgery and at different time points after surgery

surgery, and 1.2 ± 1.3 at 12 months after surgery ($p < 0.0005$, Wilcoxon signed rank test). 14 (37%) patients required oral acetazolamide before surgery and none required it after surgery.

At 1 year after surgery, of 38 eyes, 14 (36.8%) achieved a complete success, 14 (36.8%) achieved a qualified success, and 10 failed. Of the 10 failed eyes, five had IOP of >21 mmHg despite medication and five underwent further glaucoma drainage surgeries (3 of which had secondary glaucoma). In subgroup analysis, of 17 patients with open angle glaucoma, 10 (58.8%) achieved a complete success, five (29.4%) achieved a qualified success, and two failed. Of 11 patients with uveitic glaucoma, four (36.4%) achieved a complete success, three (27.3%) achieved a qualified success, and four failed. Of three patients with primary angle closure glaucoma, two achieved a qualified success, and one failed. All four patients with neovascular or congenital glaucoma achieved a qualified success. The patient with silicon oil-induced glaucoma failed. The two patients with normal-tension glaucoma also failed. Logistic regression analysis showed no significant correlation between previous glaucoma surgery and the probability of success. No patients had hypotony or vision loss. Three patients required EX-PRESS shunt removal (Table 4).

There were no significant differences before surgery and at 1 year after surgery in terms of visual acuity (logMAR, 0.75 ± 0.85 vs 0.61 ± 0.73 , $p = 0.09$, paired t test), cup-disc ratio (0.67 ± 0.2 vs 0.69 ± 0.2 , $p = 0.27$, paired t test), and mean deviation on Humphrey 24-2 visual fields (-15.3 ± 9.0 dB vs -18.4 ± 9.7 dB, $p = 0.45$, paired t test).

Discussion

Trabeculectomy has been the standard surgical treatment for glaucoma since the 1970s. However, it is associated with a wide range of postoperative complications and a lower success rate in patients with secondary glaucoma, non-Caucasians, and young patients.¹⁰ Implantation of a tube shunt is an alternative option; however, shunts are associated with complications such as hypotony, diplopia, strabismus, tube erosion, and corneal decompensation.¹¹ Compared with trabeculectomy, EX-PRESS shunt implantation achieve

Table 3. Mean difference in intraocular pressure (IOP) between before surgery and at different time points after surgery				
Repeated measures ANOVA	With outliers	P value	Without outliers	P value
Greenhouse-Geisser correction	F (2.282, 63.9)=25.94	<0.0005	F (2.514, 55.3)=23.6	<0.0005
Bonferroni post hoc test	Mean difference in IOP, mmHg		Mean difference in IOP, mmHg	
Before vs 1 day after surgery	15.7	<0.0005	13.0	<0.0005
Before vs 1 week after surgery	16.6	<0.0005	14.5	<0.0005
Before vs 1 month after surgery	15.2	<0.0005	12.0	<0.0005
Before vs 3 months after surgery	13.5	<0.0005	11.0	<0.0005
Before vs 6 months after surgery	12.0	<0.0005	9.2	<0.0005
Before vs 12 months after surgery	10.7	<0.0005	8.3	<0.001

Table 4. Postoperative complications requiring interventions

Complication	No. (%)
Hypotony with shallow anterior chamber requiring anterior chamber reformation with viscoelastic	8 (21.1)
Bleb leak requiring conjunctival repair	8 (21.1)
Antimetabolite injection	
Mitomycin C	19 (50)
5 fluorouracil	4 (10.5)
Needling with antimetabolite injection	10 (26.3)
Inflammation requiring subtenon or oral steroids	2 (5.3)
Suture lysis	7 (18.4)
EX-PRESS shunt removal	3 (7.9)

similar efficacy, better tolerability, and fewer complications of hypotony and hyphema.¹²

Although the definition of success differs in different studies, the complete success rate of EX-PRESS shunt implantation at 1 year has been reported to be 60% to 87%.¹³⁻¹⁶ The success rate was reported to be 50% lower among non-Caucasians patients (mainly patients of African or Indian origin).¹⁴ For trabeculectomy, outcomes have been reported to be similarly poor among Chinese¹⁷ and Malay¹⁸ patients. Other risk factors include young age, previous glaucoma surgery, and use of antiglaucoma medications. Glaucoma type was not found to be a risk factor for failure, but the sample comprised >85% of open angle glaucoma cases and did not include secondary glaucoma or congenital glaucoma.¹⁴

In the present study, the complete success rate at 1 year was 36.8%, which is lower than that reported in other studies. This may be attributed to differences in case mix. Open angle glaucoma only constituted 44.7% of our patients. The remainder included uveitic glaucoma (28.9%), congenital or juvenile glaucoma (7.9%), angle closure glaucoma (7.9%), and other secondary glaucomas (10.5%). These patients were at risk of trabeculectomy failure, and thus EX-PRESS shunt implantation assumed the role of augmented trabeculectomy and was an alternative to tube shunt implantation. The complete success rate of 58.8% among patients with open angle glaucoma is comparable with that reported in the literature.

Most of our patients had previous ocular surgery. However, logistic regression analysis showed no significant correlation between previous glaucoma surgery and the probability of success of the current surgery. This may be attributed to the small sample size. Of the three patients with angle closure glaucoma, two were pseudophakic prior to implantation (one of them required shunt exchange for malpositioned shunt) and one was phakic and achieved a qualified success. Although an open angle is usually a prerequisite for EX-PRESS shunt implantation, EX-PRESS shunts have been used in patients with angle closure glaucoma, usually in combination with phacoemulsification.^{14,19} To the best of our knowledge, there are no studies on EX-PRESS shunt implantation in patients with phakic angle closure glaucoma. The success in patients with angle closure glaucoma suggests that EX-PRESS shunt implantation in the area free of synechiae closure may be a viable option. The incidence of hypotony has been reported to be lower after EX-PRESS shunt implantation than after trabeculectomy.^{8,19,20} One study reported a hypotony rate of 15.6% in the first week after EX-PRESS shunt implantation, but none of these eyes developed flat anterior chamber or lens corneal touch.¹⁹ This may be because the 50- μ m internal lumen diameter of the EX-PRESS shunt provides more resistance to aqueous outflow compared with the 750- μ m smallest sclera punch in trabeculectomy, thus providing better anterior chamber maintenance, even in cases of hypotony.³ None of our three patients with angle closure glaucoma developed hypotony, although two of them required anterior chamber reformation for shallow anterior chamber.

Limitations of our study include a heterogeneous sample, multiple surgeons, differences in anti-metabolite injection practices, and the retrospective nature.

Conclusion

EX-PRESS shunt implantation is effective and safe in primary open angle glaucoma and possibly in uveitic glaucoma. Further prospective and randomized controlled studies are recommended to clarify the efficacy of EX-PRESS shunt implantation in patients with angle closure glaucoma, neovascular glaucoma, or silicone oil-induced glaucoma.

Declaration

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