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Ex – press glaucoma shunt with adjunctive amniotic membrane and mitomycin C for post – traumatic glaucoma

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Ex-press 引流钉联合羊膜植入术中应用丝裂霉素 C 治疗外伤性青光眼

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摘要

目的:观察外伤性开角型青光眼患者进行 Ex-press 引流钉联合羊膜植入术中应用丝裂霉素 C 后眼压及视力的变化。

方法:前瞻性系列病例研究。连续收集行 Ex-press 引流钉联合羊膜植入术中应用丝裂霉素 C 治疗外伤性开角型青光眼患者 18 例 18 眼,分别记录眼压(IOP)、最佳矫正视力(BCVA)、抗青光眼药物数量及并发症。所有患者随访 24mo。

结果:术后 24mo,15 眼取得了绝对成功(未使用抗青光眼药物时 IOP<21 mmHg),成功率为 88.2%(15/17)。术前 IOP 为 36.9±4.8 mmHg,术后 12mo 为 15.4±3.5 mmHg,术后 24mo 为 15.5±3.5 mmHg。术后早期有 2 例患者(11.1%)由于滤过泡纤维化出现了高眼压。大多数患者最后一次复查时 BCVA 较术前有提高。2 例患者(11.1%)术后出现一过性低眼压。术后无前房出血、脉络膜脱离、浅前房、引流器触碰虹膜或引流器脱位等并发症。

结论:Ex-press 引流钉联合羊膜植入术中应用丝裂霉素 C 治疗外伤性开角型青光眼是安全的、有效的,可以作为这类患者的选择。

关键词:Ex-press 引流钉;青光眼引流器;外伤性青光眼

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Abstract

• AIM: To evaluate intraocular pressure (IOP) control and visual rehabilitation after placement of the Ex-press® miniature glaucoma shunt with adjunctive amniotic membrane transplantation (AMT) and mitomycin C (MMC) in patients with post-traumatic open-angle glaucoma during 2y of follow up.

• METHODS: This was an interventional, 2-year, observational study. Eighteen eyes were prospectively observed (in 18 patients with traumatic secondary open-angle glaucoma) in which Ex-press miniature glaucoma filtration shunts were implanted with AMT and MMC. The outcome measures included intraocular pressure (IOP), best corrected visual acuity (BCVA), number of antiglaucoma medications, and complications. The progress of all patients was monitored for 24mo.

• RESULTS: Complete success (IOP <21 mmHg without glaucoma medications) was seen in 15 of the 17 (88.2%) eyes enrolled in the study at 24mo after the operation. IOP decreased from 36.9±4.8 mmHg preoperatively to 15.4±3.5 mmHg at 12mo and 15.5±3.5 mmHg at 24mo postoperatively. Early postoperative hypertension developed in two patients (11.1%) due to postoperative fibrosis. Most of the patients had improved postoperative BCVA values at the final follow-up visit compared to their preoperative measurements. Two patients (11.1%) developed transient hypotony. There were no complications such as hyphema, choroidal effusion, shallow anterior chamber, the device touching the iris, or extrusion of the device.

• CONCLUSION: The Ex-press miniature glaucoma filtration shunt with adjunctive AMT and MMC is effective and safe in cases of traumatic open-angle glaucoma. Surgical management is an appropriate surgical treatment in this series of cases.

• KEYWORDS: Ex-press; glaucoma drainage device; traumatic glaucoma

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INTRODUCTION

Post-traumatic glaucoma is a major complication of blunt ocular injury that sometimes requires surgical intervention[1-3]. Hyphema, angle recession, inflammation, and trabecular meshwork injuries are the most common mechanisms leading to glaucoma in patients with ocular contusion[1-3]. Traumatic glaucoma has been reported as refractory glaucoma, and the treatment of post-traumatic glaucoma is a challenge. Many methods exist to treat post-traumatic glaucoma in instances where antiglaucoma mediation has failed. The results of argon laser trabeculoplasty or yttrium-aluminum garnet (YAG)-laser trabeculoplasty have been far from satisfactory[4]. Non-penetrating trabecular surgery is not fit for these cases because the trabecular meshwork or Schlemm's canal have been severely damaged[5]. This group has also been considered at high risk for failure of glaucoma filtration surgery[6-7]. Pars plana vitrectomy with lensectomy has provided good surgical outcomes[4,8]; however, it seems excessive in some cases of mild lens subluxation. One alternative treatment is the use of drainage valves, but results have varied and patients have not been free of complications such as hypotony, choroidal effusion, and valve extrusion[9-10]. In eyes with post-traumatic glaucoma that is resistant to topical eye drops, trabeculectomy undertaken with adjunctive antimetabolites or amniotic membrane remains the first choice for treatment in some types of post-traumatic glaucoma[7,11-13].

The Ex-press® miniature glaucoma filtration shunt (Alcon Laboratories; Fort Worth, Texas, USA) is a miniature glaucoma shunt that can safely reduce intraocular pressure (IOP) in a similar way to trabeculectomy[14-16], while avoiding the need for scleral removal and iridectomy. In addition, it has a disc-like flange and a spur-like projection to prevent extrusion, allowing the device to remain stable in the eye. Its device lumen can limit the aqueous outflow in a predictable way, potentially reducing postoperative hypotony. Micro-incision glaucoma surgery with the Ex-press implant might be helpful for ocular tissue injury, IOP control, and postoperative complications in complicated glaucoma. Although use of the Ex-press miniature shunt in advanced glaucoma has been previously demonstrated[14,17-20], little available data is available about this use of the device. Additionally, to date, no reports exist about the uses of Ex-press shunt undertaken with adjunctive amniotic membrane transplantation (AMT) and mitomycin C (MMC) in patients with post-traumatic glaucoma. Thus, this interventional observational study was undertaken to assess IOP control and visual rehabilitation with use of an Ex-press miniature glaucoma shunt with adjunctive AMT and MMC in Chinese patients with post-traumatic open-angle glaucoma.

SUBJECTS AND METHODS

Subjects This interventional observational study of a consecutive case series of 18 eyes (in a population of 18 patients) with traumatic open-angle glaucoma treated with the Ex-press miniature glaucoma shunt was conducted at the Eye Center, Affiliated Second Hospital, School of Medicine, Zhejiang University, from August 2012 to May 2014. All practices and research adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients after explanation of the nature and possible consequences of the procedures. Careful clinical examination, including slit-lamp examination, gonioscopy or ultrasound biomicroscopy (UBM) examination, and B-mode ultrasonography examination, was conducted preoperatively to identify any of several potential causes of post-traumatic glaucoma[2-3]. This study excluded eyes with post-traumatic glaucoma caused by inflammation, hyphema, severe lens dislocation (degree of zonular dehiscence greater than 150°), and pupil block. The inclusion criteria were as follows: post-traumatic eyes with deep anterior chambers and wide open angles. Preoperatively, all patients in the study received medical treatment for glaucoma depending on their maximal tolerance. In addition to the clinical examination, preliminary data collected included age, sex, surgical history, number of antiglaucoma drugs, IOP measured by Goldmann applanation tonometry, and best corrected visual acuity (BCVA).

Methods All surgical procedures were performed by a single experienced ophthalmic surgeon (Yin JF). After topical anesthesia was administered, a fornix-based conjunctival flap and a 3.5×4.0 mm limbus-based scleral fiap with a depth of approximately 50% depth were created. Then, a Weck-Cel sponge soaked in a 0.4 mg/mL solution of MMC was applied under the scleral flap for 2min, after which the area was rinsed thoroughly for 2min with a balanced salt solution. Using a 26-gauge needle, a perforation through which the Ex-press shunt was inserted was made into the anterior chamber, under the scleral flap. A 15×10 mm single layer of cryopreserved AMT was then placed between the scleral flap and the Ex-press shunt with the stromal side facing down. Then, the scleral flap was sutured at the four corners with interrupted stitches using 10/0 nylon sutures. The conjunctival flap was then closed with a continuous 10-0 nylon suture.

Postoperative treatment consisted of steroid-antibiotic combination eyedrops four times a day for a week, and then tapering off over one month. Follow-up appointments occurred on day 1, day 3, week 1, week 2, month 1, month 3, month 6, month 12, and month 24. Two levels of surgical outcomes were defined: 1) Complete success: an IOP of 21 mmHg or less without antiglaucoma medications, and 2) Qualified success: an IOP of 21 mmHg or less with the help of antiglaucoma medications. In contrast, failure was defined as an IOP of greater than 21 mmHg with the use of maximally

tolerated antiglaucoma medications. Postoperative data collected included IOP, BCVA, bleb characteristics, number of antiglaucoma medications, and complications.

Statistical Analysis Statistical analysis was performed using SPSS Version 12 (SPSS; Chicago, Illinois, USA). The nonparametric Wilcoxon signed-rank test (with continuity correction) was used for statistical analyses; $P<0.05$ was considered statistically significant.

RESULTS

Eighteen eyes in 18 patients with post-traumatic open-angle glaucoma who underwent surgery between August 2012 and May 2014 were prospectively evaluated. Table 1 shows patient characteristics and preoperative clinical examination. Fifteen of the 18 patients (83.3%) were men, and the mean patient age was 44.6y (range, 23-60y). None of the eyes had previously undergone failed filtration surgery. At the preoperative gonioscopy or UBM examination, six eyes (33.3%) had angle recession. The preoperative slit-lamp examinations showed that five eyes (27.8%) had zonular loss of approximately 90° with mild lens dislocation, three eyes (16.7%) had vitreous prolapses in the anterior chamber, and six eyes (33.3%) had iridodialysis.

Table 2 shows the mean preoperative IOP was 36.9±4.8 (range 25-42) mmHg on an average of 3.4±0.5 (range 3-4) anti-glaucoma drugs. This decreased to 15.4±3.5 (range 8-20) mmHg at 24mo after surgery. The mean number of postoperative medications at last follow-up was 0.2±0.5 drugs (range 0-2). Most of the patients' BCVA values were better at the final follow-up visit compared to their preoperative measurements. The mean postoperative BCVA value at last follow-up improved to 4.3±0.6 (3.0-4.9) from a pre-operative value of 4.1±0.6 (3.0-4.9).

Table 3 shows the mean postoperative IOP changes from day 1 to month 24. Immediately after surgery, IOP was significant lower than in the preoperative measurements in all 18 eyes. Though the mean postoperative IOP trended towards showing an increase over 2y of follow up (Table 2), the reduction in pressure was found to be significant using the Wilcoxon signed-rank test at $P<0.05$ when compared with the preoperative IOP measurements. At the last visit, one eye was lost to follow up and the remaining 17 eyes had IOPs ≤21 mmHg; eight of those had IOPs of 13-17 mmHg and four had IOPs ≤12 mmHg. The preoperative IOPs were largely untreated, while the postoperative percentage decrease in pressure varied between 58.0% and 76.4% during the 2y follow-up. Two patients had a history of hypertension after surgery due to subconjunctival fibrosis. One patient's IOP was >21 mmHg at 6mo postoperatively; he received one antiglaucoma medicine, and his IOP was reduced to <21 mmHg. At 12mo after surgery, this patient's IOP was >21 mmHg again, and he received another antiglaucoma medicine. At the final examination, his IOP was well controlled at <21 mmHg. The other patient's IOP was >26 mmHg (3mo post-operation) while on three antiglaucoma medicines, and he underwent bleb separation. After bleb separation, the patient's BCVA improved to 0.8, and his IOP was <21 mmHg without topical medication. Twelve months postoperatively, this patient's IOP was >21 mmHg and he received one antiglaucoma medicine. Two patients (11.1%) developed transient hypotony that spontaneously resolved within 1wk. No complications occurred during the procedure, with no incidences of hyphema, choroidal effusion, shallow anterior chamber, device touching the iris, or device extrusion.

Table 1 Baseline demographic and clinical characteristics of the cases enrolled in the study

Characteristics	Total
No. of patients (eyes)	18 (18)
Age (a)	44.6 (range: 23-60)
Sex	
M	15
F	3
Clinical Examination (%)	
Angle recession	6 (33.3%)
Zonular loss	5 (27.8%)
Mild lens dislocation	5 (27.8%)
Vitreous prolapses to AC	3 (16.7%)
Iridodialysis	6 (33.3%)

AC: Anterior chamber.

DISCUSSION

Mechanisms of traumatic glaucoma are complex and vary according to different stages that occur after blunt ocular trauma [2-3]. In the early stage after ocular contusion, factors such as inflammation and hyphema are the main cause of elevated IOP; factors such as scar formation and angle recession gradually play an important role after injured eyes recover. This shift over time in factors leading to IOP makes the choices related to treatment more complex.

In our first consecutive series of observations for the Ex-press miniature glaucoma shunt with adjunctive AMT and MMC for traumatic secondary glaucoma, 17 patients (100%) were reported a decrease in IOP to less than 21 mmHg; in two of these patients (11.8%), IOP declines were achieved with the help of antiglaucoma eyedrops at 2y follow-up. The high success rate of this surgical management is consistent with previous reports [7,11-13] showing that patients who receive trabeculectomy with antimetabolites and/or AMT intraoperatively. The purpose of the Ex-press shunt is to divert the aqueous humor from the anterior chamber to the sub-conjunctiva. Implantation of the device is quick, reproducible, relatively noninvasive, and generally without significant risk to patients, thereby offering a significant advantage compared with the more-invasive trabeculectomy procedure. The positive outcomes of the study suggest that this relatively noninvasive procedure could result in a high success rate for traumatic angle open glaucoma that approaches that of trabeculectomy. We advocate use of the less-invasive Ex-press shunt with adjunctive AMT and MMC as a feasible surgical option in these case series.

Table 2 Changes in IOP, BCVA, and the number of antiglaucoma medications at 24mo follow-up

Time	IOP (mmHg)	No. Antiglaucoma Medications	BCVA
Pre-operation	36.9±4.8 (25-42)	3.4±0.5 (3-4)	4.1±0.6 (3.0-4.9)
24mo follow-up	15.4±3.5 (8-20)	0.2±0.5 (0-2)	4.3±0.6 (3.0-4.9)
P	*P*<0.05	*P*<0.05	*P*<0.05

IOP: Intraocular pressure; No. Antiglaucoma Medications: The average number of antiglaucoma medications used; BCVA: Best corrected visual acuity (Snellen equivalent).

Table 3 Mean postoperative IOP during 2y of follow up

Parameters	Pre-op	Day		Week		Month				
		1	3	1	2	1	3	6	12	24
No. patients	18	18	18	18	15	18	16	17	16	17
No. Antiglaucoma Medications	3.4	0	0	0	0	0	0.1	0.1	0.2	0.2
Mean IOP	36.9	8.7	9.2	10.2	11.9	12.2	14.9	14.5	15.4	15.5
SD	4.8	3.4	3.5	3.8	5.8	3.2	3.3	3.6	3.5	3.5
P		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Percentage decrease in IOP (%)		76.4	75.1	72.3	67.8	66.9	59.6	60.7	58.3	58.0

No. patients: Total number of patients; No. Antiglaucoma Medications: The mean number of antiglaucoma medications used; IOP: Intraocular pressure; SD: Standard deviation.

With lenses that are severely dislocated or subluxation-related glaucoma, lensectomy combined with vitrectomy is needed[4,8]; however, this procedure seems excessive in some cases of mild lens subluxation. The vitreous anterior limiting membranes are often ruptured, with vitreous prolapses found in the anterior chamber[3]. Filtration surgery may fail due to involvement of vitreous prolapses[3]. On the contrary, the Ex-press shunt avoids the need for scleral removal and iridectomy, possibly alleviating interference from vitreous prolapses. In our study, five eyes had mild zonular dehiscence resulting in mild lens dislocation, and three eyes had some degree of vitreous prolapse in their anterior chambers. To avoid vitreous - related side effects, we implanted the Ex-press shunt as far as possible from the zonular dehiscence. It is encouraging that at the end of the study these eyes showed strong IOP decreases with VA recovery. Our results suggest that this methodology can be safely considered as an appropriate surgical treatment in patients with glaucoma who have mild lens subluxation.

A few small case series have been reported recently about use of the Ex-press shunt in advanced glaucoma [14,17-20], and the results were somewhat controversial. Dahan *et al*[14] observed patients who had undergone unsuccessful filtration surgery previously and were either black or of mixed race; this series showed promising results using the Ex-press shunt, with a complete success rate of 90.5% (19/21) and a qualified success rate of 100% (21/21) at 12mo postoperatively. In a recent clinical study[18], the Ex-press shunt was implanted in treating eyes with complicated glaucoma, such as juvenile glaucoma, uveitic glaucoma, neovascular glaucoma, and pseudophakic glaucoma. These avenues of research produced discouraging results, in which absolute success was noted in 8/12 (66.7%) and qualified success in 10/12 (83.3%) at one year after surgery. Huerva *et al*[17] reported a case of post-traumatic glaucoma implantation with the Ex-press shunt; this patient's IOP remained at a normal level at 10mo follow-up with the help of two antiglaucoma drugs. We first reported consecutive series of refractory glaucoma caused by ocular trauma. Our results were favourable for post-traumatic open-angle glaucoma with Ex-press with adjunctive AMT and MMC. We attribute these good results with respect to lowering IOP in our study to the following reasons. First, all surgeries were conducted skillfully and there were no learning curves. Furthermore, use of AMT and MMC minimize the risk of fibrosis, thereby achieving good control of IOP.

The consistent internal diameter of the Ex-press shunt can accurately predict filtration value[14]. However, this procedure is not free of complications such as hypotony, flat anterior chamber, and choroidal effusion[16]. In a meta-analysis of Ex-press shunt implantation[16], incidences were reported of 24/246 of hypotony, 9/190 of flat anterior chamber, and 24/231 of choroidal effusion. In our small series with mid-term follow up, only two patients (11.1%) developed transient hypotony in the early stage after surgery; there were no other complications (*e. g.* shallow anterior chamber, hyphema, or choroidal effusion). Use of the Ex-press shunt treatment with adjunctive AMT and MMC seems to lead to fewer complications. This finding might be partially explained by AMT being placed between the scleral flap and Ex-press shunt and to AMT halting the rapid drainage of aqueous humor[11]. Our results demonstrated that Ex-press shunt implantation with adjunctive AMT and MMC could provide good control over aqueous outflow, contributing to a stable anterior chamber and predictable IOP.

In conclusion, we found the Ex-press miniature glaucoma shunt with adjunctive AMT and MMC an effective and safe procedure in the management of post-traumatic open-angle glaucoma in Chinese patients. This surgical management might be considered a good choice of treatment in this series of cases, especially those with mild lens subluxation. However,

there are several limitations in our study. First, it is a clinical observation with a small sample size; second, the study lacked a control group. Therefore, further randomized controlled studies with larger series would be beneficial.

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