Comparison of trabeculectomy with Ex-PRESS shunt implantation in primary-open-angle-glaucoma patients: A retrospective study

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Abstract

Purpose: To investigate the efficacy of intraocular pressure (IOP) control and medication use over time after trabeculectomy (TRBC) and Ex-PRESS shunt implantation in primary-open-angle-glaucoma (POAG) patients.

Design: Retrospective case series.

Patients and methods: A total of 33 unilateral POAG patients were enrolled, and 17 patients received traditional TRBC and 16 patients received Ex-PRESS device implantation. Data on IOP, reduction of antiglaucoma medication, and major complications were collected and analyzed after 12 months of follow up.

Results: After 12 months of follow up, both groups showed good IOP control. The mean preoperative IOP decreased from 38.5 (±6.9) to 18.2 (±11) mmHg after TRBC, and from 38.5 (±9.1) to 19.53 (±12.36) mmHg after Ex-PRESS implantation (both p < 0.05). The mean number of antiglaucoma medications prescribed at the last follow up decreased from 3.2 (±0.5) preoperatively to 1.2 (±1.4) after TRBC versus 3.3 (±0.7) preoperatively to 1 (±0.9) after Ex-PRESS implantation (both p < 0.05). Complete success rate (defined as no medication after surgery with IOP > 5 and < 18 mmHg) and qualified success rate (defined as with or without medication after surgery with IOP > 5 and < 18 mmHg) were similar (47% vs. 43% and 76.47% vs. 75%) between the two groups without statistical difference (p > 0.05). However, postoperative hypotony rate was more frequent after Ex-PRESS (37.5%) than after TRBC (17.6%).

Discussion: TRBC and Ex-PRESS implantation provided similar IOP control and reduction of postoperative medication with low incidence of postoperative complications at intermediate-term follow up. However, the Ex-PRESS implantation device may last longer but with extra costs. It is up to the surgeon to decide which procedure to use according to the patient’s situation and economic circumstances.

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1. Introduction

Trabeculectomy (TRBC; Fig. 1A) has been widely used for more than half a century for the control of intraocular pressure (IOP) in patients with glaucoma.¹ The success rate and complications of this procedure have been well described; it is now known that the complications of TRBC include hypotony, conjunctival erosions, and choroidal detachment among other adverse effects.² Thus, glaucoma surgeons continue to search for improved methods that have superior efficacy and safety compared with TRBC.

The Ex-PRESS device was approved by the United States Food and Drug Administration in 2002.³ This stainless steel device is designed to be implanted adjacent to the limbus directly under a scleral flap (Fig. 1B) to allow drainage of aqueous humor into the subconjunctival space provided there is a standardized lumen size and reduced inflammation with less tissue manipulation³,⁴ (Fig. 1C). The relatively simple technique of implanting an Ex-PRESS valve is similar to that used in standard TRBC with one obvious exception of not requiring a sclerectomy or peripheral iridectomy.
This study compares clinical parameters following standard TRBC versus Ex-PRESS shunt implantation.

2. Methods and materials

We performed a retrospective, comparative case series study on patients with primary open angle glaucoma (POAG) who had undergone implantation of Ex-PRESS miniature glaucoma implant under a scleral flap or TRBC between March 2012 and March 2013 at a single center by a single experienced surgeon.

We collected data from patients older than 18 years who presented with medically uncontrolled POAG requiring surgery for IOP reduction. Patients meeting any of the following criteria were excluded: any form of glaucoma other than POAG, history of active uveitis, and any previous ocular glaucoma surgery. Patients were evaluated on postoperative Days 1, 3, 7, and 14, and at 1, 3, 6, 9, and 12 months. Releasable sutures were removed 3 weeks postoperatively.

Data on the following clinical parameters were collected and assessed at each clinical visit: surgical complications, IOP (measured by calibrated Goldmann applanation tonometers), and the number of antiglaucoma medications required to achieve adequate IOP control. In order to compare the outcomes of TRBC and Ex-PRESS shunt implantation, qualified success was defined as an IOP between 5 and 18 mmHg with or without medication, and complete success was defined as an IOP between 5 and 18 mmHg without medication. Treatment failure was defined as an IOP <5 or >21 mmHg despite medication (early hypotony with an IOP of <5 mmHg at 1 week postoperatively was excluded), progression to no light perception, or requirement of further surgical intervention including needling bleb revision for the control of high IOP.

2.1. Description of device

The Ex-PRESS glaucoma filtration device (Alcon Laboratories, Fort Worth, TX, USA) is designed to drain aqueous fluid from the anterior chamber to the subconjunctival space and form a filtration bleb, similar to TRBC. The Ex-PRESS glaucoma device is currently available in two models: the R-model and the P-model.

In this study, we used the P-200 model for implantation. The P-200 model has a length of 2.64 mm, a decreased bevel angle, and an internal and external lumen diameter of 200 and 400 μm, respectively.

2.2. Ex-PRESS surgical technique

All patients received retrobulbar anesthesia, and a single limbal-based conjunctival incision was performed prior to gentle exposure of the scleral bed. Scleral flaps of approximately 2 × 2 mm were created in a similar manner to standard TRBC, and antifibrotic agents (mitomycin C) were applied. Variable concentrations and durations of mitomycin C treatment are commonly used. A concentration of 0.2 mg/mL was used in this study. Application time varied between 1 and 5 minutes depending on the preoperative IOP, the age of the patient, and the condition of the capsule of Tenon. For example, in patients at high risk of unsuccessful filtering surgery, such as those with high preoperative IOP, or with increased thickness of the capsule of Tenon, mitomycin C was applied for 5 minutes. However, in young patients, the duration of mitomycin C application may be 1 minute for the prevention of postoperative hypotony and further scleral malacia.

When sclerectomy or iridectomy was not required, a 25-gauge needle was used to access the anterior chamber at the point midway along the base of the scleral flap and then removed gently to avoid lateral movement that may extend the channel and cause aqueous humor to leak around the shunt. The Ex-PRESS shunt is preloaded on an injector. The shunt is introduced into the anterior chamber exclusively through the ostium created by the needle and released by applying pressure to the shaft of the inserter. The scleral flap is then sutured with 9–0 Nylon and with the tightness adjusted depending on the resultant flow during inflation of the

Fig. 1. (A) Patients received trabeculectomy with bleb formation. (B) Patients received Ex-PRESS shunt implantation with bleb formation. (C) Ex-PRESS shunt implantation provides standardized lumen size and stable filtering function.
anterior chamber with balanced salt solution using a 25-gauge needle through the temporal paracentesis. Finally, the conjunctival incision was closed using a 10–0 Nylon.

Ex-PRESS surgery can be learned easily, particularly by doctors with previous TRBC experience.

3. Results

A total of 33 patients with unilateral POAG were enrolled and were separated into following two groups according to patient choice: the TRBC group (17 patients, Group A) and the Ex-PRESS group (16 patients, Group B). All patients received regular ophthalmology outpatient department assessments at 1 and 3 days, 1 and 2 weeks, and 1, 3, 6, and 12 months postoperatively. No significant differences were observed between the two groups (Table 1), other than the significantly higher age of patients in the TRBC group as compared to the Ex-PRESS group. Preoperatively, the mean IOP values were 38.5 (±6.9) mmHg in Group A and 38.5 (±9.1) mmHg in Group B. At 12 months follow up, the mean IOP values were 18.2 (±11) mmHg in Group A and 19.53 (±12.36) mmHg in Group B. Both groups had significant reductions in IOP following surgery (p < 0.01). A significant reduction in the number of antiglaucoma medications was also observed in both groups postoperatively with reductions ranging from 3.2 (±0.5) to 1.2 (±1.4), and 3.3 (±0.7) to 1 (±0.9), following TRBC and Ex-PRESS implantation, respectively (p < 0.01 for both). The results regarding the evolution of IOP and the number of medications taken in both groups are presented in Figs. 2 and 3.

At 1-year follow up, eight out of 17 patients (47%) in Group A, and seven out of 16 patients (43%) in Group B, achieved complete success, which was defined as being medication-free with IOP between 5 and 18 mmHg. Qualified success, defined as IOP >5 and <18 mmHg with or without antiglaucoma medication, was observed in 13 out of 17 (76.47%) patients in Group A and 12 out of 16 (75.00%) patients in Group B.

Complications were generally mild, and the complication rate was similar between the groups (Table 2). However, the incidence of early hypotony on Day 1 was much higher in patients receiving Ex-PRESS surgery (17.64% in Group A vs. 37.5% in Group B); however, these complications were self-limited and resolved within 1 week. TRBC resulted in hyphema in two patients and bleb leakage in one patient with all recovering spontaneously within 1 week after treatment with medication or pressure gauze. There were no occurrences of conjunctival erosion or choroidal detachment in either group. No patients required further surgical interventions.

4. Discussion

To our knowledge, this is the first retrospective study comparing TRBC with Ex-PRESS device implantation for the control of IOP in

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Table 1

|                     | TRBC group | Ex-PRESS group | p       |
|---------------------|------------|----------------|---------|
| Sex                 |            |                |         |
| Male                | 11         | 8              | 0.44    |
| Female              | 6          | 8              |         |
| Age                 | 63.76 ± 13.37 | 52.75 ± 12.2 | 0.01*   |
| Range               | 29–80      | 34–71          |         |
| Diagnosis           |            |                |         |
| POAG                | 17         | 16             | > 0.99  |
| Preoperative IOP (mean ± SD) | 38.5 ± 6.9 | 38.5 ± 9.1 | 0.50    |
| Range               | 28.5–48.5  | 27.5–48.5      |         |
| Preoperative medication number (mean ± SD) | 3.17 ± 0.5 | 3.31 ± 0.68 | 0.27    |
| Postoperative IOP at 12 mo (mean ± SD) | 18.2 ± 11.0 | 19.5 ± 12.4 | 0.28    |
| Range               | 6–46       | 8–46           |         |
| Postoperative medication number at 12 mo (mean ± SD) | 1.2 ± 1.38 | 0.94 ± 0.97 | 0.28    |

No significant differences were found between the two groups, except for the fact that patients in the TRBC group were older compared with those in the Ex-PRESS group.

IOP = intraocular pressure; POAG = primary open angle glaucoma; SD = standard deviation; TRBC = trabeculectomy.
Taiwan. TRBC is currently the gold standard procedure for lowering IOP in POAG. However, owing to the unavoidable risk of a number of sight-threatening complications, surgeons have continued to search for safer and more efficacious procedures than TRBC. The Ex-PRESS device is a glaucoma drainage device developed within the past two decades as an alternative to standard TRBC.

In our study, both procedures provided good control of IOP. The qualified success rate was high in both groups A and B (76.5% and 75%), and the complete success rate was similar between the two groups (47% vs. 43%). These findings corroborate a number of previous studies. In 2007, Maris et al published the 1-year follow-up results of a retrospective series comparing Ex-PRESS with TRBC and demonstrated a success rate (defined as IOP < 21 mmHg) of 90% in patients undergoing Ex-PRESS surgery and 92% in patients undergoing TRBC surgery. However, other studies have reported differing results. The tube versus TRBC study revealed that the overall success rate (defined as IOP < 4 and <18 mmHg) in patients receiving the Ex-PRESS tube (82%) was higher than that in patients undergoing TRBC (66%) at 36 months follow up. This discrepancy with our study may relate to our follow-up period. A slow decline in TRBC success is common. Beckers et al reported that the success rate (defined as an IOP < 15 mmHg) following TRBC is 83.3% at 12 months follow up, and this figure decreased to 60% at 72 months follow up. Wilensky and Chen also reported a success rate (defined as IOP < 21 mmHg, or a decrease of 33% if the preoperative IOP was <21 mmHg) following TRBC of 83% at 60 months, which decreased to 73% at 120 months, and further decreased to 42% at 180 months.

Complications in both groups during our study were mild (Table 2). However, the Ex-PRESS group had a higher total complication rate compared to the TRBC group (37.5% vs. 29%) as an increased frequency of hypotony was observed in the Ex-PRESS group (37.5% vs. 17.64%). Hypotony was self-limited and resolved within 1 week without requirement of further surgical interventions or occurrence of hypotonous maculopathy in both groups. If hypotony cases in both group are excluded, the TRBC group had a higher adjusted postoperative complication rate than the Ex-PRESS group (24% vs. 6%). When compared with previous studies, the hypotony rate was significantly higher in our study. This result may be attributed to the choice of Ex-PRESS model. The Ex-PRESS P-2oo model, which has an internal lumen diameter of 200 μm, may have provided overabundant filtration of aqueous humor. The choice of the Ex-PRESS R-50 or P-50 model, with a smaller internal lumen diameter of 50 μm, may have decreased the incidence of hypotony.

The number of glaucoma medications taken postoperatively was lower than the number of glaucoma medications taken preoperatively (0.94 ± 0.96 vs. 1.18 ± 1.38). However, there was no statistical difference between the two groups (p = 0.286).

Visual acuity may alter as a result of improvement following surgery or disease progression. In our study, equivalent visual function following the surgery was observed in the majority of patients with no statistical difference observed (p > 0.05). Maris et al reported that 16% of patients undergoing TRBC, and 20% of those undergoing Ex-PRESS surgery, lost two or more Snellen lines (p = 0.603). Good and Kahook reported increased visual recovery following surgical intervention in patients undergoing Ex-PRESS surgery but did not find a significant difference in visual acuity between groups at 1 year.

The major limitation of our study is the small sample size, with a total of 33 eyes in 33 patients. Furthermore, this study was not a randomized controlled trial. The follow-up time of this study was insufficient as the success rate of filtration surgery may decrease over time. However, our study demonstrated similar results compared to previous studies.

### Table 2

| Complications          | Trabeculectomy | Ex-PRESS | p     |
|------------------------|----------------|----------|-------|
| Shallow AC             | 4/17 (24%)     | 1/16 (6%)| 0.335 |
| Bleb leak              | 1/17 (6%)      | 0/16 (0%)| > 0.99|
| Hypotony               | 3/17 (17.64%)  | 5/16 (37.5%)| 0.258 |
| Hyphema                | 2/17 (12%)     | 0/16 (0%)| 0.48  |
| Choroidal detachment   | 0/17 (0%)      | 0/16 (0%)| > 0.99|
| At least one complication | 5/17 (29%)   | 6 (37.5%)| 0.72  |
| At least one complication | 4/17 (24%)   | 1 (6%)   | 0.335 |
| but exclude hypotony   |                |          |       |

In our study, the hypotony rate was much higher in the Ex-PRESS group (37.5% vs. 17.64%). However, our study demonstrated similar results compared to previous studies.

### 5. Conclusion

The present study is a retrospective study comparing TRBC and Ex-PRESS implantation in Taiwanese patients. Both procedures provided good control of IOP and reduced the number of postoperative medications with a low incidence of postoperative complications requiring further surgical interventions over an intermediate-term follow-up period. However, although the effect of Ex-PRESS implantation device may have longer duration, it is more expensive than the other treatment options. Thus, it is up to the surgeon to select the most appropriate procedure based on the clinical and economic situation of individual patients.

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