Evaluation of Ex-PRESS Mini Glaucoma Shunt Implantation in Refractory Postpenetrating Keratoplasty Glaucoma

Halil Ates, MD, Melis Palamar, MD, Ayse Yagci, MD, and Sait Egrilmez, MD

**Purpose:** To evaluate the intraocular pressure (IOP) control and graft survival after Ex-PRESS mini glaucoma shunt implantation in refractory postpenetrating keratoplasty glaucoma.

**Methods:** The study included postpenetrating keratoplasty glaucoma cases unresponsive to medical antiglaucomatous therapy in whom 15 Ex-PRESS mini glaucoma shunt implantation was carried out. All glaucoma shunt implantations were performed in a separate session after penetrating keratoplasty. Nine operations were performed under general anesthesia and 6 were performed under local anesthesia. Topical antibiotic and topical corticosteroids were used during the postoperative first month.

**Results:** Mean age of the study population was 37.4 years (range: 10 to 80 y). IOP decreased from 41.46 mm Hg (range: 26 to 80 mm Hg) to 12.06 mm Hg (range: 8 to 25 mm Hg) over a mean follow-up of 12.2 months (range: 8 to 19 mo) \((P < 0.001; \text{Wilcoxon signed rank test})\). IOP was below 21 mm Hg in 14 of 15 eyes (93.3%) with or without antiglaucomatous drugs. Complete success (IOP < 21 mm Hg without medication) rate was 86.6%. Average number of antiglaucomatous drug usage decreased from 3.20 (range: 2 to 4) preoperatively to 0.26 postoperatively (range: 0 to 3) \((P < 0.001; \text{Wilcoxon signed rank test})\). In 93.3% of the cases, the decrease in IOP was 30% or above postoperatively. After Ex-PRESS implantation, clear grafts remained clear while edematous grafts became clearer due to IOP decrease. Neither biomicroscopy nor pachymetry showed worsening of preoperatively opaque grafts.

**Conclusion:** Ex-PRESS mini glaucoma shunt implantation may be an effective procedure for refractory postpenetrating keratoplasty glaucoma with acceptable graft failure rates in short term.

Key Words: penetrating keratoplasty, glaucoma, glaucoma drainage device, Ex-PRESS

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Glaucoma is one of the most serious complications after penetrating keratoplasty (PKP) due to its high incidence and severity, as well as the difficulty in diagnosis and treatment. Risk factors include trauma, inflammation, advanced age, aphakic, and pseudophakic bullous keratopathy. Post-PKP glaucoma represents the second leading cause of graft failure. Although retransplant opportunity exists in cases of graft rejection, there is a risk of unrecoverable vision loss in cases of glaucoma. Pathophysiological mechanisms of glaucoma development after PKP are various and identification of the exact etiology of increased intraocular pressure (IOP) is essential for effective treatment. Determination of etiology in these cases necessitates thorough evaluation of ocular history and examination of anterior chamber angle. As IOP measurement in post-PKP eyes might be deceptive, gonioscopy needs to be included in examination of suitable eyes as well as pachymetry, optic nerve examination, and visual field testing.

Glaucoma drainage devices (GDDs) can be implanted to facilitate aqueous outflow in cases of IOP whom prior treatments have failed or in cases with scarred conjunctiva or angle closure secondary to peripheric anterior synchiae. However, GDD may be associated with a greater incidence of graft failure than trabeculectomy. Ex-PRESS mini glaucoma shunt implant is a new GDD highly stable in the anterior chamber. Efficacy of Ex-PRESS shunt is similar to standard trabeculectomy while complications are lower than those of GDDs and standard trabeculectomy.

The purpose of this study was to evaluate IOP control and graft survival after Ex-PRESS mini glaucoma shunt (Optonol Inc, Kansas City, KS) implantation in refractory post-PKP glaucoma.

**MATERIALS AND METHODS**

Ex-PRESS mini glaucoma shunt was implanted to 15 post-PKP eyes with close-angle glaucoma due to peripheric anterior synchiae. Patients with neovascular glaucoma and a follow-up less than 6 months were excluded. Identification of the exact cause of IOP elevation, GDD implantation decision, complete evaluation including drainage angle, pachymetry, tonometry (dynamic contour tonometry) and optic nerve examination were all performed by the same surgeon. Dynamic contour tonometry was used because it is more reliable than Goldman applanation tonometry for measurement of IOP in corneas with increased thickness and irregular surface.

All glaucoma shunt implantations were performed in a separate session after PKP by the same surgeon (H.A.). Nine operations were performed under general anesthesia and 6 were performed under local anesthesia. The surgical technique consisted of implanting the Ex-PRESS shunt under a 5 x 5 mm partial thickness scleral flap similar to a standard limbus-based guarded trabeculectomy. Mitomycin C 0.05% was applied for 3 minutes to prevent invasion of the sclera insertion area by the surrounding fibroblastic activity and rinsed with 0.9% NaCl. Topical antibiotics and topical corticosteroids were used during the postoperative first month.
Success was defined as postoperative IOP between 5 and 21 mm Hg with or without medications and absence of need for glaucoma surgery or removal of the implant, and survival of clear graft. Laser suture lysis and bleb needling were not considered to be criteria for failure in our report.

Visual acuities were measured with Early Treatment Diabetic Retinopathy Study chart and graft examination for clarity was made by the same ophthalmologists on biomicroscopy. Central corneal graft thicknesses were measured by ultrasonic pachymetry (DGH Technology, DGH 2000, PA).

**RESULTS**

The demographic data and preoperative clinical characteristics of the 15 eyes of 15 patients enrolled (9 women and 6 men) are presented in Table 1. Mean age was 37.4 years (range: 10 to 80 y).

All of the 15 eyes (100%) had close-angle glaucoma secondary to periphere anterior synechias. In the opaque grafts, peripheric anterior synechias were visible at the relatively clear host cornea sides. The indications for PKP were congenital glaucoma and bullous keratopathy in 6 (40.0%), pseudophakic bullous keratopathy in 2 (13.4%), perforated descemetocele in 3 (20.0%), regraft in 2 (13.4%), herpetic keratitis in 1 (6.6%), and keratoconus in 1 (6.6%) (Table 2). Eight (53.3%) of the eyes had undergone trabeculectomy and 2 (20%) had undergone GDD implantation before Ex-PRESS shunt implantation (Table 2).

IOP decreased from 41.46 ± 14.29 mm Hg (range 26 to 80 mm Hg) to 12.06 ± 5.17 mm Hg (range: 8 to 25 mm Hg) over a mean follow-up of 12.2 months (range: 8 to 19 mo) (P < 0.001; Wilcoxon signed rank test) (Table 3).

The rate of qualified success (IOP < 21 mm Hg with or without medication) was 93.3%. Complete success (IOP < 21 mm Hg without medication) rate was 86.6%. The average number of antiglaucomatous drugs being used was 3.20 (range: 2 to 4) preoperatively, 0.26 postoperatively (range: 0 to 3) (P < 0.001; Wilcoxon signed rank test) (Table 3). Thirty percent or more decrease in IOP rate was 93.3%.

The average preoperative and postoperative best corrected visual acuity was 0.03 ± 0.05 and 0.08 ± 0.07, respectively (P < 0.021; Wilcoxon signed rank test) (Table 3).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. patients (eyes)</th>
<th>Age (y)</th>
<th>Sex</th>
<th>No. prior intraocular operations</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKP regraft</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>Congenital glaucoma + bullous keratopathy</td>
</tr>
<tr>
<td>Trabeculectomy</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td>Pseudophakic bullous keratopathy</td>
</tr>
<tr>
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<td>2</td>
<td></td>
<td></td>
<td></td>
<td>Perforated descemetocele</td>
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</tbody>
</table>

GDD indicates glaucoma drainage device; Phaco IOL, phacoemulsification and intraocular lens implantation; IOP, intraocular pressure; PKP, penetrating keratoplasty; TE, trabeculectomy.

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**TABLE 2. Baseline Demographic and Clinical Characteristics of the Cases Enrolled in the Study**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. patients (eyes)</th>
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PKP indicates penetrating keratoplasty.
Wilcoxon signed rank test) (Table 3). After Ex-PRESS implantation preoperatively clear grafts remained clear, edematous grafts became clearer due to IOP decrease. None of the 4 opaque grafts gained clarity after Ex-PRESS shunt implantation but no worsening was observed. Preoperative and postoperative central corneal graft thickness showed no statistical significant difference (P = 0.219; Wilcoxon signed rank test) (Table 3).

In 3 patients postoperative revisions (bleb needling) had to be performed to lower the IOP. All the revisions were successful with a resultant decrease in IOP.

### DISCUSSION

The incidence of glaucoma after PKP has been shown to range between 10% and 53%. Gonioscopy may allow determination of the etiology of glaucoma and appropriate therapeutic intervention in these patients though it may be difficult due to haziness of the host cornea and tissue alterations at the graft-host junction. One of the important issues in post-PKP glaucoma is the difficulty in monitoring IOP due to increased corneal graft thickness and high corneal astigmatism which causes error in IOP measurements. Therefore, measured IOP must be corrected according to these parameters.

In PKP patients, Zalloum et al reported a 50% higher graft failure with Molteno implants and no graft failure with trabeculectomy. In contrast, Kirkness et al reported 68% probability of controlling IOP and maintaining graft survival after GDD implantation at 26 months. Suggested causes of graft failure are direct contact of the tube with the corneal endothelium or retrograde flow of inflammatory cells into the anterior chamber. Another proposed mechanism is mechanical trauma during implantation or micromotion during eye movement and blinking which results in progressive endothelial damage.

Sherwood et al evaluated the Molteno and Shocket implant in post-PKP patients. Ninety-six percent of the patients had an IOP of 18 mm Hg or less with a mean follow-up of 22 months. Graft failure from tube-corneal endothelium touch was reported to be 42% over 22 months. Another study examining the effectiveness of Molteno implants for post-PKP glaucoma found graft rejection in 5 of 17 patients undergoing double-plate Molteno implantation. Among these 5 patients, 4 had GDD within the anterior chamber and 1 in the vitreous cavity. Alvarenga et al reported graft success with GDD to be 58.5% and 25.8% at 1 and 2 years, respectively. In addition, IOP control was reported in 74.0% and 63.1% of patients at 1 and 2 years, respectively. The study included GDD implantation before, after, or simultaneously with PKP and found the presence of a GDD as an independent risk factor for graft failure. Some studies have reported their results regarding timing of surgery and likelihood of graft survival. Both Beebe et al and Rapuano et al reported higher graft failure rates when GDD surgery was performed after PKP. In contrast, Kwon et al reported the tube-first group to be 3.8 and 4.7 times more likely to experience graft failure than the simultaneous and PK-first groups, respectively. The study also found the Ahmed implant to be 3.3 times more likely to be associated with graft failure when compared with the Baerveldt. The IOP success rate was 82% with a graft survival rate of 55% at 3 years. A study investigating the success of simultaneous PKP and Ahmed implant was performed by Al-Torbak in patients with corneal opacities and glaucoma. The cumulative probability of graft success was 92% and 50% while the probability of IOP control was 92% and 86% at 1 and 3 years, respectively. Graft failure generally due to immune rejection and tube endothelial touch occurred in 10 of 25 cases. Another study by Coleman et al reported a graft success rate of 62% at 20 months with simultaneous PKP and Ahmed implant.

Considering that graft failure may be due to direct corneal endothelial trauma from the tube, some studies have been performed to evaluate graft survival with the tube placed in the posterior segment. Arroyave et al reported a significantly higher corneal graft survival (83%) in GDD implantation within the vitreous cavity compared with the anterior chamber (48%) after 1 year. There was no significant difference in IOP control between the 2 groups. In patients undergoing PKP and pars plana GDD insertion, Sidoti et al reported 12 and 24-month IOP control success rates of 85% and 62% and graft survival rates of 64% and 41%, respectively.

The Ex-PRESS Miniature Glaucoma Device is a small nonvalved stainless-steel implant originally designed to be implanted near the limbus allowing drainage of aqueous humor into the subconjunctival space (unguarded implant). In contrast to other GDD implants the Ex-PRESS implant is very stable in the anterior chamber with 3 mm length and external diameter of 400 mm and an internal diameter usually of 50 mm (R-50). It also has an external disc-like flange and an internal spur-like projection to prevent extrusion. Several versions of the Ex-PRESS shunt are commercially available with different internal lumen diameters (30 and 50 mm, respectively). Early experience with this implant using an unguarded technique was associated with significant reduction in IOP, and acceptable short-term and long-term success, but also with a high incidence of postoperative hypotony (up to 90% in the early postoperative period). Erosion of the conjunctiva over the implant or traumatic extrusion of the implant. Dahlan and Carmichael modified the surgical technique implanting the Ex-PRESS shunt under a 5 × 5 mm partial thickness scleral flap similar to a standard limbus-based guarded trabeculectomy. In the initial case series of 24 eyes, predominantly in patients with primary open angle glaucoma, mitomycin C 0.05% was applied under the scleral flap in all.

### TABLE 3. Changes in Intraocular Pressure (IOP), Best Corrected Visual Acuity (BCVA), the Number of Antiglaucoma Medications, and Central Corneal Thickness (CCT) Before and After Ex-PRESS Mini Glaucoma Shunt Implantation

<table>
<thead>
<tr>
<th>IOP (mm Hg)</th>
<th>No. Eye Drops</th>
<th>BCVA</th>
<th>CCT (µ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-ExPRESS</td>
<td>41.46 ± 14.29 (26-80)</td>
<td>3.20 ± 0.86 (2-4)</td>
<td>0.03 ± 0.05 (0.001-0.2)</td>
</tr>
<tr>
<td>Post-ExPRESS</td>
<td>12.06 ± 5.17 (8-25)</td>
<td>0.26 ± 0.79 (0-3)</td>
<td>0.08 ± 0.07 (0.001-0.2)</td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.021</td>
</tr>
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</table>

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cases. The modified technique yielded excellent short-term results with an average decrease of 46% in IOP at 12 months and a significant reduction in the need for postoperative glaucoma medications. With the guarded approach, the rate of transient hypotony was not insignificant (20.8%), but only 2 patients (8.3%) developed choroidal effusions and only 1 (4.1%) required anterior chamber reformation. In our series all the Ex-PRESS shunts with 30 mm lumen diameter were implanted with the guarded approach described by Dahan and Carmichael. Mitomycin C 0.05% was applied under the scleral flap in all cases. Transient hypotony was significant in only 1 case and that resolved in time.

In our series, the Ex-PRESS shunt was successful in controlling glaucoma in 93.3% over a mean follow-up of 12.2 months (range: 8 to 19 mo). This success rate is similar to the previous reports. Maris et al\(^{38}\) reported a success rate of 90% for the Ex-PRESS shunt and 92% for trabeculectomy in non-PKP glaucoma patients after a mean follow-up of 11 months when success was defined as postoperative IOP between 5 and 21 mm Hg with or without medications and absence of a requirement for further glaucoma surgery or removal of the implant. Similar to our study, laser suture lysis, bleb needling and 5FU injections were not considered to be criteria for failure.\(^{38}\) In addition, both procedures were comparable with regard to reduction in the need for postoperative glaucoma medications and postoperative visual acuity.

The amount of endothelial cell damage caused by the tube implantation both at the time of surgery and in association with subsequent micromotion, probably varies with physical force and the area of contact.\(^{22}\) As Ex-PRESS mini glaucoma shunt is a steel material it is more stable than other GDDs such as Ahmed valve and Moltren implants. Moreover, it may be protected from the effects of eye movements due to its smaller and thinner external disc-like flange compared with the other GDDs’ discs. In addition, longer part of GDDs in the anterior chamber in silicone material implants compared with that of the Ex-PRESS implants increases the endothelial damage. In our series 5 edematous grafts became clear as the central corneal thickness decreased, 4 clear grafts remained clear, and 6 opaque grafts remained unchanged. Graft failure was not encountered during the mean follow-up of 12.2 months (range: 8 to 19 mo).

Alvarenga et al\(^{25}\) have shown that the number of previous failed grafts is an important predictor of graft failure (hazard ratio = 2.5, \(P = 0.016\)). Only 2 of our cases had undergone PKP twice. Finally, in contrast to the previously published series, the majority of our GDD patients carried the diagnosis of chronic angle-closure glaucoma; frequently these patients had broad iris-corneal adhesions with obliteration of the peripheral angle structures, probably due to previous surgeries especially in eyes with pseudophakia, trauma, and congenital glaucoma.

In summary, GDDs have been shown to effectively control IOP in refractory post-PKP glaucoma. The procedure is generally associated with a higher rate of graft failure than trabeculectomy, but may be warranted when trabeculectomy fails or cannot be performed. One way of improving graft survival in refractory post-PKP glaucoma seems to be implanting the new and promising Ex-PRESS mini glaucoma shunt instead of silicone GDDs. In addition, the Ex-PRESS shunt implanted under a partial thickness scleral flap may be a safe alternative or adjunct to standard guarded trabeculectomy, and may provide some additional margin of safety against early postoperative hypotony. However, relatively short follow-up period in our study needs to be considered. Results of long-term follow-up studies are needed.

REFERENCES

procedures compared to eyes having undergone trabeculectomy. **CLAO J.** 1999;25:57–60.


