

Ahmed glaucoma valve in post-penetrating-keratoplasty glaucoma: A critically evaluated prospective clinical study

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Aim: The aim was to evaluate the outcome of Ahmed glaucoma valve (AGV) in post-penetrating-keratoplasty glaucoma (PKPG). **Materials and Methods:** In this prospective study, 20 eyes of 20 adult patients with post-PKPG with intraocular pressure (IOP) >21 mmHg, on two or more antiglaucoma medications, underwent AG (model FP7) implantation and were followed up for a minimum of 6 months. Absolute success was defined as 5<IOP<21 mmHg and qualified success as 5<IOP<21 mmHg with medications or minor procedures. **Results:** The mean IOP decreased from 42.95 ± 10.24 to 17.69 ± 3.64 mmHg ($P < 0.001$) and the use of medications dropped from 2.92 to 0.39 ($P < 0.001$) after AGV implantation. The absolute success was achieved in 11 eyes and qualified success in 9. There was no significant change in best corrected visual acuity, graft clarity, or graft thickness. Six device-related complications occurred after AGV implantations which were successfully managed with medical or minor surgical therapy. **Conclusions:** Postkeratoplasty refractory glaucoma managed by AGV implantation revealed a satisfactory outcome up to 6 months of follow-up.

Key words: Ahmed glaucoma valve, hypotony, post-penetrating-keratoplasty glaucoma, tube extrusion, scleral patch

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Post-penetrating-keratoplasty glaucoma (PKPG) is a terminology applied to an elevated intraocular pressure (IOP) greater than 21 mmHg, after penetrating keratoplasty (PKP), with or without associated visual field loss or optic nerve head changes. It is the most common cause for irreversible visual loss and the second leading cause for graft failure after rejection. It is a significant clinical problem because of its frequency of occurrence, difficulty in diagnosis and monitoring, and complexity of management. The incidence of glaucoma following PKP is reported to be 9–31% in the early postoperative period^[1] and 18–35% in the late postoperative period.^[1–4] Furthermore, an increase in IOP at any time after PKP leads to a significant endothelial cell loss, with graft decompensation, as the endothelial reserve is already very low. The management of post-PKPG is still controversial and there are no clear-cut guidelines available. In the recent past, there have been a number of reports on the management of refractory glaucoma by glaucoma drainage devices (GDDs).^[5–11] However, the literature is scanty on its use for post-PKPG. This led us to undertake a study to critically evaluate the efficacy of Ahmed glaucoma valve (AGV) in PKPG.

Materials and Methods

A total of 20 eyes of 20 patients with IOP >21 mmHg, on two or more antiglaucoma medications, underwent AG (model FP7) implantation between December 2006 and January 2008; these

were adult patients (age > 18 years) attending the post-PKP follow-up clinic and glaucoma clinic at our center. Patients who had undergone previous trabeculectomy surgery were also included [Table 1]. Besides obtaining ethical clearance, a written informed consent was taken from all patients after explaining to them the details of the surgery, the postoperative prognosis and the possible complications. A detailed history regarding the pre-PKP presence of glaucoma, prior glaucoma procedures done, any previous PKP, and interval between PKP and current surgery was taken. The best corrected visual acuity (BCVA), IOP (measured with Goldmann and Tonopen), and glaucoma medications were noted. A detailed slit-lamp examination was done to note the graft clarity, peripheral anterior synechiae (PAS) in a number of quadrants, and the lens status (phakic, pseudophakic, or aphakic). Gonioscopy and fundus examination were done, wherever possible. Pachymetry (using Sonomed Pacscan 300 AP digital biometric ruler, Lac Success, New York) was done and the anterior chamber depth (ACD) (using Allergan Humphrey ultrasonic biometer USA.) was measured. Keratometry (using Bausch and Lomb Keratometer, USA), refraction, corneal topography (using Bausch and Lomb Orbscan II, USA), central corneal thickness (CCT), and ultrasound biomicroscope (UBM)-angle study (using Paradigm ultrasound biomicroscope, model P40 UBM, USA) were done wherever possible. In all cases, the FP7 valve (limbal route) was implanted with a standard surgical technique reported earlier for refractory glaucoma.^[12,13]

The patients were evaluated on postoperative day 1, at 1 week, 1 month, 2 months, 3 months, 6 months, and subsequently as and when necessary. For about 6–8 weeks postoperatively, the patients were given topical antibiotics and topical steroids (0.1% dexamethosone). Antiglaucoma medications were started if deemed necessary. To manage the complications, anterior chamber (AC) reformation, anterior vitrectomy, and tube repositioning were done. Graft infection

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Table 1: Comparative study of Ahmed glaucoma valve in eyes with glaucoma requiring penetrating keratoplasty

Authors and year	No. of eyes	Follow-up (months)	Definition of success (mmHg)	Success rate (%)
Colemann <i>et al.</i> , 1995 ^[25]	46	9.3	IOP < 22 or reduction. >20% if preoperative IOP > 22, IOP > 4 for > 2 months, no additional glaucoma surgery, no visually devastating complications	78 (1 yr)
Topouzis <i>et al.</i> , 1999 ^[24]	46	30.5	6 < IOP < 22 at last 2 visits, no additional glaucoma surgery, no visually devastating complications, no loss of light perception, no removal or replacement of AGV	76 (1 yr) 68 (2 yrs) 54 (3 yrs) 45 (4 yrs)
Al Torbak, 2003 ^[18]	25	36	5 < IOP < 21, no additional glaucoma surgery, no visually devastating complications, no loss of light perception	92 (1 yr) 86 (3 yrs)
Al Torbak, 2004 ^[19]	21	48	5 < IOP < 21, no additional glaucoma surgery, no visually devastating complications, no loss of light perception	44 (2 yrs) 35 (4 yrs)

AGV: Ahmed glaucoma valve, IOP: Intraocular pressure, PKP: penetrating keratoplasty, yr: year

was treated with topical concentrated 5% cephazoline and 1.3% tobramycin.

At each visit, BCVA, IOP, and number of antiglaucoma medications used were noted. A detailed slit-lamp evaluation of the anterior segment including the graft status and bleb functioning was carried out. Pachymetry was carried out and the ACD was recorded. A note was also made about the complications if any. Based on the IOP at the 6-month follow-up visit, success criteria were defined as the following:^[14] absolute success 5 < IOP < 21 mmHg and qualified success 5 < IOP < 21 mmHg with medications or minor procedures like AC reformation, anterior vitrectomy, and tube repositioning. As per the literature hypertensive phase, we followed the criteria of Nouri-Madhavi *et al.*, i.e., a transient rise in IOP of > 21 mmHg starting after 4 weeks of surgery and lasting upto 16 weeks.^[15]

The data was recorded on a predesigned pro forma and was then transferred onto an Excel spreadsheet. Variables were assessed for approximate normality and then were summarized by mean, standard deviation, median, and range as appropriate. STATA SE 10.0 statistical software was used for data analysis. In this study, a *P*-value of less than 0.05 was considered as statistically significant.

Results

The mean age was 42.15 ± 18.96 years, ranging from 20 years to 73 years. There were more number of patients in the >45 (60%) age group than the 18–45 (40%) age group. Males were 16 (80%) and females 4 (20%). The indications for PKP were nonhealing corneal ulcer (4), healed corneal ulcer with leucomatous corneal opacity (3), healed corneal ulcer with adherent leucoma (3), pseudophakic bullous keratopathy (PBK, 3), aphakic bullous keratopathy (ABK, 5), operated juvenile glaucoma (1), and operated macular dystrophy (1). Four patients had glaucoma before the PKP, of whom three had previously undergone trabeculectomy which had failed, i.e., had refractory glaucoma. PKP was done once in 17 (85%), twice in 2 (10%) and three times in 1 (5%). The interval between PKP and AGV implantation varied from 3 to 168 months (mean, 24.31 ± 44 months; median, 13 months).

The mean preoperative IOP was 42.95 ± 10.24 mmHg, median 44, range 26–60; it was 12.62 ± 6.23 mmHg on the first

postoperative day and 13.04 ± 4.42 mmHg at the end of the first week. A gradual rise in IOP was noted at 1 month (16.94 ± 3 mmHg) and a definitive hypertensive phase was noted at second (23.08 ± 7.98 mmHg) and third (22.31 ± 6.97 mmHg) months. The hypertensive phase resolved with the use of antiglaucoma medications (timolol eye drops 0.5% twice a day, tab acetazolamide 250 mg three times a day) given for 1 week; at the end of 1 week, all the patients had IOP less than 21 mm of Hg. On achieving this IOP, we stopped the antiglaucoma medication and the patients were kept on follow-up. The mean IOP was 19.62 ± 5.82 mmHg at 6 months and 17.69 ± 3.64 mmHg at the final follow-up. The IOP changed from 42.95 ± 10.24 mmHg to 17.69 ± 3.64 mmHg at the final follow-up which indicated a fall of 25.25 ± 11.29 mmHg (58.79%; *P* < 0.001).

The number of medications used preoperatively varied from 2 to 4 (mean 2.92 ± 0.49) and that in the postoperative period was 0–2 (mean 0.39 ± 0.65); the difference was significant (*P* < 0.001, using Wilcoxon's signed rank test). The presence of PAS, a predictive factor for the development of PKPG, was found to be present in all the eyes [Fig. 1]. Absolute success was achieved in 11 eyes and qualified success in 9 eyes. All eyes had control of IOP after AGV implantation at 6-month follow-up, with or without medications. Out of nine eyes, six were on one medication and three were on two medications for IOP reduction.

Most of the patients had poor vision i.e. hand movement close to face (<HMCF) preoperatively. There was no significant difference in the best corrected visual acuity postoperatively and it improves from 1.71 ± 0.6 logMAR units preoperatively to 1.86 ± 0.5 logMAR units postoperatively (*P* = 0.2).

Preoperative graft clarity^[16] was less than grade 1+ in 8 (40%), grade 2+ in 6 (30%), and grade 3+ or more in 6 (30%) eyes. Three eyes (15%) were pseudophakic, 2 (10%), phakic and rest 15 (75%) were aphakic. Of 15 aphakic, 7 had PKP for ABK and 8 were grafted cornea with aphakia. The mean preoperative CCT and ACD was 596.23 ± 80.29 and 2.40 ± 0.95 mm, respectively. The mean cup–disc ratio was 0.86 ± 0.12. The postoperative complications were graft infection, graft rejection, choroidals, tube corneal touch, vitreous block of the tube, tube malposition, and plate extrusion.

Immediate postoperative choroidal detachment occurred

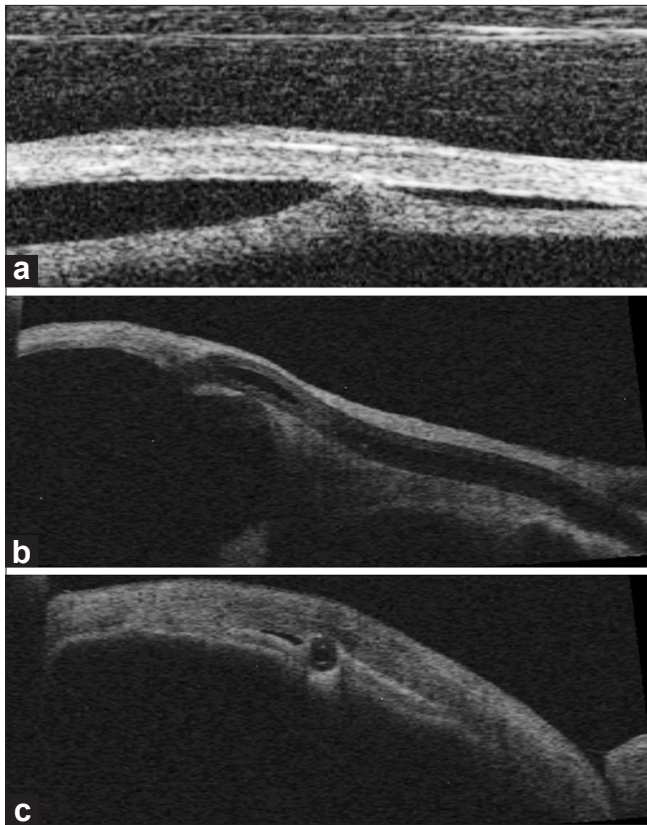


Figure 1: (a) Ultrasound biomicroscope showing peripheral anterior synechiae. (b) Ultrasound biomicroscope showing longitudinal section of Ahmed glaucoma valve tube. (c) Ultrasound biomicroscope showing cross section of Ahmed glaucoma valve tube

in three patients. The condition resolved in a short time (all within 10 days) with the use of oral steroids (tab prednisolone 1 mg/kg mg once daily) without any other complications. Two patients had shallow AC on the first postoperative day with tube corneal touch. This was managed by AC reformation. The AGV plate had extruded in one patient through the conjunctiva. This was refixed and the IOP was controlled. Another patient, an aphakic, developed blockage of the tube with vitreous, resulting in high IOP. The patient was subjected to anterior vitrectomy and the IOP was controlled without medications. Graft rejection occurred in one patient and was managed with a high dose of intravenous pulse steroids. Graft infection occurred in one patient 6 months after surgery, which required concentrated antibiotics and cycloplegic drops.

Discussion

The management of post-PKPG is an ophthalmic challenge.^[4] The primary modality of the treatment of intractable glaucoma, or patients who are not amenable to medications or able to tolerate or continue medications, are candidates for surgery. Glaucoma surgery after PKP not only requires sufficient reduction of IOP, but also requires the procedure to be minimally invasive to the corneal graft. Trabeculectomy, unless augmented by antimetabolites, usually fails due to the dense perilimbal scarring and fibrosis in these eyes.^[17] Cyclodestructive procedures frequently require repeated treatment and are associated with hypotony and phthisis

bulbi, hence are reserved only for eyes with no visual potential.^[17] GDDs have been used increasingly in several refractory glaucomas^[12-14,17] as a better alternative.

Though the use of GDDs for controlling refractory glaucoma is well known; its use in post-PKPG glaucoma is scanty.^[5-11,18-21] Kirkness was the first to report the use of GDDs in PKPG.^[5] Subsequently, it was advocated that GDDs can also be implanted either before/simultaneously with PKP (if expecting post-PKPG).

The minimum follow-up of patients enrolled in our study was 6 months. The outcome of AGV implantation surgery in eyes requiring PKP, either prior to or simultaneously, as reported in the literature is shown in Table 1. The comparative outcome of our study with that of the literature is highlighted in Table 2.

The hypertensive phase is more frequent following AGV which is due to the small surface area of the valve in comparison to its counterpart double-plate Molteno and Baerveldt, with a larger surface area.^[15] Clinically, it is characterized by the congested bleb with untreated IOPs rising to 30–50 mmHg. With the reduction of congestion and inflammation over the ensuing months, the bleb becomes less dense and the IOP stabilizes. In our study, the hypertensive phase was observed in 80% of eyes between 1 and 3 months.

Different authors have used altered success criteria with varied results.^[20,22-24] Romaniuk^[20] found that AGV successfully (IOP < 21 mmHg) controlled post-PKPG in 73.5% (13/17) eyes in 1 year. Wilson *et al.*^[23,24] defined success as 5 < IOP < 21 mmHg with no need for further glaucoma surgery, and no loss of light perception, and found the probability of success to be 87.9% at months 11–13, 80.5% at months 20–24, 73.2% at months 25–30, and 69.8% at months 41–52 for AGV. The absolute success rate was defined as IOP less than 21 mm of Hg without any medication while qualified success was defined as IOP less than 21 mm of Hg with antiglaucoma medication or with additional surgical maneuver. In our study, the absolute success rate was 11/20 (55%) and the qualified success rate was 6/20 (30%); the total was 17/20 (85%) after AGV. The qualified success rate was achieved with antiglaucoma medication in three patients; two patients qualified with tube repositioning and another qualified with anterior vitrectomy. Furthermore, we also noted that the mean number of medications used dropped from 2.92 ± 0.49 to 0.39 ± 0.65 after AGV implantation.

The fall in IOP in our series was from 47 ± 12.53 mmHg to 21.5 ± 12.9 mmHg at 6 months. Coleman *et al.* evaluated AGV in eyes with concurrent or prior PKP^[14] and found that the eyes with prior infectious keratitis or keratouveitis were at increased risk of failure (5.8 times, $P = 0.009$). However, we did not find any correlation between pre-PKP etiology and graft failure. Our study could also be corroborated with theirs who reported an effective outcome in terms of reduction and stability of IOP and maintenance of graft clarity up to 1 year postoperatively.^[16]

The incidence of graft rejection following AGV is a serious issue and previous studies have reported incidence between 15% and 41%.^[5,6] The mode of action toward the causation of rejection as put forward by Kirkness was the presence of a tidal flow of cells in and out of the tube located in the AC that may allow aqueous to come into contact with circulating lymphocytes, through the drainage tube, and that the tube

Table 2: Comparative study of Ahmed glaucoma valve in post-penetrating keratoplasty glaucoma

Authors and year	No. of eyes	Follow-up (months)	Definition of success (mmHg)	Success rate (%)
Colemann <i>et al.</i> , 1995 ^[25]	16	9.3	IOP < 22 or reduction. >20% if preoperative IOP > 22, IOP > 4 for >2 months, no additional glaucoma surgery, no visually devastating complications	78 (1 yr)
Topouzis <i>et al.</i> , 1999 ^[24]	16	30.5	6 < IOP < 22 at last 2 visits, no additional glaucoma surgery, no visually devastating complications, no loss of light perception, no removal or replacement of AGV	76 (1 yr) 68 (2 yrs) 54 (3 yrs) 45 (4 yrs)
Romaniuk <i>et al.</i> , 2004 ^[20]	17	12	Not available	73.5
Present study (Panda <i>et al.</i> , 2010)	20	6	Absolute success was defined as 5 < IOP < 21 mmHg Qualified success was defined as 5 < IOP < 21 mmHg with medications or minor procedures	55 30% with medication and 15% with additional minor surgery

AGV: Ahmed glaucoma valve, IOP: Intraocular pressure, PKP: Penetrating keratoplasty, yr = year

may also allow the retrograde passage of inflammatory cells into the AC, increasing the risk of graft rejection.^[5] The other mode of occurrence as hypothesized could be due to an alteration of the blood-ocular barrier caused by the GDD.^[6] We encountered graft rejection only in one eye in our series that had uncontrolled IOP, which however could be managed with high-dose intravenous pulse steroids, and the grafts remained clear.

The frequency of graft failure following GDDs in post-PKPG was reported to be 44%.^[8] This was attributed to corneal endothelial trauma during GDD implantation which is more relevant to post-PKPG eyes. Alvarenga *et al.* in 2004 reported their experience on the long-term follow-up of GDD and commented that the frequency of graft failure may increase following GDDs.^[4] The etiology of failure as suggested by them could be multifactorial, which includes preexisting underlying chronic inflammation, extensive PAS, multiple previous surgeries, and poor endothelial cell count drainage tube per se which may provide a conduit for the retrograde passage of inflammatory cells into the AC.^[4] We encountered one graft failure which was attributed to tube touch and accentuated by the second surgical repair for its adjustment.

Romaniuk^[20] found that the corneal grafts remained clear in 11/17 eyes (64.7%) after AGV in post-PKP eyes. However, no comparison can be made as 65% of our patient eyes had suboptimal graft clarity prior to AGV. Reduction in the central endothelial cell count as high as 65% does occur during the first two postoperative years after implant surgery.^[22] The presence of a GDD may accentuate the situation.

There was no significant change in the BCVA at the final follow-up. Most of the patients had poor vision (<hand movement close to face) initially and the vision dropped further slightly. The findings also corroborate well with those of the literature.

The postoperative complication as encountered in our series was AGV in tube blockage with vitreous resulting in a high IOP in one patient. The eye was subjected to anterior vitrectomy and the IOP was controlled without medications. Bleb needling was needed in one patient with an encapsulated AGV plate.

Other complications such as graft infection occurred in one patient and was managed with concentrated antibiotics and tarsorrhaphy in a similar manner.

In summary, this is the first report from India on the use of AGV for post-PKPG and we can conclude that implanting AGV is a viable option for controlling IOP for 6 months in post-PKPG.

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