

Clinical Experience with the Ahmed Glaucoma Valve Implant in Complicated Glaucoma

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Background: To assess clinical outcomes of the Ahmed glaucoma valve implant, an aqueous shunting device with a unidirectional valve mechanism, in eyes with refractory glaucoma.

Methods: Consecutive patients with intractable glaucoma who underwent Ahmed glaucoma valve insertion were retrospectively reviewed. Only patients with a minimum of 6 months of follow-up were included. The presence of intraocular pressure (IOP) ≥ 22 mmHg in the first 6 postoperative months was defined as a hypertensive phase (HP). This study included 19 eyes in 19 patients.

Results: The mean preoperative IOP was 32.1 ± 6.9 mmHg, with medication (mean times medication administered, 3.8 ± 1.0 ; range, 0-3). The mean postoperative IOP was 7.8 ± 2.2 mmHg on day 1, 11.3 ± 4.4 mmHg at 1 week, 19.1 ± 7.7 mmHg at 1 month, 16.5 ± 6.4 mmHg at 3 months, and 17.5 ± 0.7 mmHg at 6 months, respectively. Twelve patients (63.2%) exhibited the HP. Nine patients (49.3%) experienced the HP at 1 month and 3 patients at 2 months after the operation. At the end of 6 months of follow-up, 11 patients (57.9%) who had exhibited the HP required additional anti-glaucoma medication to control the IOP (mean times medication was administered, 1.0 ± 1.1 ; range, 0-2). Complications associated with the valve included hyphema in 1 case, choroidal effusion in 2 cases, iris plugging of the tube in 1 case, bleb encapsulation in 3 cases, and PK graft failure in 1 case. Postoperative hypotony resolved within 1 week.

Conclusion: The Ahmed glaucoma valve implant was safe and effective in this series. The hypertensive phase peaked in the first to second months after surgery. (*Chang Gung Med J 2003;26:904-10*)

Key words: Ahmed glaucoma valve, intraocular pressure, hypertensive phase, refractory glaucoma.

Various aqueous shunting devices, including restrictive and nonrestrictive implants, are used to manage complicated glaucoma that is resistant to medical therapy and traditional filtering surgery. The non-restrictive (valveless) devices, such as Molteno and Baerveldt valves, consist of an implant

with an open tube. The valveless device has been associated with the development of hypotony after the early postoperative period.^(1,2) The restrictive (i.e., valved) devices, such as Krupin and Ahmed, contain a design with restriction to flow to eliminate the incidence of hypotony.^(3,4)

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The Ahmed glaucoma valve implant (New World Medical, Rancho Cucamonga, CA, USA) was introduced to the market in 1993.⁽⁴⁾ It is composed of a silicon drainage tube (0.635-mm outer diameter, 0.317-mm inner diameter) and a 184-mm² polypropylene body (16 mm long × 13 mm wide × 1.9 mm thick). The body consists of a specially tapered chamber, with a large inlet to a small outlet, to create a venturi-flow effect and to provide resistance to aqueous flow.^(4,5) This study describes our experience with the Ahmed glaucoma valve and investigates the intermediate-term effectiveness in patients with glaucoma refractory to other treatments.

METHODS

We retrospectively reviewed patients with intractable glaucoma who underwent Ahmed glaucoma valve insertion at Chang Gung Memorial Hospital between October 2000 and April 2002. Only patients with a minimum of 6 months of follow-up were included in the current study. Data on age, gender, glaucoma diagnosis, duration of glaucoma, total number of glaucoma medications administered, and prior ocular surgical history were recorded. Preoperative and postoperative ocular examinations included visual acuity, intraocular pressure (IOP), slit lamp biomicroscopy, optic disc figure, and visual field change. Postoperative IOP was measured on day 1, and at 1 week, 1 month, 2 months, 3 months, 4 months, 5 months, 6 months, and monthly thereafter. The hypertensive phase was defined as an IOP ≥ 22 mmHg in the first 6 postoperative months. Anti-glaucoma medication was added to control IOP when the hypertensive phase developed. The number of times glaucoma medication was administered was recorded. Postoperative complications were also documented.

All surgeries were performed under local anesthesia except for 2 children who received general anesthesia. A fornix-based conjunctival flap incision, with radial relaxing dissection, was made posteriorly. A pocket was created in the superior quadrant between 2 adjacent rectus muscles (either the superior rectus and lateral rectus or the superior rectus and medial rectus). Before placement of the implant, the tube was primed by injecting balanced salt solution (BSS) with a 26-gauge cannula to open

the valve mechanism. Then the body of the implant was inserted into the pocket, with the leading edge of the device around 8–10 mm from the limbus; it was sutured to the sclera with 9-0 nylon sutures passed through the fixation platform on both sides of the valve. A scleral tunnel, with a 2.5–3.5-mm circumferentially oriented, half-thickness scleral incision that was parallel to the limbus, was created using a crescent knife 5 mm posterior to the limbus. The anterior chamber was entered with a sharp 23-gauge needle at approximately 2–3 mm posterior to the limbus, parallel to the iris. The tube was bevel-cut to an anterior angle of 30° and was trimmed to ensure that there was no contact with the iris or corneal endothelium after insertion. After the proper length of tube had been adjusted, the drainage tube was inserted under the scleral tunnel and into the anterior chamber. Finally, the conjunctival wound was closed with 9-0 nylon sutures.

Data on 19 eyes in 19 patients, including 8 males and 11 females, were collected. The ages ranged from 8 to 84 (mean, 53.1 ± 23.2) years. The procedure was performed over the superior temporal quadrant in 12 eyes and was performed over the superior nasal quadrant in 7 eyes. Preoperative diagnoses are listed in Table 1.

Table 1. Preoperative Diagnosis

Aphakia	6
Congenital cataract post lens extraction	2
Penetrating keratoplasty	3
Trauma	1
Pseudophakia	12
Neovascular glaucoma	5
Penetrating keratoplasty	4
One-eye case with prior TPPV	3
Phakia	1
Sturge-Weber syndrome with choroidal hemangioma	

RESULTS

The mean preoperative IOP was 32.0 ± 6.9 mmHg under the maximally tolerated anti-glaucoma medication (mean number of times medication was administered, 3.8 ± 0.9). Postoperative mean IOP was 7.8 ± 2.2 mmHg (on day 1), 11.3 ± 4.4 mmHg (at 1 week), 19.1 ± 7.7 mmHg (at 1 month), 18.4 ± 6.3 mmHg (at 2 months), 16.5 ± 6.4 mmHg (at 3

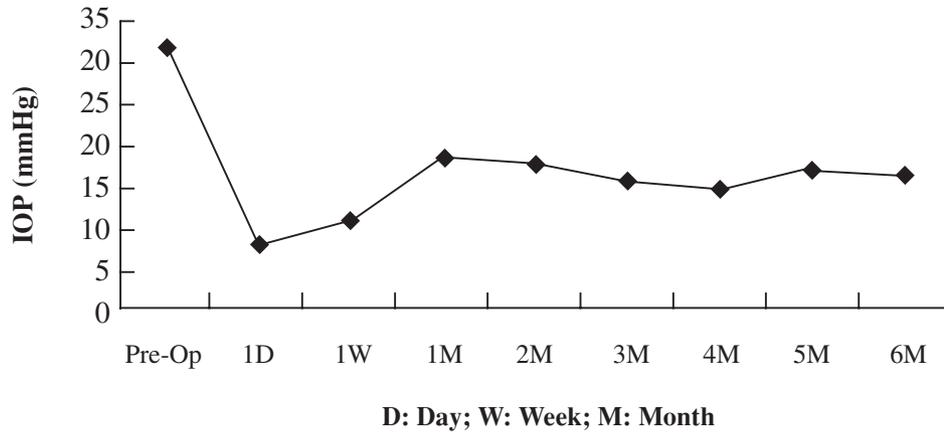


Fig. 1 Mean IOP from the baseline to 6 months of follow-up.

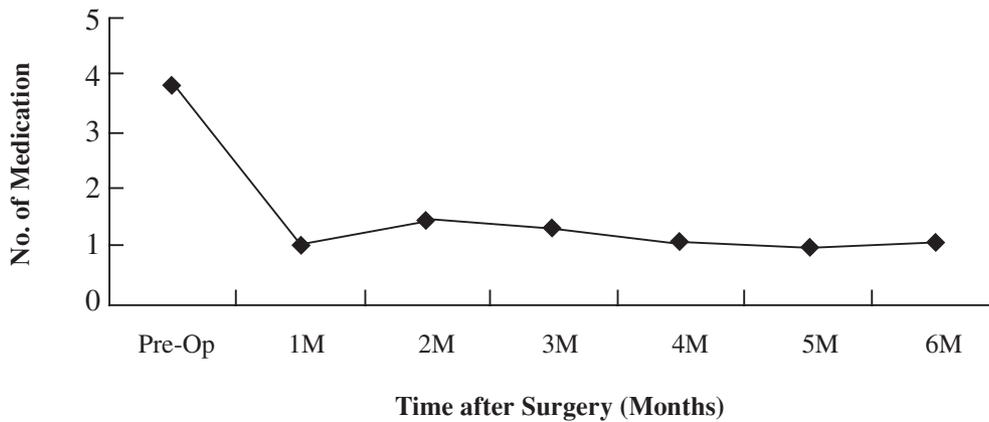


Fig. 2 Mean no. of anti-glaucoma medications administered before and after Ahmed glaucoma valve implantation.

months), 15.5 ± 4.9 mmHg (at 4 months), 18.2 ± 4.6 mmHg (at 5 months), and 17.5 ± 0.7 mmHg (at 6 months) (Fig. 1). Twelve patients (63.2%) exhibited a hypertensive phase (IOP ≥ 22 mmHg) during the 6-month period of follow-up. Nine patients developed a hypertensive phase in the first month after surgery, and 3 patients developed it in the second month. The mean number of times anti-glaucoma medication was administered before and after Ahmed glaucoma valve implantation is shown in Fig. 2. At 6 months postoperatively, a total of 11

patients (57.9%) had required anti-glaucoma medication to control IOP. No patient required further surgical intervention during the 6 months of follow up in this study.

Postoperative complications are shown in Table 2. Common complications in the early postoperative phase included hyphema (1 patient), choroidal effusion (2 patients), and iris plugging of the tube (1 patient). The most frequent late postoperative complication was bleb encapsulation (3 patients). In 1 patient who had previously received penetrating

keratoplasty, graft failure occurred after 6 months. Other complications, such as tube-cornea contact, tube/plate exposure, diplopia, etc., were not reported in the current study.

Table 2. Postoperative Complications (N=19 eyes)

Hyphema	1 (5.3%)
Choroidal effusion	2 (10.6%)
Iris plugging of tube	1 (5.3%)
Graft failure	1 (5.3%)
Bleb encapsulation	3 (15.9%)
Tube-cornea contact	0
Tube/plate exposure	0
Diplopia	0

DISCUSSION

The concept of designing a drainage device for glaucoma control was introduced several decades ago.⁽⁶⁻¹⁰⁾ Although these devices possess the potential to regulate the flow of drainage, complications associated with the procedure mean that is difficult for them to replace a traditional trabeculectomy as the primary treatment modality for glaucoma surgery. With improvements in the design, materials, and manufacturing deficiencies, the role of glaucoma drainage devices has progressively improved due to fewer problems with poor flow control and tissue compatibility.⁽¹¹⁻¹⁷⁾ The Ahmed glaucoma valve implant, the first and only officially approved aqueous shunt in Taiwan, was introduced here in 2000. Under the unique situation with the health insurance system in this country, it has assumed a place of last resort to manage complicated glaucoma when a conventional trabeculectomy is contraindicated or not available for a patient. For this reason, its indication for use in Taiwan is relatively restricted, and its popularity is less than that in Western countries.

In general, a successful outcome was achieved in the majority of eyes with 6 months of follow-up in this study, although variable indications and differences in criteria for success might make this result difficult to compare with previous studies.^(4,5,18-20) However, we found that many patients (63.2%) experienced a hypertensive phase after insertion of the Ahmed glaucoma valve in this study. The hypertensive phase, originally reported by Molteno and Dempster, is a phenomenon in which the bleb under-

goes a striking sequence of change in the surrounding tissue and may result in the formation of bleb fibrosis and inadequate control of IOP.⁽²¹⁾ According to the previous literature, the Ahmed glaucoma valve is associated with a higher incidence of the hypertensive phase, which peaked in the first month and had stabilized by 6 months after the operation.^(5,22) Regarding this point, this study showed comparable results in that most incidences of the hypertensive phase were exhibited in the first and second months after surgery. The higher incidence of the hypertensive phase could be related to the biomaterial and the shape and consistency of the end plate.^(16,17) It was suggested that the characteristics of the Ahmed glaucoma plate, being made of polypropylene with an extremely rigid consistency, may enhance more micro-motion in the postoperative period and attract white cells and collagen to grow on the surface of the plate, resulting in the formation of bleb fibrosis and subsequent elevation of IOP.^(16,17,22) Regarding deficiencies in design and materials, a new Ahmed glaucoma valve was introduced in October 2002. The new plate (New World Medical), a so-called "flexible plate", is made of a silicon material with a softer consistency and a smoother surface. In addition, the tapered profile of the end plate also makes it much easier to insert the plate. It will still take time to evaluate the benefits of the new Ahmed plate.

There were no serious postoperative complications in this study. Only 1 patient presented with limited hyphema, which later spontaneously resolved. According to our personal clinical experiences, it is very important to choose the proper tract to enter the anterior chamber, especially so as to avoid damage to the ciliary body, in order to prevent incidences of hyphema. For those cases of neovascular glaucoma, hyphema developing during the surgical procedure is not uncommon. However, we suggest injecting some viscoelastic material, such as Healon or Viscoat, into the anterior chamber to stop the bleeding, and aspirating the viscoelastic material and blood clot at the end of surgery. A lower incidence of postoperative hypotony with the Ahmed glaucoma valve has been documented.^(4,5,22) However, transient postoperative hypotony did occur, and 2 patients developed choroidal effusion in this study. The IOP in those patients quickly recovered, and none of those patients required anterior chamber reformation. One eye in this study resulted in iris

plugging of the tube; this complication was relieved by surgical intervention in which the iris plug was easily removed by passing a spatula through the paracentesis at the limbus. The other eye with previous keratopathy developed corneal decompensation and graft failure during the follow-up period. According to the previous literature, the incidence of corneal decompensation and graft rejection associated with various glaucoma drainage implants was reported to range from 18% to 28%.^(2,23-27)

There are several mechanisms which may explain the development of graft failure. First, intermittent tube-corneal contact or eye rubbing can progressively damage the corneal endothelial cells.^(24,27,28) Second, aqueous communication between the anterior chamber and extraocular shunt reservoir can trigger an immunological mechanism of antigen and antibody reactions resulting in graft failure.^(24,29,30) However, since the Ahmed glaucoma valve possesses a specific one-way valve system design, the latter proposed mechanism for those who received the Ahmed implant with prior penetrating keratoplasty seems somewhat unlikely.⁽²⁵⁾

Several studies have reported ocular motility disturbance after implantation of Molteno and Baerveldt drainage devices.^(2,14,31) The Ahmed glaucoma valve, with a 185-mm² polypropylene body, is larger than the single-plate Molteno implant and smaller than the Baerveldt implant. In our study, we found no complaints of motility disturbance and imbalance (diplopia). Theoretically, the superior-temporal quadrant is considered better than the superior-nasal quadrant for implantation of an Ahmed glaucoma valve to avoid optic nerve damage.⁽³²⁾ Although there were 7 patients (36.8%) who received an Ahmed glaucoma valve over the superior-nasal quadrant in our study, we noted no incidence of optic neuropathy following implantation. As far as we know, the length of the Ahmed device is 16 mm. The average distance from the limbus to the optic nerve in the super-nasal quadrant is around 28 mm, and 33 mm from the limbus to the optic nerve. According to the above anatomical considerations, we have to agree that the superior-temporal quadrant should be the first option if it is clinically available. However, implantation in some cases in this study was performed over the superior-nasal quadrant because prior ocular surgery had resulted in severe conjunctival scarring rendering the superior-nasal

quadrant unavailable.

In summary, the Ahmed glaucoma valve implant is relatively effective in lowering IOP in complicated glaucoma. The majority of patients exhibited a hypertensive phase with a peak in the first to second months after the operation. If clinicians weigh the benefits/risks of implantation and choose the indication depending on an individual patient's needs, the incidence of postoperative complication should be limited.

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使用Ahmed青光眼瓣膜於複雜性青光眼之臨床經驗

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背景： 本文旨在評估運用單向瓣膜原理的房水引流管，Ahmed 青光眼瓣膜，於複雜性青光眼的臨床結果。

方法： 回顧性連續收集因他種方法困難處理而接受Ahmed 青光眼瓣膜，且追蹤至少6個月之頑固型青光眼病患。若術後6個月內眼壓高於或等於22毫米汞柱則被定義為眼壓高原期。本文共收集19位病患之19隻眼睛。

結果： 術前平均眼壓為 32.1 ± 6.9 毫米汞柱；平均使用藥物為 3.8 ± 1.0 種。術後平均眼壓分別為： 7.8 ± 2.2 毫米汞柱（第1天）， 11.3 ± 4.4 毫米汞柱（第一週）， 19.1 ± 7.7 毫米汞柱（1個月）， 16.5 ± 6.4 （3個月），和 17.5 ± 0.7 （6個月）。共有12位病人（63.2%）出現眼壓高原期；其中9位病人發生於術後第1個月，3位病人發生於術後第2個月。到了術後6個月仍有11位病人需要使用青光眼藥物，平均使用藥物為1.0種。術後併發症包括：前房出血（1位），脈絡膜下積水（2位），虹彩堵塞引流管（1位），濾泡纖維化（3位），和角膜移植失敗（1位）等。術後暫時性眼壓過低之患者均於術後一週內自行恢復。

結論： 本研究結果顯示Ahmed 青光眼瓣膜運用在複雜性青光眼是安全和有效的方法。眼壓高原期多在術後第1個月和第2個月出現。

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關鍵字： Ahmed 青光眼瓣膜，眼壓，眼壓高原期，頑固型青光眼。