

# Managing high risk glaucoma with the Ahmed valve implant: 20 years of experience

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## Abstract

• **AIM:** To estimate the efficacy and safety of the Ahmed implant in patients with high risk for failure after glaucoma surgery.

• **METHODS:** In 342 eyes of 342 patients with refractory glaucoma, even with application of medical treatment, the Ahmed valve was introduced for intraocular pressure (IOP) control, in the period of the last 20y. The nature of glaucoma was neovascular in 162 eyes, pseudophakic or aphakic in 49 eyes, inflammatory in 29 eyes and non working previous antiglaucomatic surgical interventions in 102 eyes.

• **RESULTS:** Follow-up ranged from 18 to 120mo with a mean follow-up of 63.2mo. IOP before the operation decreased from  $31.6 \pm 10.4$  mm Hg to  $18.3 \pm 5.4$  mm Hg (no systemic treatment) at the end of follow up period. When we compared the IOP values before the operation using ANOVA showed statistically significant difference ( $P < 0.001$ ). The success rate was 85.2% during the first semester, 76.8% at 12mo and 50.3% at the end of follow up period (18 to 120mo after implantation). Success rate was 25.7% in neovascular glaucoma, 63.2% in aphakic glaucoma and 73.8% in non working previous antiglaucomatic surgical interventions. Complications due to the implant were: serous choroidal detachment in 14.8%, blockage of the tube in 2.8%, malposition of the tube in 4.9%, suprachoroidal hemorrhage in 2.1%, cataract progression in 39.6% (phakic eyes), shallow anterior chamber in 9.2%, hyphaema in 28.9%, exposure of valve in 2.6%, exposure of tube in 9.3%, hypotony in 4.9% and conjunctival fibrosis in 41.5%.

• **CONCLUSION:** Despite the fact that Ahmed valve implant had suchlike results as other implants concerning the IOP control, complications rate due to hypotony or over filtration in the first days after the intervention are not that frequent as with other valve implants.

• **KEYWORDS:** Ahmed valve; high risk glaucoma; neovascular glaucoma; aphakic glaucoma; pseudophakic glaucoma; inflammatory glaucoma

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## INTRODUCTION

Glaucoma is an acquired degeneration of the optic nerve and a major leading cause of blindness worldwide<sup>[1-3]</sup>. The main purpose of therapy is to maintain the intraocular pressure (IOP) in low levels<sup>[1]</sup>. Commonly used treatments for reducing IOP are pharmaceutical, laser trabeculoplasty or surgical<sup>[1,4]</sup>. Medication includes various drugs that are given either in the form of drops or orally, alone or in combination, in order to achieve the best possible result<sup>[1,4]</sup>.

When medication is not enough to control IOP, we resort to laser trabeculoplasty and if it fails in surgical treatment<sup>[4]</sup>. The most widely used methods are trabeculectomy and the insertion of glaucoma drainage implants (GDIs). The failure of trabeculectomy in most cases is mainly due to the failure of the filter to function due to fibrous tissue obstruction or external scarring and conjunctival fibrosis<sup>[5-6]</sup>.

The most interesting modification in the effort to avoid fibrosis of the infiltration ampoule is the insertion of implants for the drainage of the aqueous humor (AH). Various materials have been used for this purpose and many methods are reported, but few of them have been widely applied<sup>[4,7]</sup>. Better results from the clinical applications of the different implants were observed with the aqueous humoral drainage systems from the anterior chamber in the space below the conjunctiva<sup>[6,8]</sup>.

Implant insertion is associated with various intraoperative and post-operative complications that may occur after surgery such as hypotony, hyphaema, cataract, corneal decompensation and failure to control IOP as well as diplopia and transcorneal tube erosion because of the presence of a foreign body<sup>[9]</sup>. One of the modifications to the implants is the addition of a valve mechanism<sup>[10]</sup> to reduce postoperative hypotonia. The Ahmed valve is one of the commonly used branch drain valves.

Previous studies have shown that the use of this type of valve reduces the rate of hypotony<sup>[10]</sup>, anterior chamber flattening, and related complications.

The purpose of this prospective study is to evaluate the efficacy and safety of the Ahmed glaucoma valve in patients with refractory glaucoma.

### SUBJECTS AND METHODS

This study took place in the First University Ophthalmological Clinic of General Hospital of Athens G. Gennimatas. Patients were selected being informed about their participation, agreeing in writing with full awareness of the procedure. The hospital ethics committee approved the survey, in line with the principles of the Helsinki Declaration.

The study presents our results and observations from the use of the Ahmed valve in various forms of high risk glaucoma.

A total of 342 eyes from 342 patients with Ahmed valve implants were enrolled in the study, from 1996 to 2015 (20y). Patients' age ranged from 18 to 74y (mean 62±3y). Totally 181 patients (53%) were male and 161 (47%) were female. Of 47.4% (n=162) had neovascular glaucoma, 14.3% (n=49) aphakic or pseudophakic glaucoma, 8.5% (n=29) inflammatory glaucoma (Figure 1) and 29.8% (n=102) previously had one or more unsuccessful antiglaucomatic surgeries.

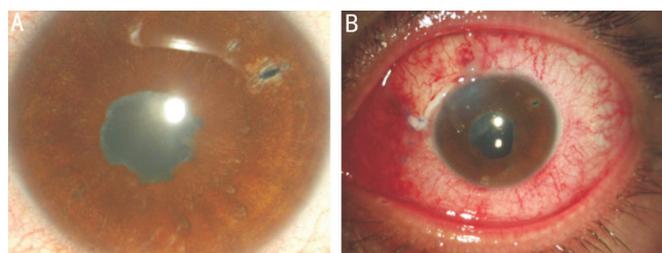
Patients that were enrolled in the study had at least 1y follow-up after the valve insertion. Patients who undergone cataract surgery remained in the study while patients who undergone penetrating keratoplasty and/or retinal detachment were excluded. In 2 patients, a second valve was placed. The preoperative value of the IOP ranged from 23 to 47 mm Hg, with an average of 31.6±10.4 mm Hg with local or systematic treatment.

Periodic postoperative monitoring was performed on day 1, week 1 (5 to 9d), 1<sup>st</sup> month (25-35d), 3<sup>rd</sup> month (75-105d), 6<sup>th</sup> month (150-210d), and every 6mo after the operation. The mean duration of postoperative follow-up was 63.2mo. Postoperative examination included measurement of visual acuity, IOP, slit lamp examination and funduscopy.

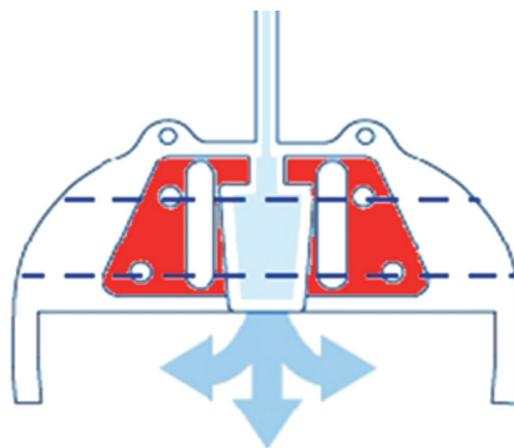
In our study, successful surgery was considered when IOP was less or equal to 22 mm Hg without treatment or at least with one antiglaucomatic drug.

**Ahmed's Glaucoma Valve** Ahmed's valve consists of an elastomeric plate made of propylene, with a total plate area of 184 mm<sup>2</sup> and a height of 2 mm, which ends in a silicone drainage tube. Lately the Ahmed valve plate is made of silicone (flexible). The plate is covered by a silicone membrane that acts as a valve when the IOP is less or equal to 8 mm Hg (Figure 2).

**Surgical Technique** A standard surgical protocol was followed. All patients received local anaesthesia prior to surgery. Then, an incision was made at the limbus and the conjunctiva was fashioned, making a deep pocket between the



**Figure 1 Inflammatory glaucoma before (A) and on the 1<sup>st</sup> post-operative day after a combined phacoemulsification and Ahmed valve insertion (B).**



**Figure 2 Ahmed glaucoma valve mechanism** It was presented as velocity of fluid flowing through the tube and then below the Ahmed's glaucoma valve body.

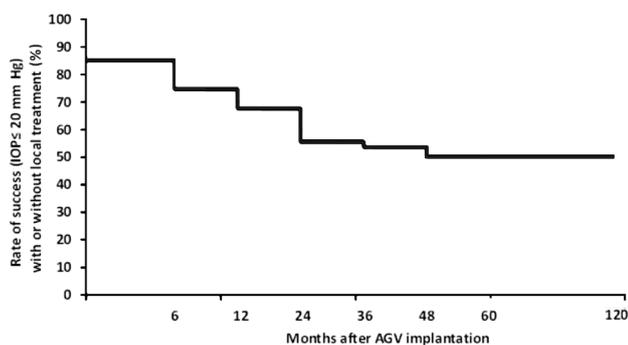
rectus muscles to configure the space in which the valve would be placed. A 6 mm×6 mm sclera flap was prepared at half thickness of the sclera, or the Ahmed's glaucoma valve (AGV) would be covered with a pericardial graft (Tutoplast, IOP, Inc., Costa Mesa, CA, USA). The valve was then primed before insertion. The body of the AGV was positioned 8 mm from the limbus and the immobilisation was done with 2 pre-positioned non-absorbable sutures 5-0. The entrance to the anterior chamber was performed by a 23 gauge needle, from a scleral tunnel of about 2 mm. If the anterior chamber was narrow, viscoelastic was used before placement. The tube was anterior and parallel to the plane of the iris and was trimmed to a length of 2-3 mm. It was covered with a scleral flap or with pericardial xenograft, which was secured with 2 sutures nylon 10-0. Finally, the conjunctiva was anchored to the limbus with vicryl 8-0.

### RESULTS

Patient follow-up ranged from 18 to 120mo with an average follow-up time of 63.2mo. IOP reduced from 31.6±10.4 mm Hg to 18.3±5.4 mm Hg (only with topical treatment) at the last test. Comparison of preoperative IOP values using ANOVA demonstrated statistically significant difference ( $P<0.001$ ).

Total success rate was 85.2% at the first 6mo, 76.8% at 12mo and 50.3% at the last examination (18-120mo after implantation) (Figure 3).

The success rate varied, with 25.7% in neovascular glaucoma at the last follow up visit with 54.9%, 46.2%, 38.2%, 33.3%



**Figure 3** Success rate of reduced IOP, with or without local treatment, postoperatively.

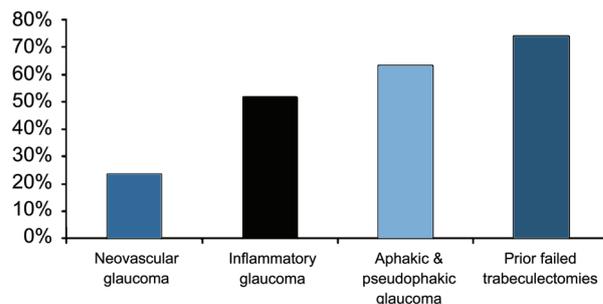
and 30.2% at 6, 12, 24, 36, 48mo respectively; 51.7% in inflammatory glaucoma at the last follow up visit with 82.7%, 79.3%, 75.8%, 65.5% and 58.6% at 6, 12, 24, 36, 48mo respectively; 63.2% in pseudophakic and aphakic glaucoma at the last follow up visit with 91.8%, 85.7%, 79.6%, 71.4% and 67.3% at 6, 12, 24, 36, 48mo respectively; and 73.8% in glaucoma with previous failed trabeculectomies at the last follow up visit with 89.2%, 87.2%, 84.3%, 81.3% and 77.4% at 6, 12, 24, 36, 48mo respectively (Figure 4).

There was a statistically significant reduction in the number of medications between the preoperative and postoperative period. The average number of antiglaucomatic medications used by patients, before the Ahmed valve was implanted, was  $3.5 \pm 0.7$ . During postoperative follow-up, medication needed to regulate the IOP was  $0.8 \pm 0.6$  mm Hg at 6mo,  $1.2 \pm 0.5$  mm Hg at 12mo,  $2.1 \pm 0.4$  mm Hg at 24mo,  $1.9 \pm 0.7$  mm Hg at 36mo,  $2.2 \pm 0.2$  mm Hg at 48mo and  $2.3 \pm 0.3$  mm Hg at 60mo ( $P < 0.001$ ) (Figure 5).

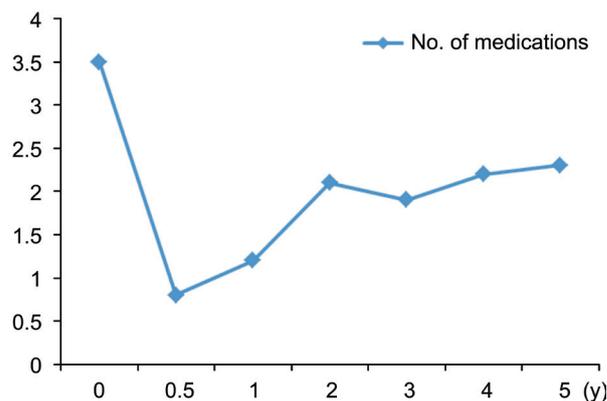
Complications occurred early on, but also in the late postoperative period (Table 1). The most common early postoperative complication encountered was hyphaema in 99 patients and happened in 52 patients with neovascular glaucoma, 5 with inflammatory glaucoma, 16 with pseudophakic and aphakic glaucoma and 26 with glaucoma with previous failed trabeculectomies. It was of low grade and got absorbed in the first postoperative week. The most common late postoperative complication was conjunctival fibrosis and did not depend on the type of glaucoma. Cataract progression (116 patients) happened in phakic eyes, which was treated surgically with phacoemulsification. Hypotony and shallow anterior chamber had a smooth distribution in all incidents. Choroidal detachment was noticed in aphakic and pseudophakic glaucomas. There was a blockage of the tube, as a result of prolapse of the iris or vitreous in the lumen of the tube. Further complications that encountered were malposition of the tube (Figure 6), tube or valve exposure (Figure 7) due to conjunctival erosion, suprachoroidal hemorrhage.

**DISCUSSION**

The aim of this study was to evaluate the efficacy and safety



**Figure 4** Success rate of reduced IOP depending on the type of glaucoma.



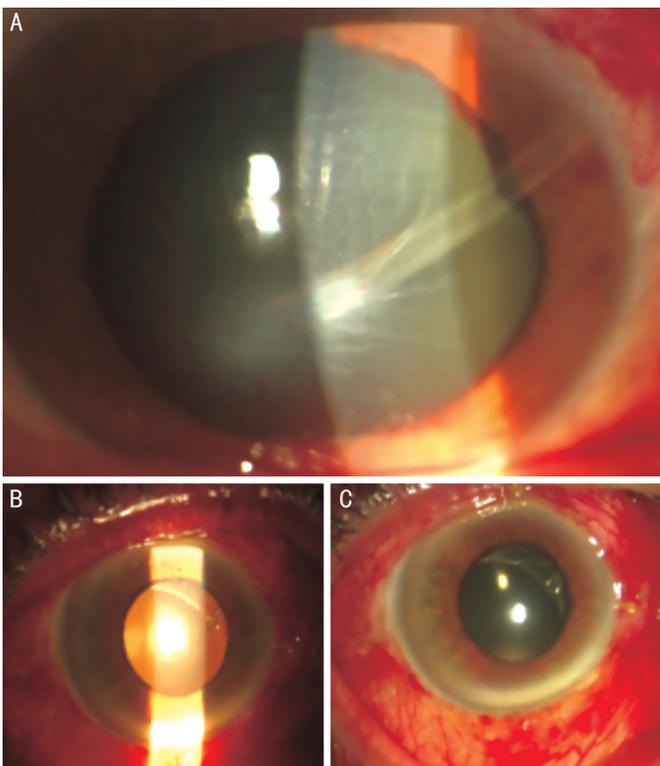
**Figure 5** Chart showing the mean number of medications pre-operatively and during follow-up period in patients with Ahmed glaucoma implant.

**Table 1** Complications associated with the use of AGV

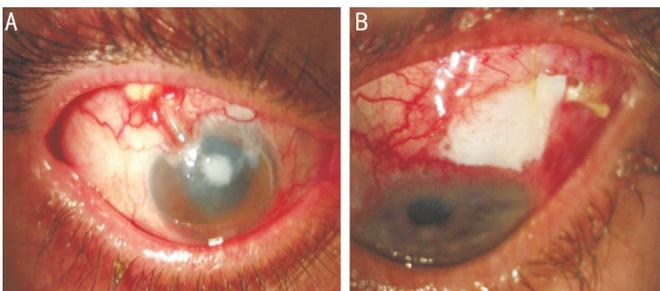
Complications	n (%)
<b>Early</b>	
Hyphaema	99 (28.9)
Choroidal detachment	51 (14.8)
Shallow anterior chamber	31 (9.2)
Hypotony	16 (4.9)
Suprachoroidal hemorrhage	7 (2.1)
<b>Late</b>	
Conjunctival fibrosis	142 (41.5)
Cataract progression	116 (39.6)
Tube exposure	32 (9.3)
Malposition of tube	17 (4.9)
Blockage of the tube	10 (2.8)
Valve exposure	9 (2.6)

of the Ahmed glaucoma valve in patients with refractory glaucoma. Our results showed that AGV is safe and effective. Mean IOP at final exam was 18.3 mm Hg, a reduction of 50.3% from preoperative values. Moreover patients were on fewer glaucoma medications and there was no major complication occurred.

The most serious cause of failure of glaucoma filtering surgeries is the blockage of the infiltrating site that occurs



**Figure 6 Malposition of the tube** A: The end of the tube is in contact with the cornea; B, C: The tube is behind the iris.



**Figure 7 Tube (A) or valve (B) exposure.**

either directly due to encapsulation or late due to fibrosis, resulting in increased IOP<sup>[11-12]</sup>.

Blocage of the infiltrating site is more common in high risk glaucoma due to: 1) a fibrotic membrane that blocks the pathway from the anterior chamber and causes intraoperative hemorrhage, scarring and fibrosis of the conjunctiva in neovascular glaucoma<sup>[12-13]</sup>; 2) inflammatory cells and inflammatory debris that accelerate wound healing in inflammatory glaucoma<sup>[12,14-15]</sup>; 3) vitreous incarceration into the filtering site because of the modification of the anatomical elements of the anterior chamber from the cataract surgery<sup>[11-12,16]</sup> or the biological alteration of the aqueous by a fibroblast stimulant released from the vitreous in the aphakic and pseudophakic glaucoma<sup>[12]</sup>; 4) the preexisting subconjunctival fibrosis, solid attachment of the Tenon's capsule and the epidermal tissue and the increased number of fibroblasts and inflammatory cells in the conjunctiva of patients who have undergone previous antiglaucomatic ocular surgery<sup>[17-18]</sup>.

Glaucoma drainage devices (GDD's) are being used with increased frequency for the treatment of complicated glaucoma cases or glaucomas that don't respond to medical therapy<sup>[6-7]</sup>.

The end plate of GDD's is fixated to the equatorial sclera and it is encapsulated by an overlying fibrous capsule that develops postoperatively, which creates a big cyst in Tenon's capsule. AH diffuses through this capsule wall and into periorbital spaces, capillaries, and lymphatics and despite the development of scar tissue, there is sufficient exchange of AH along the large surface of the bleb and, as a result, a sufficient reduction of IOP<sup>[9,19]</sup>.

Histopathological studies have shown that the inner layer of the infiltrative bleb is not covered by epithelium and is an open collagen matrix with a sparse diffuse fibroblast population. The outer wall of the bleb includes layers of gradually thicker collagen with a greater number of fibroblasts and near the outer surface there is a fibrovascular layer with varying inflammatory infiltration by mononuclear cells<sup>[7]</sup>. The mechanism by which AH is moved through the bleb wall is the simple passive diffusion which is proportional to the graft surface and inversely proportional to the density of the overlying tissues<sup>[7]</sup>. The use of various GDD's and lately of the Ahmed valve in refractory glaucoma reduces the failure rate of surgery<sup>[20-21]</sup>. The posterior exit of the tube is located within the anterior chamber transferring the active site of the sclerostomy away from the corner of the anterior chamber, thus providing communication with the AC in eyes with extended synechias as well as a pathway of escape of the AH from the eye<sup>[22]</sup>. Although scar tissue is formed around the posterior exit of the tube which is located in the AC, its lumen remains open and thus communication with the anterior portion of the insert is maintained<sup>[20,22]</sup>.

The creation of a space where AH is drained is ensured by the Ahmed valve due to the presence of the episcleral plate providing a surface that is not affected by the development of fibrous tissue. This is because the fibroblasts cannot adhere solidly to the insertion materials and thus remains a space between the growing fibrous tissue and the surface of the plate<sup>[22]</sup>. This insert therefore generates a large, outer, encapsulated bleb, which usually provides a sufficient filter surface to cause reduction of IOP<sup>[23]</sup>. The design of the Ahmed valve with a hardened end-plate has an advantage because it provides a large space of bleb creation. The size of the end-plate influences the level of the IOP to a point, but not the overall success rate of the operation<sup>[23-24]</sup>.

The rate of success in regulating IOP was 50.3% in our cases. This is quite satisfactory and similar to the rates reported in the international literature.

The main advantage of Ahmed's insertion is the controlled drainage of the AH, so postoperative hypotonia, shallow AC,

choroidal detachment and cataract development are more rare and less severe.

In conclusion, we can say that in high-risk glaucoma surgery the use of Ahmed's valve is a treatment of choice, on one hand because of the satisfactory regulation of IOP and on the other hand due to the fewer and milder complications of the procedure.

### ACKNOWLEDGEMENTS

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