AHMED AND BAERVELDT GLAUCOMA DRAINAGE IMPLANTS: LONG-TERM RESULTS AND FACTORS INFLUENCING OUTCOME

JACOB J., STALMANS I., ZEYEN T.

ABSTRACT

Purpose: To evaluate the clinical outcome of patients who received an Ahmed or Baerveldt implant for refractory glaucoma at the University Hospitals Leuven and to identify the factors which may influence the outcome.

Methods: Retrospective study including 62 eyes with uncontrolled glaucoma, who underwent the implantation of a drainage device between January 2002 and December 2008. Criteria for complete success were an intraocular pressure (IOP) $\leqslant$ 21 mmHg and $>$ 5 mmHg, and a minimum 20% decrease in IOP compared to baseline, without additional medications at 2 consecutive visits after 3 months. Qualified success was defined as the same criteria with additional medications. If these criteria were not met, if additional glaucoma surgery was needed, or if the eye became phtitic, the case was classified as failure. Other outcome measurements were IOP reduction, additional glaucoma medications at the last follow-up, visual acuity, visual field, and complications.

Results: Over a mean follow-up period of 25 $\pm$ 21,91 months, the mean intraocular pressure decreased from 27,98 $\pm$ 6,5 mmHg to 15,2 $\pm$ 5,87 mmHg (mean drop of 45%) at the last visit. Overall success (i.e. with or without medication) was 67.3%. Visual acuity improved or remained unchanged in 52/62 (83,9%) of patients. Eight patients (12,9%) had complications with significant visual loss (at least two Snellen lines worse) and five patients (8,1%) needed further surgery due to complications. No significant outcome predictors could be established.

Conclusion: Ahmed and Baerveldt implants are a safe and effective procedure for lowering the IOP in the management of refractory glaucoma.

KEYWORDS

glaucoma, drainage device, glaucoma surgery

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INTRODUCTION

Glaucoma drainage devices (GDD) have been developed to aid filtration by shunting aqueous to a site away from the limbus, such as the equatorial subconjunctival space. GDD have a silicone-rubber tube placed into the anterior chamber, or through the pars plana into the vitreous cavity. Aqueous flows out through the device to an extraocular reservoir, which is created by placing an explant plate in the equatorial region on the sclera. The explant plate is constructed from polypropylene or silicone rubber to which fibroblasts cannot adhere tightly. By the process of encapsulation a potential space for drainage is created. Aqueous then passes through the capsule via the process of passive diffusion and is absorbed by periocular capillaries and lymphatics. It is the fibrous capsule around the end-plate that causes the major resistance to aqueous flow with drainage implants. (1)

Aqueous shunts, or GDD, can be categorized as nonvalved devices, which have no flow restrictor, or valved devices, which have a flow restrictor that should minimize the risk of postoperative hypotony. The most popular nonvalved devices are the Molteno (Molteno Ophthalmic Limited, Dunedin, New Zealand) and Baerveldt (Advanced Medical Optics, Santa Ana, California, USA) designs. The most widely used valved device is the Ahmed (New World Medical, Rancho Cucamonga, California, USA). (1,2) The devices are generally reserved for difficult glaucoma cases in which conventional filtering surgery has failed or is likely to fail, e.g. eyes with excessive conjunctival scarring after extensive surgery or neovascular glaucoma. Aqueous shunts have been successful in controlling IOP in a variety of glaucomas. (3)

In this retrospective study, we report the results using Ahmed and Baerveldt implants in refractory glaucoma at the University Hospitals Leuven as well as several factors that may influence the outcome.

PATIENTS AND METHODS

Patients

We reviewed the medical records of consecutive patients who had undergone Ahmed or Baerveldt glaucoma drainage device insertion for uncontrolled glaucoma after medical treatment, laser trabeculoplasty, diode laser cyclodestruction or previous trabeculectomy at University Hospitals Leuven between January 2002 and December 2008. The type of glaucoma drainage device was a choice made by the experienced surgeon (TZ) and was mainly determined by the oil-filling in eyes with previous vitrectomies. The Baerveldt implant was used in eyes with silicone oil glaucoma because the presence of silicone oil is a risk factor for failure of the Ahmed device due to obstruction of the valve mechanism. The following information was documented for each patient: age; gender; race; glaucoma diagnosis; preoperative VA, medications, visual field parameters (MD and PSD), IOP (mean of three visits prior to surgery) and lens status; total number of operations before the shunt surgery including the number of glaucoma operations; date of the valve surgery; GDD; tube position; intraoperative and postoperative complications and postoperative reinterventions; postoperative visual acuity and IOP recorded on 1 day, 2 days, 1 week, 2 weeks, 1 month, 3 months, 6 months, 12 months, 18 months, 2 years, 3 years, 4 years, 5 years and 6 years (depending on the length of follow-up) after the glaucoma drainage surgery; number of postoperative glaucoma medications at the last visit; visual field parameters of 28 patients were recorded at 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, 5 years and 6 years after surgery. Seventeen patients were followed with Goldmann perimetry; these visual fields were interpreted by an independent glaucoma specialist. Another eleven patients were followed with automatic perimetry, Humphrey or Octopus. Progression determination was based on point wise regression analysis using Peridata (PeriData Software GmbH, Huerth, Germany). Progression was defined as two adjacent test locations with a difference of 5 dB (p=95%) or one test location with a difference of 10 dB (p=95%)

on two consecutive visual fields. In patients who had penetrating keratoplasty, the corneal diagnosis, number of penetrating grafts before surgery, and status of the graft in the preoperative and postoperative period were recorded. If the information could not been obtained from the patient's records at University Hospitals Leuven, the patient's ophthalmologist was contacted. In patients who underwent bilateral glaucoma drainage device surgery, only the right eye was included in the study. Intraocular pressure was measured with a Goldmann applanation tonometer. The VAs throughout the period studied were converted to logMAR to facilitate the statistical analysis. Improvement of VA was defined as at least two Snellen lines better than the preoperative visual acuity, worsening of VA was at least two lines worse.

Design features

Table 1 lists the major design features of the Ahmed and Baerveldt shunts as used in this case-series. The explant plates are constructed from polypropylene (Ahmed devices) or silicone rubber (Baerveldt devices) and have identical silicone-rubber tubes with an outside diameter of approximately 600 μm and an inside diameter of approximately 300 μm that connect the explant plate to the anterior chamber or vitreous cavity. The plate of both drainage devices has fenestrations, which allow fibrous bands to develop that reduce the profile of the bleb. At the junction of the tube and the plate, both devices have a rim through which the tube empties onto the explant plate surface. This rim ensures a substantial physical separation between the posterior tube orifice and the fibrous capsule surrounding the device and thus inhibiting obstruction of filtration. The Ahmed device contains a valve consisting of thin silicone elastomer membranes designed to open when the IOP is 8 mmHg and thus reducing the incidence of early postoperative hypotony.(4)

Surgical procedure

Implantations were all performed by the same surgeon (T.Z.). A supratemporal fornix-based conjunctival flap was created. The sclera was prepared by dissecting the remaining Tenon's capsule and resecting scar tissues and wetfield cautery hemostasis was performed gently. At this point the procedure differs for the Ahmed and Baerveldt implant.

In the case of an Ahmed drainage device, the recti muscles were identified, but no attempt was made to isolate them. After priming the Ahmed valve by injecting balanced salt solution into the tube until the fluid passed through the valve, the implant's polypropylene body was fixated to sclera, approximately 8 to 10 mm posterior to limbus and between adjacent rectus muscle insertions, with two 8-0 nylon sutures through the fixation holes. In 15 patients, a constrictive absorbable 6-0 Vicryl suture was tied around the tube close to the plate as an additional precaution to prevent early hypotony.

The procedure for a Baerveldt implant (BGI) was as follows: The superior and lateral recti muscles were hooked. The 350-mm^2 BGI was placed beneath the muscle bellies of the superior and lateral recti muscles and secured using two interrupted 8-0 nylon sutures through the fixation holes under direct visualization. No implants were placed inferiorly, one implant was placed superonasally because of temporal scleral thinning after penetrating trauma. To avoid ocular hypotony in the early postoperative stage after placement of a Baerveldt glaucoma implant, all patients received a combination of an incomplete occlusion stent with a ligature.

Table 1: *Aqueous shunts*

Implant type	*Ahmed*	*Baerveldt*
N° of models	47	15
Surface area	184 mm^2	350 mm^2
Explant material	Polypropylene	Silicone
Valved/nonvalved	Valved	Nonvalved
Shunt tube material (inner diameter)	Silicone (300 μm)	Silicone (300 μm)

Fig. 1: Ahmed implant ©Med Rounds

A 3-0 Supramid thread was pulled through the silicone lumen to serve as an incomplete occlusion stent. To facilitate removal of this stent, the end of the thread was externalized underneath the conjunctiva in the infratemporal fornix. To prevent excessive drainage during the immediate postoperative days, a constrictive absorbable 6-0 Vicryl suture was tied around the tube close to the plate. Only 3 patients received a ligature without an incomplete occlusion stent.

To avoid high early postoperative pressure before dissolution of the ligature suture, a fenestration was created intraoperatively on the extraocular portion of the tube to allow a slight aqueous flow. The fenestration of 1 to 2 mm was created with a 15° microsharp blade in a longitudinal fashion on the tube, proximal to the absorbable occluding ligature.

From this point, the procedure for Ahmed or Baerveldt implant is identical.

The tube was cut to the appropriate length to extend 2 mm into the anterior chamber and beveled anteriorly. A 23-gauge needle was used to enter the anterior chamber, iris plane parallel. For pars plana placement in vitrectomized eyes, the tube was trimmed to have an intraocular segment of 4 mm and was inserted through the pars plana through the tract of a 23-gauge needle and then secured to the sclera with an X-shaped nylon 8-0. A viscoelastic was injected via a paracenthesis into the anterior chamber. The tube position with respect to angulation and length was checked after introduction into the anterior or posterior chamber, so as to avoid touching either the corneal endothelium, the iris or the lens. Glycerin-preserved donor sclera was placed over the tube and secured with 10-0 nylon sutures at the corners to prevent erosion of the tube through the conjunctiva. Conjunctiva was reopposed to the limbus using 9-0 Vicryl sutures. A subconjunctival injection of Celestone® was given inferiorly. Topical antibiotics and steroids were prescribed for use four times daily for 8 weeks and then tapered for another 4 weeks. Surgical removal of the incomplete occlusion stent for BGI was performed after at least 4 weeks if the IOP was too high after the absorption of the Vicryl ligature suture.

Five patients received intraoperative mitomycine C before the placement of the end-plate. Fourty-one tubes were inserted into the anterior chamber, and twenty-two were inserted into the vitreous cavity. Concurrent surgery included pars plana vitrectomy in 5 eyes and removal of a previous GDD in 1 eye. In eight patients, an explant due to a previous scleral buckling procedure was present; it was removed in 3 patients.

Fibrous infiltration of the wall of the bleb often results in a reversible rise in intraocular pressure about one to four months after surgery. This can be treated by massaging the bleb, needling the bleb and injection of antimetabolites. (5)

In case of an encapsulated bleb, needling of the bleb was performed in the outpatient clinic as follows. The patient was prepared with instillation of Iopidine®, Unicaine® and Braunol®. At the slit lamp, the patient was instructed to look down to expose the entire bleb. Needling was performed with a Stiletto 45° 23-gauge knife (BD Visitec). The knife was introduced into the subconjunctival space 1 mm from the edge of the bleb and advanced for 3 to 5 mm into the bleb in the direction of the end-plate. The knife was then partially withdrawn from the bleb and the direction changed to parallel the edge of the bleb, and with sweeping motions, several tears were made in the capsular edge. The knife was then

Fig. 2: Baerveldt implant ©Abbott Medical Optics Inc.

withdrawn. When 5-fluorouracil (5-FU) was injected, it was done into the subconjunctival space adjacent to the bleb. Slit-lamp examination with Seidel test and tonometry was performed afterwards. If necessary, an additional massage of the bleb was performed with a cotton-tipped applicator.

Statistical analysis

Complete success was defined as
1. Intraocular pressure $\leqslant$ 21 mmHg and $>$ 5 mmHg and a minimum 20% decrease in IOP compared to baseline without additional medications at two consecutive visits after 3 months with a minimum follow-up of 6 months.
2. No additional glaucoma surgery.
3. No development of phthisis.

Qualified success was consistent with the above criteria but with additional medications.

Failure was defined as
1. IOP $>$ 21 mmHg or $\leqslant$ 5 mmHg or less than 20% decrease in IOP from baseline at two consecutive visits after 3 months with a minimum follow-up of 6 months.
2. or additional glaucoma surgery.
3. or phthisis.

Kaplan-Meier survival curves were used to calculate long-term probability success rate. Statistical comparison was performed using Wilcoxon signed rank tests. The log rank test was used to check for the relationship between each of the categorical risk factors and failure. Cox regression was done for the continuous risk factors. Fisher exact tests were used to test the relationship between absolute success and qualified success versus the risk factors. The Mann-Whitney U test was used for continuous and ordinal risk factors. All p-values were two-sided. All analysis have been performed using the statistical package SAS (version 9.2).

RESULTS

Table 2 summarises the demographics of the study population. The mean age of the patients was 50 $\pm$ 17,1 years (range, 14-81 years) and mean preoperative IOP was 27,98 $\pm$ 6,5 mmHg (range 14,3-51) with a mean of 2,74 $\pm$ 1,17 glaucoma medications. The mean number of prior ocular surgical procedures was 2,94 $\pm$ 1,61 and 59,7% of patients had previous failed filtering surgery. Thirty-four patients (55%) had previous laser trabeculoplasty or diode laser cyclodestruction. Fifteen eyes were implanted with a 350-mm^2 Baerveldt implant and 47 eyes received an Ahmed implant.

Postoperative data are summarized in Table 3. The mean follow-up period was 25 $\pm$ 21,91 months (range, 2-72 months). The mean postoperative IOP at the last visit was 15,2 $\pm$ 5,87 (range, 0-31) mmHg ($p < 0,0001$ between pre- and postoperative values) with a mean number of antiglaucoma medication of 0,87 $\pm$ 1,14 (range, 0-4) ($p < 0,0001$). Figure 3 represents the IOP at the various visits; the mean IOP stabilized at 16,0 mmHg.

The overall surgical success rate (with or without medications), based upon two consecutive visits after 3 months with a minimum follow-up of 6 months, was 37/55 eyes (67,3%).

Seven patients could not be assessed as failure or success because of limited follow-up.

Twenty eyes (36.3%) have been classified as a complete success, 17 (31%) as a qualified success. Overall success (i.e. with or without medication) was 67.3%. Eighteen eyes (32,7%) were classified as failures. The majority (8/15) failed because a second GDD operation was performed as deemed necessary by the operating surgeon due to increasing intraocular pressure. In one patient, a trabeculectomy was performed and another patient developed phthisis. Three additional failures were due to an insufficient reduction of IOP (no reduction of 20% below baseline) and the remaining 5 patients failed because the IOP was above 21 mmHg despite anti-glaucoma medications and postoperative interventions such as needling, 5-FU injection, removal of the incomplete occlusion stent, tube irrigation and placement of a tube-extender (6).

The cumulative life-table survival overall success rates using the Kaplan-Meier survival curve (Figure 4) were 87,47% at 6 months (n=55), 74,01% at 12 months (n=42), 60,66% at 24 months (n=26) and 56,62% at 36 months (n=22) (Table 4) (Fig. 4).

Table 2: *Patient characteristics*

Age (years), mean ± SD	50 ± 17,1	
Range	14-81	
Gender, n (%)		
Male	32 (51,6%)	
Female	30 (48,4%)	
Race, n (%)		
White	54 (87,1%)	
Black	6 (9,7%)	
Other	2 (3,2%)	
Tube implant, n (%)		
Ahmed	47 (75,8%)	
Baerveldt	15 (24,2%)	
Diagnosis, n (%)		
POAG	7 (11,3%)	
SOAG	41 (66,1%)	
Traumatic glaucoma		12 (19,4%)
Silicone oil glaucoma		8 (12,9%)
Uveitic glaucoma		4 (6,5%)
ICE		4 (6,5%)
Neovascular glaucoma	6 (9,7%)	
CACG	6 (9,7%)	
Congenital glaucoma	3 (4,8%)	
Juvenile glaucoma	1 (1,6%)	
Preoperative intraocular pressure, mean ± SD	27,98 ± 6,54	
Range	14,3 - 51	
Glaucoma medications, mean ± SD	2,74 ± 1,17	
Visual acuity (LogMAR), mean ± SD	0,87 ± 0,53	
Previous operations, mean ± SD	2,94 ± 1,61	
Previous failed filtering surgeries, n (%)	37 (59,7%)	
Lens status, n (%)		
Phakic	11 (17,7%)	
Aphakic	15 (24,2%)	
Pseudophakic	36 (58,1%)	

POAG: primary open-angle glaucoma
SOAG: secondary open-angle glaucoma
ICE: iridocorneal-endothelial syndrome
CACG: chronic angle-closure glaucoma

Table 3: *Results*

Follow-up		
Mean ± SD	25 ± 21,91	
Range (months)	2 - 72	
IOP (last visit) p < 0.0001*		
Postoperative range	0 - 31	
Mean ± SD	15,2 ± 5,87	
Postoperative medication (last visit) p <0.0001*		
Number of medications per patient	0 – 4	
Mean ± SD	0.87 ± 1,14	
Surgical outcome (%)		
Success	37/55 (67,3%)	
Complete success		20/55 (36,4%)
Qualified success		17/55 (31%)
Failure	18/55 (32,7%)	
Postoperative visual acuity LogMAR (last visit) p=0,13481*		
Mean ± SD	0.91 ± 0.54	

* Wilcoxon signed rank test

Table 4: *Life-table survival data (overall success)*

Survival time	*Survival*	*Lower limit of 95% CI*	*Upper limit of 95% CI*	*N° of patients*
6	87,47	75,45	93,84	55
12	74,01	59,22	84,12	42
24	60,66	43,24	74,23	26
36	56,62	38,68	71,13	22

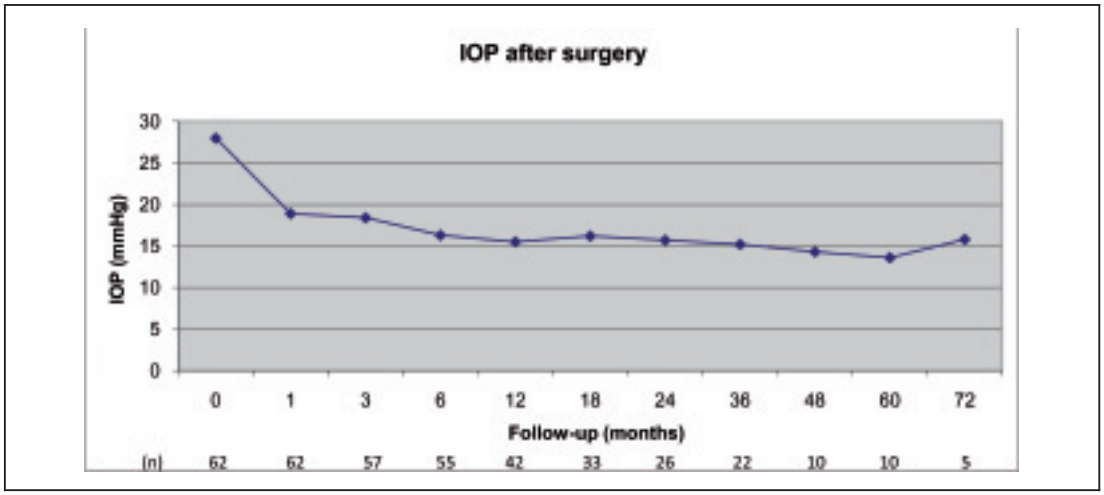

Fig. 3: Mean intraocular pressure

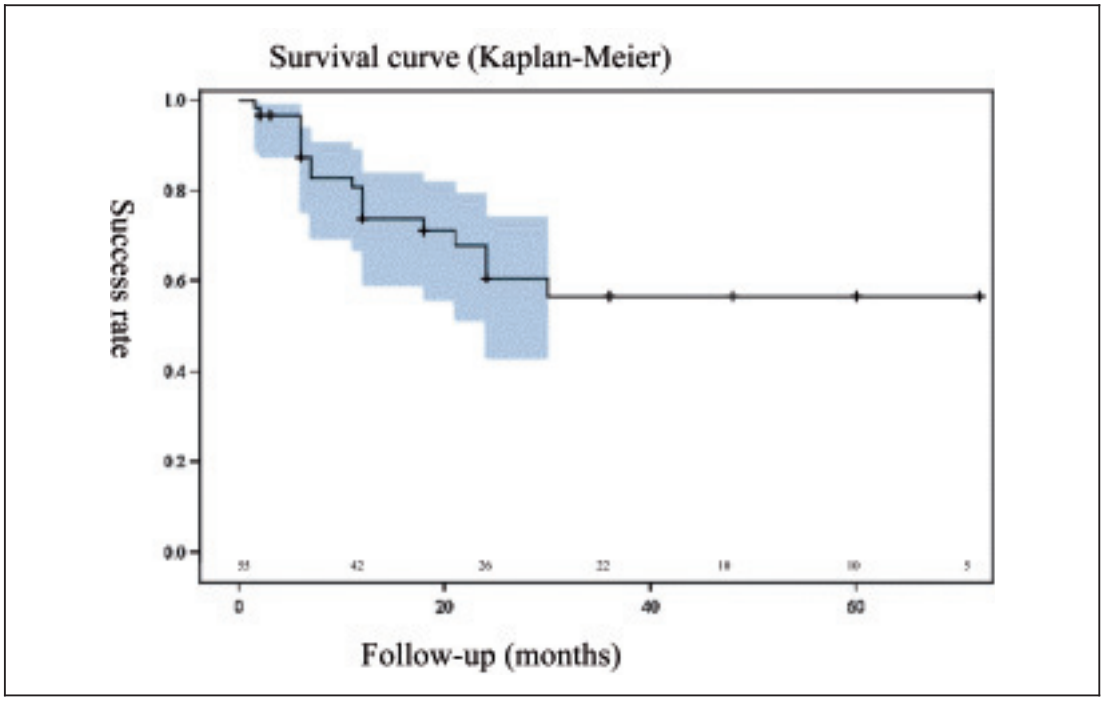

Fig. 4: Kaplan-Meier survival curve of overall success (with or without medications) with 95% CI for patients after inplantation of Ahmed or Baerveldt drainage device.

Twenty-seven eyes were given postoperative anti-glaucoma medications: 7 needed one medication, 15 two medications, 3 three medications and 2 four medications.

The postoperative visual acuity improved (at least 2 Snellen lines better than the preoperative visual acuity) in 8 eyes and remained the same (within 1 line of preoperative visual acuity) in 44 eyes. The Wilcoxon signed rank tests indicated no significant difference ($p > 0,1$ at each timepoint) in visual acuity based on logMAR units with respect to baseline and 3 months, 6 months, 12 months, 18 months, 2 years after the operation and VA at last visit. Visual acuity worsened (at least 2 lines worse than the preoperative visual acuity) in 10 eyes. The main reason for a decrease in visual acuity were corneal problems in five patients: corneal edema and graft decompensation. One patient developed uveitis and cystoid macular edema, another decrease in VA was due to worsening of glaucomatous optic nerve damage. Two patients developed a retinal detachment more than 30 months after surgery with significant visual loss. Loss of light perception developed in one patient resulting from phthisis bulbi.
Visual fields were considered stable in 14 patients (50%) and worse in 9 patients (32,2%). Five patients were classified as having possible progression on visual fields because the progression could not be confirmed on two consecutive visual fields. Sufficient data regarding the visual fields (we recorded the visual fields of 28 patients) were not available on all patients during the follow-up period. These patients had mainly neovascular glaucoma, penetrating keratoplasty with glaucoma, or traumatic glaucoma with a vision not good enough to obtain visual fields. In twenty-six patients, the follow-up period of the available visual fields was too short to draw any conclusion.

There were a total of 11 patients with penetrating keratoplasties included in the current study. The most common diagnosis was traumatic corneal decompensation (6 patients) followed by corneal decompensation due to multiple prior incisional surgeries (5 patients). Seven patients had a clear corneal graft at the time of the glaucoma drainage device surgery. Three of these grafts failed within 6 months after the aqueous shunt insertion, one graft was complicated with a perforation due to Candida keratitis which required a second graft.
Eight patients experienced an intraoperative complication. A hyphema occurred in seven patients with spontaneous resolution, one patient had a scleral perforation that was sutured before continuing the GDD surgery.
Postoperative interventions are listed in Table 5. Twenty-one patients needed postoperative interventions. The most frequently performed postoperative interventions were irrigation of the tube (7) (10 patients), removal of the incomplete occlusion stent (7 patients) and injection of 5-FU (5 patients).
Transient complications occurred in 17/62 eyes of which the majority occurred during the first 2 months (Table 6). The most frequent transient complication was choroidal effusion (10 patients), followed by corneal edema (6 patients), vitreous hemorrhage (4 patients) and uveitis (4 patients).

Five patients needed further surgery due to complications. One patient suffered from uveitis of unknown origin postoperatively and was treated with intravitreal antibiotics, complicated by hypotony one and a half year later, finally resulting in phthisis. In one eye a herniation of vitreous into the tube causing obstruction required a vitrectomy, 2 months later a PKP was performed for corneal decompensation. Two patients had a retinal detachment 31 months and 33 months postoperatively treated with pars plana vitrectomy and one eye developed a major choroidal hemorrhage which required drainage.
Age, gender, race, type of implant (Ahmed or Baerveldt), diagnosis, preoperative intraocular pressure, number of preoperative antiglaucoma medications, total number of incisional surgeries, total number of previously failed filtering surgeries, concomitant procedures, visual acuity, lensstatus and previous penetrating keratoplasty were analysed as possible risk factors for outcome. Cox regression analysis, Fisher exact tests and Mann-Whitney U tests established no significant predictors. There was no significant difference in the success rates between Ahmed or Baerveldt devices ($p=0,0976$) in this study.

Table 5: *Postoperative interventions*

	N° of patients (total 21 patients)
Ligature	3
Anterior chamber reformation	1
Needling	4
Tube irrigation	10
5-FU injection	5
Removal of incomplete occlusion stent	7
Piercing of the valve mechanism	1
Needling + celestone® injection	1
Tube-extender	1
Trimming of the tube	2
Revisal of scleral flap	1

Table 6: *Transient postoperative complications*

	N° of patients
Choroidal effusion	10
Tube obstruction	2
Uveitis	4
Hypotony with shallow or flat anterior chamber	1
Diplopia	3
Corneal edema	6
Vitreous hemorrhage	4
Ptosis	1

DISCUSSION

Aqueous shunts are mostly used after failure of medical, laser, and conventional filtering surgery to treat glaucoma. They are successful in controlling IOP in a variety of complex glaucomas. There are 4 commercially available aqueous shunts currently used. Too few high-quality direct comparisons of the available shunts have been published to assess the relative efficacy or complication rates of specific devices beyond the implication that larger-surface-area explants provide more enduring and better IOP control. (3)
Previous studies (8,9,10,11,12) on Ahmed and Baerveldt implants indicated that IOP was reduced to a mean value varying from 12,1 mmHg (8) to 19,8 mmHg (9). In the present study, preoperative IOP of 27,98 ± 6,5 mmHg decreased to 15,2 ± 5,87 mmHg at last visit with a mean postoperative IOP of 16,0 mmHg, which compares favorably with these other reports. Use of antiglaucoma medication decreased from 2,74 (60/62 patients) to 0,87 (27/62 patients). Compared to previous studies (4,8,9,10,11,12) who report a postoperative antiglaucoma medication use of 0,8 (11) to 1,6 (10), the use of postoperative medication in this study is relatively low.

In this study, the overall success rate was 67,3% at 25 months. In previous studies, the reported success rates vary between 62% (13) and 96% (12). The analysis of these results are influenced by study population, variable criteria for success and variable follow-up periods. The high success rate from the tube group in the Tube versus Trabeculectomy (TvT) study (96%) (12) was a success rate reported at 1 year follow-up. In this study, we used identical criteria for success with a success rate at 1 year of 74%. It should be noted that our study population has a mean of 2,94 ± 1,61 previous intraocular surgeries in comparison with 1,3 ± 0,5 in the tube group of the TvT study. More prior incisional surgeries are a significant risk factor for failure. (11) Our success rate at a mean follow-up time of 25 months (67,3%) compares favourably with other studies that use similar but not identical criteria for success and that have a comparable time of follow-up. Lloyd et al (13) report a success rate of 62% at a mean follow-up of 17,3 ± 7 months, Goulet et al (9) have a success rate of 62% at 2 years follow-up. Krishna et al (11) state a success rate of 71% at 2 years follow-up and Roy et al (10) report a success rate of 81,2% at a mean follow-up of 37,6 months. Our study population has a mean of previous intraocular surgeries that is substantially higher than the population studies by Goulet et al (1,7 ± 1,4) and Krishna et al (1,7 ± 1,1).
Visual acuity improved or remained unchanged in 52/62 (83,9%) of our patients, this result exceeds previously reported results ranging from 56,7% of patients (8) to 73% of patients (10). The incidence of corneal graft failure (3/7 patients or 42,9%) in the current study is similar to that reported in previous studies (19%-50%). (14,15)
Thirteen (21%) of the 62 patients required a secondary surgical intervention. These included a second aqueous shunt insertion or an in-

tervention due to a major complication (8%). A second tube shunt procedure can control refractory glaucoma and avoid hypotony and phthisis over the long term in highly complicated glaucomatous eyes, although there is a risk of corneal decompensation and vision loss. (16) PKP related glaucoma and irido-corneal-endothelial syndrome (ICE) related glaucoma accounted for 7 cases that needed additional surgery. Thirteen percent of the patients in this study needed a second glaucoma drainage implant, which is similar to the 10,5% reported by Ayyala et al. (4) In the TvT study, only 1 patient of the tube group required a reoperation for glaucoma, a cyclophotocoagulation for inadequately controlled IOP but this finding was after a follow-up of only 1 year. Five patients (8%) needed further surgery due to major complications. This is also the rate of reoperations for complications in the tube group of the TvT study. (15) Roy et al (9) report a rate of 6/48 patients (12,5%) and Ayyala et al (4) report 12 reoperations for complications on 85 patients (14,1%).
Twenty-one patients (33,9%) required postoperative interventions, which is similar to the 28,2% reported by Ayyala et al (4) and the 29% reported by Gedde et al. (17)
Postoperative complications following glaucoma drainage surgery are common. (10) In our study, the most common complications were transient, resolved without further surgery and left vision unaltered. The most frequent transient complication was choroidal effusion (16,2%), followed by hyphema (11,3%), corneal edema (9,7%), vitreous hemorrhage (6,5%) and uveitis (6,5%). Three patients experienced transient diplopia. This is similar to previous reports. (4,8,10,11,13,14,17) None of our patients suffered from end-plate or tube exposure in contrast with the findings of Ayyala et al. (4) They report tube exposure in 5 patients and plate exposure in 4 patients as the most frequent late post-operative complication and the most common indication for a secondary surgical intervention. Syed et al. (8) report 2 patients with plate extrusion, Krishna et al. (11) report 1 patient with tube extrusion.
In our study, no significant predictors for outcome were established. Roy et al (10) report visual acuity better than 20/400 and previously failed glaucoma surgeries to be associated with a better prognosis. In contrast, Souza et al (18) find previous filtration surgery to be a significant risk factor for glaucoma valve implantation failure in refractory glaucoma. In our study, there was a failure rate of 29,73% among patients with previously failed filtering surgeries versus 28% among other patients, and this difference was not significant (p=0,6024). Patients with neovascular or traumatic glaucoma were more likely to have a poorer outcome. (10,19) We found a failure rate of 33,33% of patients with traumatic glaucoma versus 28% failures for patients with other types of glaucoma. This difference was not statistically significant. Krishna et al (11) report younger age, high preoperative intraocular pressure and more prior incisional surgeries as significant risk factors for failure at 2 years. Black race was associated with a higher failure rate among the neovascular patients. We found a difference of 33,33% failures among black patients compared to 29,63% failures among white patients, but again this difference was not statistically significant.

There was no significant difference in the success rates between Ahmed or Baerveldt devices (p=0,0976) in this study. This is consistent with the retrospective study of Tsai et al. (20) However, it is important to note that our patients were not randomly assigned to Ahmed or Baerveldt devices. The Baerveldt implant was mainly used in eyes with silicone oil glaucoma. Furthermore, the Baerveldt group was relatively small, and our study was not powered to calculate a difference between the two devices.
There are some limitations to our study. The study is of retrospective nature and because of the high heterogeneity in time of follow-up, 7 patients could not be assessed as failure or success. The neovascular, CACG, congenital and juvenile glaucomas are groups that contain small numbers of patients and therefore it is difficult to draw substantial conclusions from these groups.

In conclusion, the favorable results of this study indicate that Ahmed and Baerveldt implants are an effective and safe surgical procedure for glaucoma refractory to other surgical or medical management methods. Despite common post-

operative complications, the relatively low rate of major and sight-threatening complications may further promote using these devices for eyes with refractory glaucoma.

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REFERENCES

(1) FCIOFFI G.A. – Basic and clinical science course: section 10: glaucoma. San Francisco: American Academy of Ophthalmology 2008-2009; 187-215.
(2) SCHWARTZ K.S., LEE R.K., GEDDE S.J. – Glaucoma drainage implants: a critical comparison of types. *Curr Opin Ophthalmol 2006; 17: 181-189.*
(3) MINCKLER D.S., FRANCIS B.A., HODAPP E.A. et al. – Aqueous shunts in glaucoma. *Ophthalmology 2008; 115: 1089-1098.*
(4) AYYALA R.S., ZURAKOWSKI D., SMITH J.A. et al. – A clinical study of the Ahmed glaucoma valve implant in advanced glaucoma. *Ophthalmology 1998; 105: 1968-1976.*
(5) HILLE K., MOUSTAFA B., HILLE A., RUPRECHT K.W. – Drainage devices in glaucoma surgery. *Klin Oczna 2004; 106(4-5): 670-81.*
(6) SARKISIAN S.R., NETLAND P.A. – Tube extender for revision of glaucoma drainage implants. *J Glaucoma 2007; 16 (7): 637-639.*
(7) HILL R.A., PIROUZIAN A., LIAW L. – Pathophysiology of and prophylaxis against late Ahmed glaucoma valve occlusion. *Am J Ophthalmol 2000: 129 (5): 608-612.*
(8) SYED H.M., LAW S.K., NAM S.H. et al. – Baerveldt-350 implant versus Ahmed valve for refractory glaucoma. *J Glaucoma 2004; 13: 38-45.*
(9) GOULET R.J., PHAN A.T., CANTOR L.B., WUDUNN D. – Efficacy of the Ahmed S2 glaucoma valve compared with the Baerveldt 250-mm^2 glaucoma implant. *Ophthalmology 2008; 115: 1141-1147.*
(10) ROY S., RAVINET E., MERMOUD A. – Baerveldt implant in refractory glaucoma: long-term results and factors influencing outcome. *Int Ophthalmol 2001; 24(2): 93-100.*
(11) KRISHNA R., GODFREY D.G., BUDENZ D.L. et al. – Intermediate-term outcomes of 350-mm^2 Baerveldt glaucoma implants. *Ophthalmology 2001; 108: 621-626.*
(12) GEDDE S.J., SCHIFFMAN J.C., FEUER W.J. et al. – Treatment oucomes in the Tube versus Trabeculectomy study after one year of follow-up. *Am J Ophthalmol 2007; 143: 9-22.*
(13) LLOYD M.A., BAERVELDT G., HEUER D.K., MINCKLER D.S., MARTONE J.F. – Initial clinical experience with the Baerveldt implant in complicated glaucomas. *Ophthalmology 1994; 101(4): 640-50.*
(14) COLEMAN A.L., HILL R., WILSON M.R. et al. – Initial clinical experience with the Ahmed glaucoma valve implant. *Am J Ophthalmol 1995; 120(5): 23-31.*
(15) COLEMAN A.L., MONDINO B.J., WILSON M.R., CASEY R. – Clinical experience with the Ahmed glaucoma valve implant in eyes with prior or concurrent penetrating keratoplasties. *Am J Ophthalmol 1997; 123: 54-61.*
(16) BURGOYNE J.K., WUDUNN D., LAKHANI V., CANTOR L.B. – Outcomes of sequential tube shunts in complicated glaucoma. Ophthalmology 2000; 107: 309-314.
(17) GEDDE S.J., HERNDON L.W., BRANDT J.D. et al. – Surgical complications in the Tube versus Trabeculectomy study during the first year of follow-up. *Am J Ophthalmol 2007; 143: 23-31.*
(18) SOUZA C., TRAN D.H., LOMAN J. et al. – Long-term outcomes of Ahmed glaucoma valve implantation in refractory glaucomas. *Am J Ophthalmol 2007; 144(6): 893-900.*
(19) SIDOTI P.A., DUNPHY T.R., BAERVELDT G. et al. – Experience with the Baerveldt glaucoma implant in treating neovascular glaucoma. *Ophthalmol 1995; 102: 1107-1118.*
(20) TSAI J.C., JOHNSON C.C., KAMMER J.A. et al. – The Ahmed shunt versus the Baerveldt shunt for refractory glaucoma II: longer-term outcomes from a single surgeon. *Ophthalmol 2006; 113(6): 913-7.*

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Adress for correspondence:
Dr. Julie JACOB
University Hospitals Leuven
Ophthalmology Campus St. Raphael
Kapucijnenvoer 33
3000 Leuven
BELGIUM
E-mail: juliejacob@hotmail.com