African Vision and Eye Health
ISSN: (Online) 2410-1516, (Print) 2413-3183

Surgical outcomes of glaucoma drainage device surgery in an African context

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Dates:
Received: 17 Sept. 2025
Accepted: 29 Nov. 2025
Published: 13 Feb. 2026

How to cite this article:
Van der Lecq T, Geragotellis A, Steven D, Du Toit N. Surgical outcomes of glaucoma drainage device surgery in an African context. Afr Vision Eye Health. 2026;85(1), a1132. https://doi.org/10.4102/aveh.v85i1.1132

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Background: The use of glaucoma drainage devices (GDDs) in the management of glaucoma is increasing; however, there is a paucity of data comparing the surgical outcomes of different devices in an African context.

Aim: The aim of the study was to compare the surgical outcomes of the Ahmed glaucoma valve and the aurolab aqueous drainage implant (AADI) device in glaucoma cases within an African context.

Setting: Patient data were obtained from Groote Schuur Hospital and Eerste River Hospital in Cape Town, South Africa.

Methods: The study was a comparative retrospective review of the medical records of consecutive adult patients who received GDD surgery over a 2-year period using standardised surgical techniques.

Results: A total of 76 patients/eyes were included in the study, 48 in the Ahmed group and 28 in the AADI group. The overall 1-year and 2-year qualified success rates were 75% and 77.1% respectively, for the Ahmed, and 78.6% and 85.7% respectively, for the AADI (P = 0.757; P = 0.873). The mean intraocular pressure (IOP) in the Ahmed group decreased from 32 ± 12 mmHg to 16 ± 6 mmHg at 2 years, compared to 33 ± 13 mmHg to 14 ± 6 mmHg at 2 years in the AADI group. Most (63, 82.9%) patients required postoperative glaucoma medications.

Conclusion: The Ahmed and AADI groups achieved comparable success rates over a 2-year period. A similar IOP reduction was achieved with no difference in the need for medication between the two groups.

Contribution: This study adds to the knowledge of GDD surgical outcomes in an African context.

Keywords: Ahmed glaucoma valve; aurolab aqueous drainage implant; glaucoma; glaucoma drainage device.

Introduction

Glaucoma remains a leading cause of irreversible blindness.[1] The global prevalence is anticipated to increase from 76.0 million to 111.8 million between 2020 and 2040.[2] Sub-Saharan Africa has demonstrated the highest burden of this condition, with an estimated 6.5 million adults in the region affected in 2020.[3] Elevated intraocular pressure (IOP) remains the only modifiable risk factor in glaucoma, and surgical techniques offer a long-term solution to reduce IOP. Lowering IOP has been shown to reduce or prevent glaucoma progression, especially if the target pressure for the patient can be achieved.[4,5]

Although trabeculectomy remains the gold standard surgical procedure for glaucoma, the use of glaucoma drainage devices (GDDs) is increasing, especially because of comparable IOP reduction and better surgical success rates.[6,7] Recent evidence supports the use of these devices.[7,8] Two of the most popular GDDs are the Ahmed-FP7 valve (New World Medical, Rancho Cucamonga, CA, United States) and the Baerveldt-350 non-valved glaucoma implant (BVT) (Abbott Medical Optics, Santa Ana, CA, United States). The Aurolab aqueous drainage implant (AADI) (Aurolab-350, Madurai, India) is a new cost-effective non-valved GDD that has been less well researched.

While there is growing evidence to suggest the efficacy of using the Ahmed and the AADI device in Asian populations,[9,10,11,12] there is a paucity of evidence in disproportionately affected African population groups, whose under-representation in published glaucoma studies was highlighted in a systematic review and meta-analysis.[13] Research on contextually relevant management

strategies for glaucoma in Africa is essential to assist policy formation and planning to improve outcomes.[14] The aim of this study was to analyse the surgical outcomes of the Ahmed and the AADI in an African context.

Research methods and design

Setting

This retrospective review evaluated the medical records of patients who received GDD surgery at Groote Schuur Hospital and Eerste River Hospital, a tertiary and secondary level, respectively. These facilities are located in the Western Cape province, South Africa (SA). In the regional population of approximately 6 million people, the demographic profile is as follows: coloured people (47.5%), black African people (35.7%), Indian/Asian people (0.8%) and Caucasian people (16.0%).[15]

Inclusion criteria

The cohort of the study was formed by consecutive cases of adult patients with refractory glaucoma (inability to achieve the target IOP on maximum tolerable medical therapy or laser therapy). One eye from each patient was included in the study. In those who received bilateral surgery, the eye operated on initially was included in the study.

Exclusion criteria

Any patients operated on during the specified inclusion window with missing records were excluded from the study. In addition, patients with eyes receiving two or more GDDs were excluded.

Baseline data collection

Data were collected from preoperative assessments, the surgery and follow-up visits at 1 day, 1 week, 6 weeks, 3 months, 6 months, 1 year, 2 years and 3 years postoperatively. Baseline data parameters included: age, gender, glaucoma diagnosis, previous ophthalmic procedures (surgical and laser), best-corrected visual acuity based on the Snellen chart, Goldmann applanation tonometry and number of glaucoma medications. Follow-up visits included the evaluation of visual acuity, IOP, number of glaucoma medications and postoperative complications. Ethnicity data for individual patients were not included, as these data are not routinely collected in the medical records of South Africa.

Surgical technique

All participants underwent the insertion of an Ahmed or AADI device from 01 January 2016 to 31 December 2018. The standardised surgical procedure was performed by qualified ophthalmologists and ophthalmology residents.

The Ahmed glaucoma valve used in the study was the FP7 model with a silicon valve mechanism designed to avoid hypotony. The device has the following specifications: a length of 25.4 mm, an internal tube diameter of 305 µm and a footplate of 182 mm^2.[16] The AADI is a non-valved device with the following specifications: a length of 35 mm, an internal tube diameter of 300 µm and a footplate of 350 mm^2. This device only differs from the BVT in the type of medical-grade silicon used.[17]

A standardised surgical technique was used as described by the Ahmed versus Baerveldt Study Manual,[18] and intraoperative complications were recorded. The procedure was performed under general or local (subtenon block) anaesthesia depending on the needs of the patient. The primary surgeon was either a qualified ophthalmologist or an ophthalmology resident. A clear corneal traction suture was inserted parallel to the limbus, facilitating the creation of a superotemporal or superonasal peritomy. After achieving adequate hemostasis, mitomycin-c (0.2 mg/mL or 0.4 mg/mL) was applied to the sub-tenon space for a duration of 2 min according to the surgeon's preference. In the case of the Ahmed, priming was performed with balanced salt solution. The plate of both devices was sutured either with 8/0 Prolene or 6/0 Mersilene at least 8 mm posterior to the surgical limbus. In most cases, the tube was inserted into the anterior chamber parallel to the iris plane with alternative placements including the ciliary sulcus and pars plana. The AADI was tied with a 10/0 nylon suture and additionally cannulated with a 3/0 supramid suture based on the surgeon's preference. A scleral patch graft from banked donor sclera was placed over the tube with closure of the overlying Tenon's and conjunctiva using interrupted 10/0 nylon sutures. Intracameral cefuroxime (0.1 mg/mL) was injected at the end of the surgery. In some cases, because of surgeon preference, 0.5 mL of Celestone was injected into the subconjunctival space. Subsequently, in cases of neovascular glaucoma (NVG), 1.25 mg of intravitreal bevacizumab (Avastin®, Genentech, San Francisco, CA, United States) was injected intracamerally.

Outcome measures

Complete success of the GDD was recorded when all the following criteria were met: (1) IOP of 5 mmHg – 18 mmHg at the last visit or more than 20% reduction at the last visit (compared to baseline), (2) no glaucoma medications, (3) no significant vision loss (> 2 Snellen lines), (4) no vision-threatening complications (endophthalmitis, choroidal effusion or suprachoroidal haemorrhage) and (5) no further surgical intervention needed. Qualified success was recorded if the following criteria were met: (1) IOP of 5 mmHg – 18 mmHg at the last visit or more than 20% reduction at last visit (compared to baseline) and (2) use of glaucoma medications, or (3) occurrence of surgical intervention for non-vision-threatening complication. Failure was recorded if any of the following criteria were met: (1) IOP outside the 5 mmHg – 18 mmHg range or < 20% reduction at last visit despite glaucoma medications or maximal medical therapy, (2) vision-threatening complications, (3) *de novo* glaucoma procedure required and (4) progression to no light perception (NLP) vision. These outcome measures were chosen to approximate those used in the Ahmed versus Baerveldt Study[19] and the Ahmed Baerveldt Comparison Study.[20]

Statistical analysis

The collected data were stored in a Microsoft 2010 Excel spreadsheet. IBM SPSS version 27 was used for data analysis (IBM Inc., Chicago, Illinois, United States). Descriptive analysis entailed categorical variables presented as frequencies and percentages, while the mean (± standard deviation [s.d.]) and range (minimum to maximum) were calculated for the normally distributed continuous variables. The independent *t*-test was used to compare the means between the two groups for the normally distributed variables. Chi-squared test was used to compare proportions between the groups. Kaplan–Meier survival curves were plotted to show time to failure, and log rank (Mantel–Cox) was used to test the differences between the survival rates of groups compared. A *P*-value < 0.05 indicated statistical significance.

Ethical considerations

Ethical approval was obtained from the University of Cape Town Human Research Ethics Committee prior to the start of the study (reference number: 275/2021). The methods of the study adhered to the Declaration of Helsinki. We obtained a waiver for patient consent from the ethics committee to analyse the anonymised retrospective data.

Results

A total of 76 participants (76 eyes) underwent GDD implantation, with 48 patients receiving the Ahmed and 28 patients receiving the AADI device. The mean age of participants was 55 years, and 37 (51.3%) participants were women. The baseline characteristics, including glaucoma diagnosis, preoperative procedures and number of preoperative anti-glaucoma medications (AGM), are highlighted in Table 1. Neovascular glaucoma was the most common glaucoma diagnosis in 34.2% (n = 26) of patients, followed by primary open-angle glaucoma (POAG) in 22.4% (n = 17) patients. Fifty-five patients (72.4%) had received a previous surgical procedure, with trabeculectomy the most commonly performed in 12 (15.8%) cases. The mean follow-up time was 17.4 (s.d. 8.8) and 19.7 (s.d. 7.7) months in the Ahmed and AADI groups, respectively. Overall, there were 57 (75%) participants followed up to 1 year, and 49 (65%) participants followed up to 2 years.

Intraocular pressure

There was a reduction in the mean IOP measurement at all follow-up visits compared with the baseline measurement in both groups (Figure 1). The mean IOP in the Ahmed group decreased from 32 ± 12 mmHg at baseline to 18 ± 12 mmHg at 1 year and 16 ± 6 mmHg at 2 years. In comparison, the mean IOP in the AADI group decreased from 33 ± 13 mmHg to 17 ± 7 mmHg at 1 year and 14 ± 6 mmHg at 2 years.

The mean IOP reduction rate in the cohort was 38.5% at 1 year and 45% at 2 years. The mean IOP reduction rate at 1 year in the Ahmed and AADI groups, respectively, was 37.6% and 40.1% (P = 0.781); at 2 years, this improved to 42.6% and 40.1% (P = 0.425), respectively.

Glaucoma medication

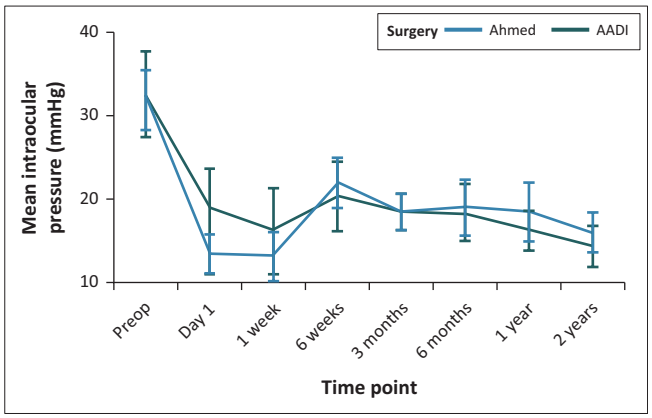
Preoperatively, 93% (71/76) of patients were using four antiglaucoma medications (AGM). In total, 63 (82.9%) patients required glaucoma medication to be restarted postoperatively. The mean number of medications in the Ahmed group decreased from 3.92 ± 0.28 preoperatively to 2.2 (95% confidence interval [CI], 1.8–2.7) at 1 year postoperatively and 2.4 (95% CI, 1.8–2.9) at 2 years postoperatively. The mean AGM use in the AADI group decreased from 3.96 ± 0.19 preoperatively to 2.4 (95% CI, 1.7–3.0) at 1 year postoperatively and 2.6 (95% CI, 2.0–3.3) at 2 years postoperatively. There were no significant differences between the mean number of medications at 1 and 2 years between the Ahmed and AADI groups (Table 2).

TABLE 1: Baseline characteristics.

Category	Overall (N = 76 eyes)			Ahmed (n = 48 eyes)			AADI (n = 28 eyes)			*P*
	Mean ± s.d.	*n*	%	Mean ± s.d.	*n*	%	Mean ± s.d.	*n*	%	
Age (years)	55 ± 13	-	-	57 ± 13	-	-	52 ± 13	-	-	0.104
Sex (female)	-	37	48.7	-	25	52.0	-	12	43.0	0.435
Glaucoma diagnosis										
Primary open-angle glaucoma (POAG)	-	17	22.4	-	8	17.0	-	9	32.0	0.478
Neovascular glaucoma (NVG)	-	28	34.2	-	19	40.0	-	7	25.0	0.478
Uveitic glaucoma	-	17	19.7	-	6	12.0	-	9	32.0	0.373
Primary angle-closure glaucoma (PACG)	-	5	6.6	-	4	8.3	-	1	3.6	0.873
Juvenile open-angle glaucoma (JOAG)	-	2	2.6	-	2	4.2	-	0	0.0	1.000
Post-retinal surgery	-	4	5.3	-	4	8.3	-	0	0.0	1.000
Preoperative IOP (mmHg)	32 ± 12	-	-	32 ± 12	-	-	33 ± 13	-	-	0.972
Previous surgery/interventions										
Trabeculectomy (Trab) only	-	12	15.8	-	7	14.6	-	5	17.9	0.881
Phacoemulsification (Phaco) only	-	12	15.8	-	8	16.7	-	4	14.3	0.912
Other†	-	52	68.4	-	33	68.7	-	19	67.8	0.944
Glaucoma medications	3.93 ± 0.25	-	-	3.92 ± 0.28	-	-	3.96 ± 0.19	-	-	0.982

s.d., standard deviation; IOP, intraocular pressure; AADI, Aurolab aqueous drainage implant.

†, trabeculectomy and phacoemulsification, intravitreal Avastin®, pars plana vitrectomy, pan-retinal photocoagulation, selective laser trabeculoplasty, previous tube, or various combinations of the mentioned treatments.



Note: Error bars denote 95% confidence interval.
CI, confidence interval; preop, preoperative.

FIGURE 1: Trends in mean intraocular pressure reduction following Ahmed and aurolab aqueous drainage implant implantation.

TABLE 2: Mean anti-glaucoma medication requirement at baseline and follow-up according to drainage device.

Timepoint	Ahmed	AADI	*P*
Baseline	-	-	0.380
Mean ± s.d. anti-glaucoma medications	3.92 ± 0.28	3.96 ± 0.19	-
Number of participants	48	28	-
1 year	-	-	0.703
Mean anti-glaucoma medications	2.2	2.4	-
95% CI anti-glaucoma medications	1.8–2.7	1.7–3.0	-
% reduction	45	40	-
Number of participants	39	21	-
2 years	-	-	0.529
Mean anti-glaucoma medications	2.4	2.6	-
95% CI anti-glaucoma medications	1.8–2.9	2.0–3.3	-
% reduction	40	35	-
Number of participants	30	19	-

CI, confidence interval; s.d., standard deviation; AADI, aurolab aqueous drainage implant.

Treatment outcomes

In the entire cohort, the proportion of surgeries with complete success at 1 year and at 2 years was 6.6%. Overall, qualified success was higher with 76.3% at 1 year and 80.3% at 2 years. This was similar in both groups (Table 3). The overall failure rate was 17.1% at 1 year and 13.2% at 2 years. The *P*-value for the log-rank test to compare survival (success) probability between the two device groups was $P = 0.369$ (Figure 2a).

Discussion

Our study compared the surgical outcomes of the Ahmed and the non-valved AADI device in the treatment of refractory glaucoma in an African context. The AADI drainage device was designed as a cost-effective alternative to the BVT, comparable to the BVT 350 mm^2, with an equivalent foot plate surface area.[21]

The 1-year and 2-year qualified success rates were 75% and 77.% for the Ahmed, and 79% and 86% for the AADI ($P = 0.757$; $P = 0.873$). Studies comparing the Ahmed and AADI have published lower qualified success rate with the AADI device, especially in the first year.[10,12] Pathak Ray and Rao[12] reported a 1-year qualified success rate of 58% in the Ahmed group versus 27% in AADI group ($P < 0.001$). Pandav et al.[10] reported qualified success rate at 1 year of 55% in the Ahmed and 45% in the AADI, although not statistically significant. Both studies used less stringent, complete and qualified success criteria compared to the current study.

In the current study, complete success at 1 and 2 years occurred in only 6% and 8% for the Ahmed, and 7% and 4 % for the AADI ($P = 0.879$; $P = 0.614$). The studies published by Pandav et al.[10] and Pathak Ray and Rao[12] were able to achieve comparably higher proportions of complete success, especially with the AADI device. In the two studies, at 1 year, complete success occurred in 11% and 22% in the Ahmed group versus 38% and 65% in the AADI groups. Although our more stringent success criteria may account for our lower complete success rates, the effects of other factors must be considered. These may include: the role of surgeon experience (Pathak Ray et al. used a single fellowship trained surgeon), differences in the postoperative course with IOP volatility requiring AGM control, and the influence of differences in demographic groups.[9,22]

Both Ahmed and AADI devices were found to lower IOP and glaucoma medication use when compared to baseline values, and no significant difference in IOP and AGM usage was noted between the Ahmed and the AADI groups at the various time points.

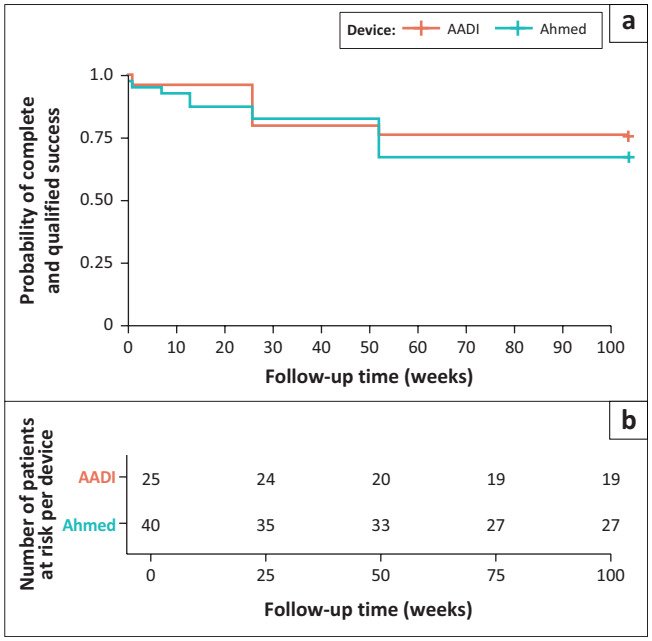
In contrast, in a pooled analysis of two multicentre randomised controlled trials (Ahmed vs Baerveldt Study, and Ahmed Baerveldt Comparison Study) involving 514 eyes with failed trabeculectomy or high risk for trabeculectomy, the BVT was shown to demonstrate a comparable but significantly lower IOP and AGM usage versus the Ahmed at all time points between 6 months and 5 years, except in IOP control at 2 years.[23] The retrospective comparison study ($n = 395$) by Pandav et al. found significantly lower IOP and AGM in the AADI group at 3 months, 6 months, 12 months, 18 months and 2 years.[10] Additionally, it must be noted that the postoperative IOP reduction achieved in the Ahmed group in our study was comparable with the AADI group 4–6 weeks postoperatively. This is consistent with existing literature that compares the Ahmed to either the BVT or AADI.[10,24,25,26] The relative delay in IOP reduction in the non-valved BVT/AADI is expected based on the presence of ligature, which limits flow in early postoperative period.

The mean percentage decrease in IOP in our study was 38% and 45% at 1 and 2 years. The Ahmed group had a mean IOP of 16 ± 6 mmHg (50% reduction from baseline) compared with 14 ± 6 mmHg (58% reduction from baseline, $P = 0.197$) in the AADI group at 2 years. Studies based in other low- and middle-income countries revealed similar findings. Alzendi et al. showed similar IOP reductions in the Ahmed group versus the BVT group with pressures of 14.0 ± 4.8 mmHg (60% from baseline) versus 15.8 ± 6.2 mmHg (53% from baseline),

TABLE 3: Success with glaucoma drainage device.

Timepoint	Outcome	Ahmed (n = 48)		AADI (n = 28)		Total		P
		n	%	n	%	n	%	
At 1 year	Complete success	3	6.3	2	7.1	5	6.6	0.986
	Qualified success	36	75.0	22	78.6	58	76.3	0.757
	Failure	9	18.8	4	14.3	13	17.1	0.841
At 2 years	Complete success	4	8.3	1	3.6	5	6.6	0.614
	Qualified success	37	77.1	24	85.7	61	80.3	0.873
	Failure	7	14.6	3	10.7	10	13.2	0.865

AADI, aurolab aqueous drainage implant.



AADI, aurolab aqueous drainage implant.

FIGURE 2: (a) Time to failure by drainage device. (b) Number of patients at risk during the follow-up period.

respectively (P = 0.536).[9] Pandav et al. reported a 2-year mean IOP reduction to 14.5 ± 5.5 mmHg (52% from baseline) in the Ahmed group versus 12.3 ± 3.8 mmHg (59% from baseline) in the AADI group (P < 0.01).[10] Lastly, Philip et al. found a reduction in the overall 2-year mean IOP to 15.7 ± 2.5 mmHg (49% from baseline) in their AADI group.[27] Notably, the AVB study found IOP reductions to 16.5 ± 5.1 mmHg (47% from baseline) in the Ahmed group versus 13.8 ± 4.6 mmHg (57% from baseline) in the BVT group (P = 0.026).[19]

In this study, there was no difference in the AGM reduction in the Ahmed and AADI groups (40% vs 35%, P = 0.529), respectively. This is lower than other studies. At 2 years, Pandav et al. found AGM reductions of 46% in the Ahmed versus 73% in the AADI (P < 0.01),[10] with other studies also reporting much higher AGM reductions in their AADI groups at 1 year and 2 years (79% – 82% and 76%), respectively.[27,28]

This study had some limitations. It was a retrospective review with a relatively small sample size of patients and poor follow-up rates. The small sample size limited the statistical power of the study, the calculated estimates and the generalisability of our findings. The poor follow-up rates hindered our ability to determine differences over a longer time period, such as those reported in the Ahmed versus Baerveldt Study[19] and the Ahmed Baerveldt Comparison Study.[20]

In addition, surgeons with varying levels of experience performed the surgeries, possibly contributing to the outcomes. The use of anti-vascular endothelial growth factor agents and intraoperative antimetabolites also varied among surgeons and may have also influenced surgical outcomes. The influence of these factors requires further study. In addition, IOP was used as a surrogate measure of success because it is the only clinically modifiable risk factor to prevent glaucoma progression.

Conclusion

This study demonstrated comparable IOP reduction and postoperative AGM use in both GDD groups up to 2 years in our African cohort.

Acknowledgements

Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRediT authorship contribution

Tshilidzi van der Lecq: Conceptualisation, Formal analysis, Methodology, Writing – original draft. Alexander Geragotellis: Formal analysis, Writing – original draft, Writing – review & editing. David Steven: Conceptualisation, Investigation, Writing – original draft, Writing – review & editing. Nagib du Toit: Writing – original draft, Writing – review & editing.

All authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication, and take responsibility for the integrity of its findings.

Funding information

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Data availability

The data that support the findings of this study are available on request from the corresponding author, Tshilidzi van der Lecq, upon reasonable request.

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