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Intermediate-Term Outcomes of an Affordable Aqueous Drainage Implant in Adults with Refractory Glaucoma

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Purpose: To report the outcomes of Aurolab Aqueous Drainage Implant (AADI) (Aurolab, Madurai, India) surgery in adults with refractory glaucoma.

Design: Retrospective, noncomparative, interventional case series.

Participants: Patients 18 years of age or older who underwent AADI surgery between January 2012 and December 2015 for refractory glaucoma with a minimum follow-up of 2 years.

Methods: Case records of eligible patients were evaluated for demographics, best-corrected visual acuity (BCVA), and indication for AADI surgery. The intraocular pressure (IOP) and the number of antiglaucoma medications (AGMs) were recorded at baseline, at 1, 3, 6, 9, 12, 18, and 24 months, and at the last visit after 24 months if any from the case files. Complications during or at any time point after surgery were also recorded.

Main Outcome Measures: Cumulative failure rate of the AADI was defined as IOP $>$ 18 mmHg or not reduced by 30% below baseline on 2 consecutive follow-up visits after 3 months, IOP $\leq$ 6 mmHg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma, or loss of light perception vision.

Results: A total of 158 eyes of 158 patients with a mean age of 45.4±17.4 years and mean follow-up of 41.9±14.7 months were included in the analysis. Secondary open-angle glaucoma (n = 71, 45%) was the most common form of glaucoma. The mean preoperative IOP was 34.7±9.9 mmHg with 3.2±0.7 AGMs. At 1 year, the mean IOP decreased to 15.10±6.7 mmHg with 1.5±1.1 medications, and this was maintained at 2 years. Kaplan–Meier estimates showed that the cumulative probability of failure was 9.5% (95% confidence interval [CI], 5.8–15.2) at 1 year, 27.8% (95% CI, 21.5–35.5) at 2 years, 38.9% (95% CI, 31.1–47.8) at 3 years, and 50.1% (95% CI, 40.5–60.6) at 4 years. Forty-seven complications were observed in 38 eyes (24%), most of which were transient and did not require surgical intervention. The AADI tube exposure (n = 1), retraction (n = 1), plate exposure (n = 1), and plate displacement (n = 1) were seen rarely.

Conclusions: The AADI appears to have good efficacy and safety for managing eyes with refractory glaucoma. Longer follow-up studies are required to determine long-term cumulative failure rates. *Ophthalmology Glaucoma 2019;■:1–9 © 2019 by the American Academy of Ophthalmology*

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Aqueous drainage implants have become the mainstay in the management of eyes with refractory glaucoma, which typically involve eyes with prior failed trabeculectomy or secondary glaucomas that are known to be high risk for failure of trabeculectomy,[1] such as neovascular or uveitic glaucoma. Most of these eyes have scarred conjunctiva due to previous attempts at glaucoma-filtering surgery and thus require alternate routes of aqueous drainage to lower intraocular pressure (IOP). The majority of these drainage implants consist of a tube that shunts the aqueous out of the anterior chamber and an endplate placed at the equatorial region of the eye that serves as a reservoir of aqueous. A survey of the surgical practice patterns of the American Glaucoma Society membership in 2008 included 125 participants, with a marked increase in the use of aqueous shunts from 17% in 1996 to 50% in 2008. Most surgeons preferred drainage devices in patients who had undergone prior surgery or who had neovascular or uveitic glaucoma compared with trabeculectomy with mitomycin-C.[2]

The most commonly used drainage devices are the Baerveldt glaucoma implant (Abbott Medical Optics, Abbott Park, IL), which is without a valve mechanism, and the Ahmed glaucoma implant (New World Medical, Cucamonga, CA), which has an intrinsic valve mechanism to prevent overfiltration and thus prevent hypotony. Two randomized controlled trials evaluated the safety and efficacy of the Baerveldt versus the Ahmed valve for treating eyes with refractory glaucoma and found the Baerveldt to have lower failure rates at 5 years, but it carried a slightly higher risk of hypotony.[3-5]

Despite the proven efficacy of these devices in managing complicated eyes with intractable glaucoma, the cost burden

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prohibits their widespread application, especially in the developing world where patients' socioeconomic status is an important determinant for choosing treatment options.[6] Greater severity of glaucoma usually leads to more medications and escalating costs of treatment.[7] Most devices are imported from the West, expensive, and unaffordable to a large majority of patients with refractory glaucoma. Thus, there is a need for newer and more affordable drainage implants to address the situation and meet the increasing demand of drainage implants. The Aurolab Aqueous Drainage Implant (AADI; Aurolab, Madurai, India) is a new, low-cost drainage implant based on similar principles as the Baerveldt implant, is without a valve, and has been shown to be effective in lowering IOP in some recent studies.[8-11] However, most of these studies have reported outcomes up to 1 year and have small sample sizes. We report intermediate-term outcomes, up to 4 years follow-up, in a relatively large sample of eyes with refractory glaucoma from a tertiary eye care center in South India.

Methods

This retrospective study was approved by the institutional ethics committee of the Aravind Eye Hospital, Madurai, and was conducted per the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients before undertaking surgery. Case records of patients older than 18 years of age who underwent AADI surgery between January 2012 and December 2015 for uncontrolled glaucoma despite maximal tolerated medical therapy, failed trabeculectomy, or secondary glaucomas deemed as high risk for failure of trabeculectomy were identified from a computerized database, and data of those patients with a minimum of 2 years follow-up were included in the analysis. Patients with incomplete records were excluded.

Patients' demographics such as age, gender, and residence were noted from the case files followed by the recording of baseline best-corrected visual acuity (BCVA) and preoperative glaucoma parameters, including type of glaucoma, underlying etiology in secondary glaucomas, baseline IOP (Goldmann Applanation Tonometry), number of antiglaucoma medications (AGMs), surgical history, visual field assessment including mean deviation and pattern standard deviation, and the date of AADI surgery. The IOP, number of AGMs, BCVA, complications, and re-surgery if any were recorded at day 1, months 1, 3, 6, 9, 12, 18, and 24, and the last visit after 24 months if any from the case files.

Surgical Technique

A similar operative technique was used in all patients for placement of the 350-mm^2 AADI. All procedures were performed by a single surgeon (G.V.P.). A fornix-based conjunctival peritomy was fashioned spanning 5-clock hours. Blunt dissection was used to lyse adhesions of conjunctiva and Tenon's capsule from the sclera in the selected quadrant. The superior and lateral recti muscles (for superotemporal implantation) or inferior and medial recti muscles (for inferonasal implantation) were sequentially isolated, and 1 wing of the AADI was placed beneath adjacent muscle bellies. The explant was then secured to the sclera 9 to 10 mm posterior to the limbus using 2 interrupted sutures of 9-0 nylon (Aurolab) through the fixation holes. The suture knots were rotated into the fixation holes to prevent erosion through the conjunctiva. A non-compressing 9-0 nylon suture in the form of a box mattress was used to stabilize the tube to the sclera. The tube was ligated in a watertight fashion near the tube-explant junction using 2 interrupted 6-0 polyglactin sutures (braided coated polyglactin 910 violet; Ethicon, Johnson & Johnson Ltd, Mumbai, India). The absence of flow through the tube was confirmed by irrigation of balanced salt solution into the tube via a 27-gauge cannula. The tube was trimmed to an appropriate length with the bevel facing anteriorly and was inserted into the anterior chamber just anterior and parallel to the iris through a 23-gauge needle track initiated 2 to 2.5 mm posterior to the limbus. Viscoelastic material was not routinely used to maintain the anterior chamber. A piece of donor cornea or sclera was then secured over the tube entry site. One to 2 fenestrations (resulting in 2 to 4 slits) were made in the tube between the tissue patch graft and the ligation suture depending on the level of preoperative IOP using a TG 160-6, 5.5-mm length $^1/_2$ circle spatulated needle (Ethicon, Johnson & Johnson Ltd.). Conjunctiva and Tenon's capsule were reapproximated to the limbus and closed with 8-0 polyglactin sutures (Aurolab).

Postoperatively, topical antibiotics were used 4 times daily for 4 weeks, topical steroid drops for 12 weeks in a tapering dose, and topical cycloplegic eye drops once at night for 8 weeks were prescribed.

Primary Outcome Measure

Cumulative failure rate of the AADI at 2 years was defined as IOP $>$18 mmHg or not reduced by at least 30% below baseline on 2 consecutive follow-up visits after 3 months, IOP $\leq$ 6 mmHg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma or a complication, or loss of light perception vision. Complete success was defined as achieving these IOP levels without AGMs, and qualified success was considered when IOP control was achieved with AGMs. Cumulative rates of complete and qualified success were also calculated for IOP ranging between 6 and 15 mmHg and 6 and 21 mmHg for the purpose of comparison with other studies. Reoperation for glaucoma or a complication was defined as additional surgery requiring a return to the operating room including cyclodestruction surgery. Complications leading to more than 2 lines loss in visual acuity for 2 consecutive visits were termed as "vision threatening."

Statistical Analysis

All continuous variables were described as mean with standard deviation or median with interquartile range (IQR), and categoric variables were described as proportions (n, %). Visual acuity was converted to logarithm of minimum angle of resolution (logMAR) for statistical analysis. Group-wise comparisons were made between continuous variables using the Student t test or Wilcoxon rank-sum test for nonparametric variables. The chi-square test or Fisher exact test was used to analyze group differences across categoric variables. Comparison of IOP between pre- and post-AADI at different time intervals was carried out using 2-way analysis of variance with Bonferroni adjustments.

Survival analysis was performed using the failure of the AADI as the censoring variable, and Kaplan−Meier curves were plotted to depict cumulative survival rates at various time points. Time to failure was defined as an interval between the time of surgery and failure.

Differences between survival curves were determined using the log-rank test. The survival probability for each outcome was assessed using the Cox proportional hazards models and displayed using hazard ratios (HRs) with 95% confidence intervals (CIs). Covariates used for adjusting HRs were those with a $P < 0.1$ in univariate models and those that have been shown to influence failure rates in previous studies.

Table 1. Baseline Demographics and Clinical Characteristics of Patients

Variable	Mean/N	SD (95% CI) or %
Age (yrs)	45.4	17.4 (42.7–48.18)
Gender (n, % men)	118	75%
Preoperative IOP (mmHg)	34.7	9.9 (33.1–36.2)
Preoperative AGM	3.2	0.7 (3.1–3.3)
Preoperative BCVA (logMAR)	0.56	0.5 (0.48–0.65)
Mean deviation (dB)	−20.6	7.9 dB (−22.4 to −18.8)
PSD (dB)	9.2	3.6 (8.4–10.0)

AGM = antiglaucoma medication; BCVA = best-corrected visual acuity; CI = confidence interval; dB = decibels; IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution; PSD = pattern standard deviation; SD = standard deviation.

Data were entered into Microsoft Excel (Redmond, WA) and analyzed using STATA (version 12.1, I/C, Forth Worth, TX) statistical analysis software package. $P < 0.05$ was considered statistically significant.

Results

A total of 195 eyes underwent AADI during the study period, of which 158 eyes of 158 patients with a minimum of 2 years were included in the analysis. There were no significant differences in eyes with a follow-up of <2 years versus those with >2 years (Table S1, available at www.aaojournal.org). The baseline demographic and clinical features of the study population are shown in Table 1.

The different etiologies of glaucoma included in the study along with their mean IOP and number of AGMs at the time of AADI are presented in Table 2. The most common type of glaucoma in our patient cohort was secondary open-angle glaucoma (n = 71, 45%) followed by primary open-angle glaucoma (POAG) (n = 38, 24%). The most common forms of secondary open-angle glaucomas were uveitic and aphakic glaucoma (n = 12 each, 8%), and the most common forms of secondary angle-closure glaucomas were iridocorneal endothelial syndrome (n = 5, 3%) and postpenetrating keratoplasty glaucoma (n = 6, 4%). There were 21 patients (n = 13%) whose fellow eyes were blind as the result of disease. Ninety-seven eyes (61%) had prior trabeculectomy with mitomycin C, of which 2 eyes underwent repeat trabeculectomy and 3 eyes had cyclophotocoagulation due to persistent increased IOP. An additional 19 eyes in the cohort had previous pars plana vitrectomy with silicone oil injection or gas tamponade, of which 3 underwent prior trabeculectomy before AADI. Twenty-eight eyes (18%) were treatment naive, that is, did not have prior surgery for glaucoma at the time of AADI surgery, of which most were secondary glaucomas, including Sturge–Weber syndrome (n = 4), iridocorneal endothelial syndrome (n = 3), aphakic glaucoma (n = 3), uveitic glaucoma (n = 3), and neovascular glaucoma (n = 3).

The median preoperative IOP was 32 mmHg (IQR, 28–42 mmHg) and ranged from 16 to 58 mmHg with a median of 3 AGMs (IQR, 3–4 medicines). The episcleral plate of the AADI was placed in the inferonasal quadrant in 84 eyes (53%), superotemporal quadrant in 69 eyes (44%), inferotemporal quadrant in 4 eyes (2.5%), and superonasal quadrant in 1 eye (0.6%). The median IOP values at different time points are shown in Figure 1, and mean values are shown in Table 3.

The mean IOP decreased significantly at 1 month by 32% from baseline and by 56% at 1-year follow-up, and the mean number of AGMs also decreased by 50% (Table 3). The IOP decreased significantly from the previous visit at all time points ($P < 0.001$) up to the 6-month period, after which it stabilized (Fig 1). For those with no coexistent ocular pathology, the BCVA reduced marginally from 0.35±0.5 logMAR preoperatively to 0.42±0.6 logMAR at 12 months follow-up ($P = 0.22$) and remained at the same level at the last follow-up (0.45±0.7 logMAR, $P = 0.19$). For those with coexistent

Table 2. Distribution and Clinical Characteristics of Different Glaucoma Etiologies in the Study

Type of Glaucoma	N	Mean IOP at Baseline	No. of AGMs	Previous Trabeculectomy (n, %)
POAG	38	30.5±8.4	3.4±0.7	32 (84%)
JOAG	12	34.5±13.7	3.1±0.8	10 (83%)
PACG	14	32.6±11.4	3.3±0.7	13 (93%)
Congenital glaucoma†	7	35.7±9.7	3.3±0.7	6 (86%)
Developmental glaucoma‡	2	39±4.2	3	0
Secondary OAG:	71	36.3±9.3	3.1±0.7	31 (44%)
• Uveitic glaucoma*	12	42.6±9.6	2.4±0.9	9 (75%)
• Aphakic glaucoma*	12	41±8.7	3.4±0.6	5 (42%)
• Neovascular glaucoma*	10	42.6±9.6	3.3±0.4	2 (20%)
• PXF glaucoma*	11	30.6±8.4	2.8±0.6	8 (73%)
• Sturge–Weber syndrome	4	26.5±5.5	3.3±0.5	0
Secondary ACG:	14	39.4±9.1	3.3±0.7	6 (43%)
• ICE syndrome*	5	42±7.1	3.4±0.9	1 (20%)
• Post PK glaucoma*	6	40±6.1	3.6±9.5	0

ACG = angle-closure glaucoma; AGM = antiglaucoma medication; ICE = iridocorneal endothelial syndrome; IOP = intraocular pressure; JOAG = juvenile open-angle glaucoma; OAG = open-angle glaucoma; PACG = primary angle-closure glaucoma; PK = penetrating keratoplasty; POAG = primary open-angle glaucoma; PXF = pseudoexfoliation.
*Most common secondary glaucoma reported.
†Eyes of patients with congenital glaucoma who are now adults with clinical records of congenital glaucoma evident at birth or soon after were included.
‡Eyes with Axenfeld–Rieger anomaly considered a developmental anomaly were included.

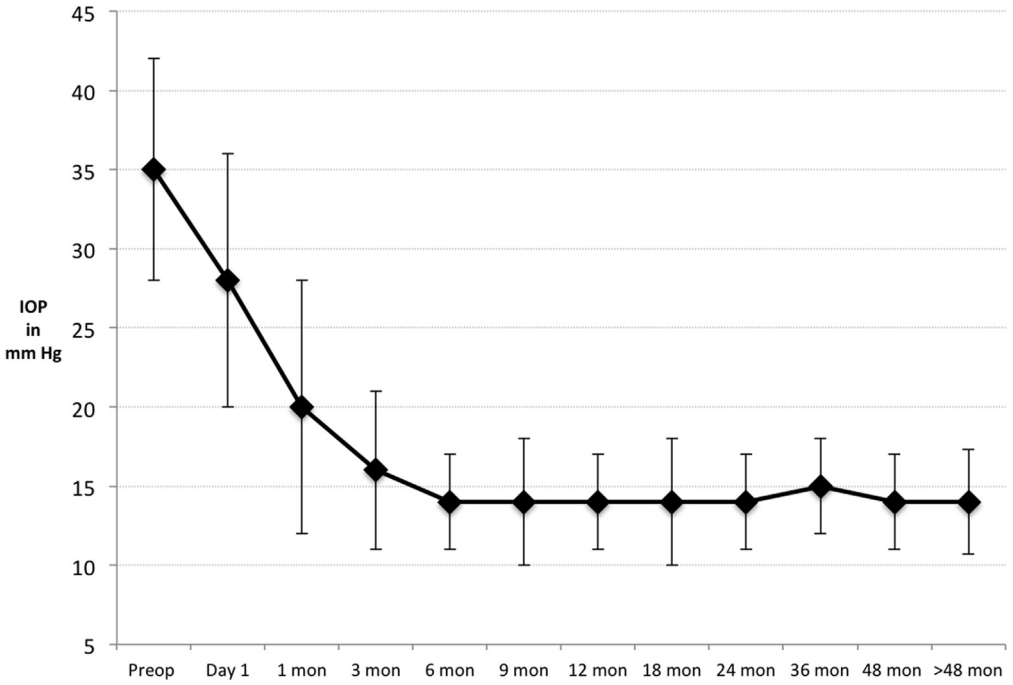

Figure 1. Median IOP values from baseline to final follow-up. IOP = intraocular pressure.

pathology, corneal (n = 17, 11%) and retinal diseases (n = 23, 15%) were the most common cause for the decrease in vision during follow-up.

Forty-seven complications were seen in 38 eyes (24%) during the study period (Table 4). During the early postoperative period (<3 months), choroidal detachment was the most common complication followed by fibrinous reaction in the anterior chamber and hypotony. Choroidal detachment was the most common complication between 3 months and 1 year. Tube occlusion was seen in 2 eyes, and 1 eye had retinal detachment. Delayed complications (>1 year) occurred in the form of corneal decompensation, graft failure, and delayed hypotony. Significant vision loss occurred in 9 eyes (5.7%) as the result of corneal decompensation (n = 3), retinal detachment (n = 1), aqueous misdirection (n = 1), and hypotony maculopathy (n = 4). Re-surgery (44 procedures) was performed in 38 eyes (24%) during the follow-up period (Table 5), of which cataract surgery was the most common intervention followed by pars plana vitrectomy.

Tube ligation, tube trimming, and choroidal detachment drainage were interventions in the early postoperative period, and cataract surgery and pars plana vitrectomy were the most common procedures in the later period (Table 5). Pars plana vitrectomy with silicone oil injection was required for 1 case of aqueous misdirection, 1 case of tube occlusion with vitreous, 2 cases of persistent hypotony, and 1 case of retinal detachment.

Table 3. Intraocular Pressure Comparisons at Different Time Points in the Study

IOP	Mean	SD (95% CI)	No of AGMs	*P* Value*
Baseline	34.70	9.9 (33.1–36.2)	3.2±0.7	
Day 1	27.90	11.5 (25.3–30.6)	2±0.9	0.002
1 month	23.36	11.7 (21.5–25.2)	2.1±0.9	0.001
3 mos	17.60	8.9 (16.2–19.0)	1.5±1.1	<0.001
6 mos	15.30	6.6 (14.3–16.3)	1.6±1.9	0.002
9 mos	14.55	5.9 (13.5–15.5)	1.7±2.1	0.17
12 mos	15.18	6.6 (14.1–16.3)	1.5±1.1	0.67
18 mos	15.10	6.7 (13.8–16.1)	1.4±1.0	0.98
24 mos	15.60	6.7 (14.5 -16.7)	1.5±1.1	0.27
36 mos (n = 55)	16.20	7.1 (14.3–18.0)	1.7±1.1	0.54
48 mos	15.30	7.6 (12.5–18.1)	1.5±1.2	No observations

AGM = antiglaucoma medication; CI = confidence interval; IOP = intraocular pressure; SD = standard deviation.
**P* value compared with the previous IOP.

Table 4. Complications at Different Time Points During Follow-up*

Complication	≤3 Mos	3–12 Mos	>12 Mos	Total
Choroidal detachment	8 (5%)	5 (3%)	—	**13 (8%)**
Corneal decompensation	2 (1%)	—	3 (2%)	**5 (3%)**
Graft failure	—	1 (0.6%)	2 (1%)	**3 (2%)**
Macular edema	2 (1%)	2 (1%)	—	**4 (2.5%)**
Fibrin in AC	4 (2.5%)	1 (0.6%)	—	**5 (3%)**
Aqueous misdirection	1 (0.6%)	—	—	**1 (0.6%)**
Anterior uveitis	1 (0.6%)	1 (0.6%)	1 (0.6%)	**3 (2%)**
Hypotony	2 (1%)	—	2 (1%)	**4 (2.5%)**
Tube exposure	1 (0.6%)	—	—	**1 (0.6%)**
Tube retraction	1 (0.6%)	—	—	**1 (0.6%)**
Plate exposure	—	1 (0.6%)	—	**1 (0.6%)**
Plate displacement	—	1 (0.6%)	—	**1 (0.6%)**
Tube occlusion by vitreous	—	2 (1%)	1 (0.6%)	**3 (2%)**
Tube occlusion by iris	—	1 (0.6%)	—	**1 (0.6%)**
Retinal detachment	—	1 (0.6%)	—	**1 (0.6%)**
Total	**22 (14%)**	**16 (10%)**	**9 (6%)**	**47 (30%)**

AC = anterior chamber.
Boldface indicates the total number of different types of complications at different time points during follow-up.
*All % are out of total patients (n = 158).

Explantation of the AADI was performed in 1 eye after aqueous misdirection that developed retinal detachment after vitrectomy and in 2 eyes for significant plate exposure and displacement.

Considering success as IOP between 6 and 18 mmHg or at least 30% reduction from baseline, failure was seen in 62 eyes (39%) at 4 years. Of these, 50 (81%) were due to inadequate IOP control or hypotony, 3 (5%) were due to complications, and 9 (14%) were due to re-surgery. Table 6 shows the cumulative rates of complete and qualified success at various time points based on different outcome criteria. Kaplan–Meier estimates showed that the cumulative probability of failure was 9.5% (95% CI, 5.8–15.2) at 1 year, 27.8% (95% CI, 21.5–35.5) at 2 years, 38.9% (95% CI, 31.1–47.8) at 3 years, and 50.1% (95% CI, 40.5–60.6) at 4 years. The Kaplan–Meier plot for cumulative failure at the various time points is shown in Figure 2.

Those with secondary glaucomas had lower failure rates compared with primary glaucoma (log-rank $P = 0.01$) (Fig 3). However, there were no differences in failure rates between eyes with open-angle and angle-closure glaucoma (log-rank $P = 0.75$) (Fig 4). Likewise, there were no differences in the cumulative failure rates with different forms of glaucoma (Table 7, log-rank $P = 0.22$).

Cox proportional hazards showed that, after adjusting for age and gender, eyes with secondary glaucoma had a 58% lower risk of

Table 5. Re-surgery at Different Time Points During Follow-up

Re-surgery	≤3 Mos	3–12 Mos	>12 Mos	Total
Tube ligation	1 (10%)	—	—	**1 (2.2%)**
Tube trimming	1* (10%)	—	2 (15%)	**3 (7%)**
Tube repositioning	—	—	1 (8%)	**1 (2.5%)**
PPV ± SOI	1 (10%)	2 (10%)	2 (8%)	**5 (11%)**
CD drainage	2 (20%)	1 (5%)	—	**3 (7%)**
Scleral patch graft	1* (10%)	1* (5%)	—	**2 (4%)**
Repeat AADI	1 (10%)	1 (5%)	2 (15%)	**4 (9%)**
AADI exchange	1 (10%)	—	—	**1 (2.5%)**
AADI explantation	1* (10%)	2* (10%)	—	**3 (7%)**
Iris repositioning	1 (10%)	—	—	**1 (2.5%)**
Cataract surgery	—	8 (40%)	4 (31%)	**12 (27%)**
Repeat PK	—	2 (10%)	2 (15%)	**4 (9%)**
Cyclophotocoagulation	—	2* (10%)	1 (8%)	**3 (7%)**
Synechiae release		1* (5%)	—	**1 (2.2%)**
Total	**10 (100%)**	**20 (100%)**	**14 (100%)**	**44 (100%)**

AADI = Aurolab Aqueous Drainage Implant; CD = choroidal detachment; PK = penetrating keratoplasty; PPV = pars plana vitrectomy; SOI = silicone oil infusion.
Boldface indicates the total number of different types of resurgeries at different time points during follow-up.
*Same eye.

Table 6. Complete and Qualified Success Based on Different Success Criteria at Different Time Points

	Complete Success (≤21)*	Qualified Success (≤21)*	Complete Success (≤18)†	Qualified Success (≤18)†	Complete Success (≤15)‡	Qualified Success (≤15)‡
12 mos	91.7 (86.3–95.2)	91.7 (86.3–95.1)	90.5 (84.7–94.2)	91.1 (85.5–94.6)	89.2 (83.2–93.2)	89.2 (83.3–93.2)
24 mos	79.1 (71.9–84.7)	80.4 (73.3–85.7)	71.5 (63.8–77.9)	73.4 (65.8–79.6)	63.3 (55.3–70.2)	66.5 (58.5–73.2)
36 mos	62.5 (53.7–70.1)	72.3 (63.8–79.2)	49.5 (40.7–57.6)	59.5 (50.4–67.5)	34.6 (27.1–42.3)	44 (35.2–52.4)
48 mos	49.6 (40.1–58.5)	64.6 (54.4–73.1)	34.7 (26.1–43.6)	48.5 (38.1–58.2)	18.9 (12.7–26.2)	30.8 (21.7–40.3)

*Success = IOP range 6–21 mmHg or 20% reduction from baseline.
†Success = IOP range 6–18 mmHg or 30% reduction from baseline.
‡Success = IOP range 6–15 mmHg or 40% reduction from baseline.

failure (HR, 0.42; 95% CI, 0.20–0.86; $P = 0.02$), and those with a history of trabeculectomy also had a 50% lower risk of failure (HR, 0.50; 95% CI, 0.25–0.98; $P = 0.045$).

Discussion

In this study, we report the intermediate-term outcomes of eyes that underwent AADI surgery for intractable glaucoma due to a myriad of causes. The overall failure rate of surgery was 39%, and the cumulative failure rate of surgery gradually increased with time from 9% at 1 year to 50% at 4 years. A significant reduction was achieved in both IOP and the number of AGMs during the course of follow-up. One-fourth of eyes had a complication, although vision-threatening complications were seen in only a few. Actual tube-related complications such as tube exposure, retraction, plate exposure, and displacement were seen in 4 eyes, of which 3 eyes underwent AADI explantation. Likewise, re-surgery rates were low, with cataract surgery being the most common re-surgery for visual rehabilitation.

A pooled analysis of 5-year outcomes from 2 large randomized controlled trials comparing the Ahmed valved glaucoma drainage device with the Baerveldt's nonvalved implant showed that the Baerveldt group had a lower failure rate and lower mean IOP on fewer medications than the Ahmed group, although the Baerveldt implantation carried a higher risk of hypotony.[3] The analysis involved 514 eyes with failed trabeculectomy or high risk for trabeculectomy failure, a cohort similar to ours. The cumulative failure rate in the Baerveldt group was 37% at 5 years, which was lower than 50% at 4 years in our study. The lower success rate in our study may be due to the more severe nature of glaucoma in our subjects compared with previous studies. When considering the success threshold at 21 mmHg, our success rates are comparable to the outcomes from the Baerveldt group. Surprisingly, we also found that secondary glaucomas had a lower failure rate compared with primary glaucomas. This is difficult to explain but may be due to the fact that eyes with secondary glaucoma had AADI as the primary surgery and had lesser conjunctival scarring leading to better IOP control. However, this phenomenon needs further study.

The mean IOP in the Baerveldt group (13.2±4.7 mmHg) at 5 years was similar to what we report at all time points between 2 and 4 years in our study. Likewise, patients in the large pooled analysis required 1.5±1.4 AGMs, similar to the

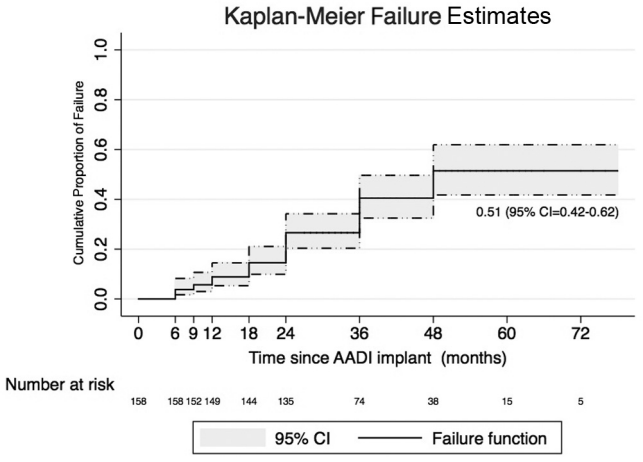

Figure 2. Kaplan–Meier plot showing cumulative failure rate with 95% CI of the AADI at different time points. AADI = Aurolab Aqueous Drainage Implant; CI = confidence interval.

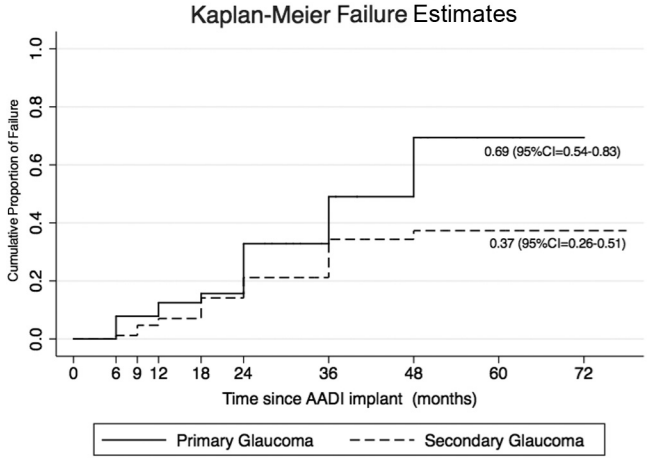

Figure 3. Kaplan–Meier plot showing comparison of failure rates between primary and secondary glaucoma groups at various time points. AADI = Aurolab Aqueous Drainage Implant; CI = confidence interval.

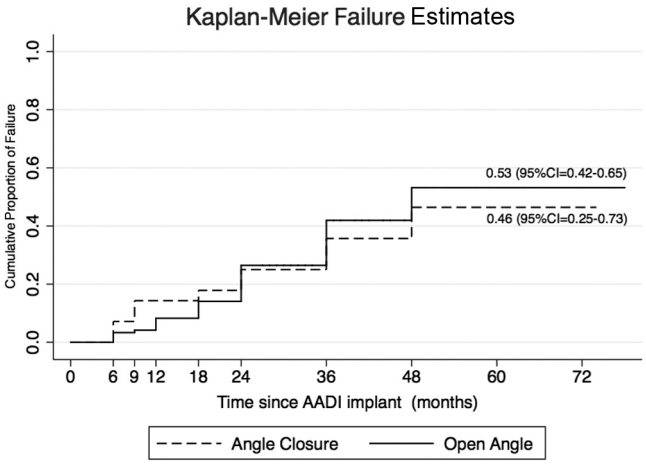

Figure 4. Kaplan–Meier plot showing comparison of failure rates between angle closure and open-angle glaucoma groups at various time points. AADI = Aurolab Aqueous Drainage Implant; CI = confidence interval.

1.5±1.2 drugs reported from our cohort. Many previous studies have reported similar results with the Baerveldt implant. In a recent study, Bouhenni et al[12] compared primary versus secondary Baerveldt implant for management of glaucoma by a single surgeon between 1994 and 2010 and reported a failure rate of 61% at 5 years in the secondary group. In a cohort of 42 uveitic eyes with glaucoma, Chhabra et al[13] reported the 25% cumulative probability of failure at 5 years based on definitions of failure similar to our study. El Wardani et al[14] showed 3-year failure rates ranging from 15% to 37% in eyes receiving the Baerveldt implant, although eyes that had combined phacoemulsification with Baerveldt had a higher failure rate. Marchini et al[15] used a slightly modified technique for Baerveldt implant insertion and reported a cumulative failure rate of 28% at 4 years in a cohort of 160 eyes.

Although most of these studies, including ours, report relatively high failure rates of more than 25% at 4 to 5 years follow-up, IOP reduction in eyes with refractory glaucoma is difficult to achieve and may depend on the underlying etiology. We believe that our failure rates with the AADI at 2, 3, and 4 years follow-up are relatively similar to results reported with the Baerveldt implant for refractory glaucomas included in our cohort.

The Baerveldt implant has also been used for treatment-naïve eyes to reduce IOP. In the Tube Versus Trabeculectomy study,[16] 107 eyes, the majority of which had POAG, with or without prior trabeculectomy were included in the primary tube group and implanted with the 350 mm^2 Baerveldt implant. At 5 years, the cumulative rate of failure in these eyes with tubes was 29%.[16] In our cohort of 38 eyes with POAG, we found a slightly higher failure rate of 44% at 4 years. This may be explained by the fact that POAG eyes in our study had a more advanced disease as evidenced by higher mean IOP (30.5 vs. 25.1 mmHg) at baseline and more than 80% had previous trabeculectomy. Namavari et al,[17] using a retrospective study design, have shown an excellent success rate of 84% for treatment-naive eyes with predominantly open-angle glaucoma at 1 year using the Baerveldt implant as the primary surgical treatment. Our results in the POAG group are similar to the results reported in the literature using the Baerveldt implant.

Complications were experienced by 1 in 4 eyes after the AADI implant, transient choroidal detachment due to hypotony being the most common one. There were few vision-threatening complications such as retinal detachment and graft failure in eyes with preexistent penetrating keratoplasty. In the Ahmed versus Baerveldt study, Budenz et al[5] reported a slightly higher cumulative rate of complications (56% at 5 years) in the Baerveldt group, although approximately 24% experienced vision-threatening complications. Bouhenni et al[12] reported rates of complications similar to our study.[12] The incidence of re-surgery after AADI was also similar to that reported in the literature for the Baerveldt implant.[3,13,15,18] Cataract surgery was the most common surgery required in our cohort after the AADI implant. The protruding tip of the tube inside the anterior chamber may cause disturbances in the milieu and resultant cataract genesis. There was minimal need for tube trimming and ligation, and only 1 eye each experienced tube exposure, retraction, plate exposure, and displacement. These low rates of tube-related complications may be because the surgeries were performed by a single glaucoma surgeon (G.V.P.), initially under the observation of senior surgeon PP, both of who were well experienced with placing other glaucoma drainage devices, such as the Ahmed and Baerveldt implants. The only noticeable difference in AADI implantation when compared with the Baerveldt glaucoma implant is that the episcleral plate and

Table 7. Cumulative Failure Rates at Different Time Points Per the Primary Diagnosis

Diagnosis	POAG	JOAG	PACG	SOAG	SACG
Time					
6 mos	5.3 (1.3–19.4)	8.3 (1.2–46)	14.3 (3.8–46)	1.4 (0.2–10)	0
12 mos	7.9 (2.6–22)	16.7 (4.4–52)	14.3 (3.8–46)	5.6 (2.1–14.3)	14.3 (4–46)
18 mos	10.5 (4.1–26)	25 (8.8–59.1)	21.4 (7.5–53)	14 (8–25)	14.3 (4–46)
24 mos	23.7 (13.1–41)	58.8 (33–84)	35 (17–65)	22.5 (14–34)	14.3 (4–46)
36 mos	47.7 (31.4–67)	58.8 (33–84)	45 (23–74)	36 (25–50)	26.5 (9–64)
48 mos	71.5 (52.8–87)	58.8 (33–84)	72 (33–98)	39 (27–54)	26.5 (9–64)

JOAG = juvenile open-angle glaucoma; PACG = primary angle-closure glaucoma; POAG = primary angle-closure glaucoma; SACG = secondary angle-closure glaucoma; SOAG = secondary open-angle glaucoma.

tube of AADI is less stiff and of silicone material, and the amount of barium to add for AADI was chosen by Aurolab and was not exactly equivalent to the Baerveldt glaucoma implant.

The AADI implant has been used for managing glaucomas in the recent past. Pathak Ray and Rao[8] reported 1-year results from a retrospective comparative series between the AADI (n = 52) and the Ahmed valve (n = 36) and found greater IOP reduction with AADI.[8] They also reported a failure rate of 8% at 1 year, similar to our results. In another separate and noncomparative series, the same authors reported short-term outcomes from 54 eyes with refractory glaucoma and a minimum of 3 months follow-up. They again reported a low overall failure rate of 8% at last follow-up, but the study was underpowered to report on cumulative failure rates at different time points.[9] More recently, Rathi et al[10] reported outcomes from a randomized controlled trial comparing results from the AADI and Ahmed implant in 38 eyes with refractory glaucoma. At 6 months, the authors reported a higher success rate in the AADI group (79%) compared with the Ahmed implant group (47%).

The drawbacks of our study are the retrospective study design and the lack of data on endothelial cell counts after AADI placement. The main advantages of the study are the relatively large sample of eyes with refractory glaucoma and good follow-up of a minimum of 2 years.

In conclusion, AADI surgery appears to be a viable option for glaucoma refractory to other surgical or medical management methods. Longer follow-up studies will be required to determine cumulative failure rates with the AADI. In addition, head-to-head prospective comparative studies with the Baerveldt implant will be important to establish whether the AADI is as good as the Baerveldt for managing these complicated glaucomas. Last, a cost-effectiveness analysis will be essential to understand whether the lower cost of the AADI translates into a lower overall cost of treatment for these patients.

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Abbreviations and Acronyms:
AADI = Aurolab Aqueous Drainage Implant; **AGM** = antiglaucoma medication; **BCVA** = best-corrected visual acuity; **CI** = confidence interval; **HR** = hazard ratio; **IOP** = intraocular pressure; **IQR** = interquartile range; **logMAR** = logarithm of minimum angle of resolution; **POAG** = primary open-angle glaucoma.

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