
# Outcomes of Glaucoma Drainage Device Implantation and Trabeculectomy with Mitomycin C in Glaucoma Secondary to Aniridia

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**Title Page**

**Complete title:**
**Outcomes of Glaucoma Drainage Device Implantation and Trabeculectomy with Mitomycin C in Glaucoma Secondary to Aniridia**

**Short title: AADI Versus Trabeculectomy in Aniridia**

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## INTRODUCTION

Glaucoma or ocular hypertension associated with aniridia has been reported to occur in 6% to 75% of patients, and generally develops during the first two decades of life. Intraocular pressure (IOP) elevation has been variably attributed to angle closure due to progressive anterior rotation of the rudimentary iris, cleavage abnormalities of anterior chamber angle, and dysgenesis of the Schlemm canal. Glaucoma associated with aniridia is frequently refractory to medical management, with most patients requiring incisional surgery.[1]

Goniosurgery, trabeculotomy, trabeculectomy, glaucoma drainage devices (GDDs), and cyclodestructive procedures have all been used to manage glaucoma association with aniridia with variable success rates.[1-9] Trabeculectomy is the most commonly performed primary surgical procedure, but GDDs have beend increasingly utilized as an alternative.[2,4,7,8,9] The Aurolab Aqueous Drainage Implant (AADI; Aurolab, Madurai, India) is a relatively new, cost effective shunt resembling the Baerveldt glaucoma implant, which has shown efficacy and safety similar to other GDDs.[10] This study compares the efficacy and safety of AADI placement and trabeculectomy with mitomycin C (MMC) in patients with glaucoma associated with aniridia .

## METHODS

This retrospective, comparative case series was approved by the Institutional Ethics Committee of the Aravind Hospital, Madurai, India, (RET201900331) and conformed to the ethical tenets of the Declaration of Helsinki. Medical records of patients who underwent trabeculectomy with MMC or the non-valved AADI implantation for glaucoma secondary to congenital aniridia between April 2005 and February 2015 were included in the study. In patients who underwent

bilateral surgery, the eye operated first was analyzed. Patients with follow-up of less than 12 months were not included in the analysis unless they reached a failure endpoint. Patients with previous glaucoma surgery or those who did not receive MMC with trabeculectomy were also excluded.

The data extracted from the medical record included age at diagnosis of glaucoma, age at surgical treatment, gender, family history of aniridia, laterality, history of previous intraocular surgeries, lens status, and any concomitant ocular disorders. Best-corrected visual acuity (BCVA), IOP, glaucoma medications, and cup:disc ratio were recorded at baseline and 1, 3, 6, and 12 months after surgery, as well as annually thereafter. Also noted were the duration of follow-up, complications, and reoperations.

**Surgical Procedures**

**AADI Implantation:** The same surgical procedure was used for all patients, for implantation of the 350mm$^2$ AADI, and all surgeries were performed by the same surgeon (GVP). The surgical technique and the postoperative regimen has been described in detail elsewhere.[10]

**Trabeculectomy with MMC:** A fornix-based conjunctival flap was raised as per the standard technique, and a triangular partial thickness scleral flap was dissected. This was followed by application of freshly prepared mitomycin C (MMC) 0.2 mg/ml using saturated Weck-Cel sponges for 2 minutes. A copious amount of balanced salt solution (BSS) was used to irrigate the surgical site after the sponges were removed. A paracentesis was performed followed by sclerostomy using a Kelly punch, and a broad based peripheral iridectomy. The scleral flap was then sutured with 10-0 nylon suture (Aurolab, Madurai, India), and the conjunctiva was closed with 8-0 polyglactin suture (braided coated polyglactin 910 violet; Ethicon, Johnson & Johnson

Ltd, Mumbai, India). Postoperatively topical steroid drops were used for 12 weeks in a tapering dose, a topical antibiotics 4 times daily for 2 weeks and cycloplegic eye drops once a day for a month.

**Primary Outcome Measure**

Surgical failure was defined as IOP > 21 mmHg or reduced < 20% from baseline at 2 consecutive follow-up visits after 3 months, IOP ≤ 5 mmHg on 2 consecutive follow-up visits after 3 months, reoperation for glaucoma or a complication, or loss of light perception vision. Eyes that had not failed by these criteria were categorized as successes. Eye that achieved success without supplemental glaucoma medications were classified as complete successes, while eyes requiring glaucoma medications were considered qualified successes.

**Statistical Analysis**

All continuous variables were described as mean with standard deviation (SD) or median with interquartile range (IQR), and categorical variables were described as proportions (n, %). Age at surgery, baseline IOP, cup to disc ratio were analyzed using independent t-test; baseline BCVA was presented as median (IQR) and analyzed using the Mann-Whitney U test; categorical variables were analyzed using a chi-square test to ascertain the comparability of the two groups.

Data was presented as mean (SD) for IOP and IOP glaucoma medications were analyzed using paired t-test; median (IQR) for logMAR visual acuity was analyzed postoperatively using Wilcoxon-sign rank test. Comparison of IOP between groups was analyzed using independent t-test and Mann-Whitney U test was used to compare medications and visual acuity between groups.

Fisher's exact test (difference in the total number of patients with postoperative complications and reoperations between treatment groups); data reported as number (percentage) of eyes in each cohort. The Kaplan Meyer plot for cumulative failure at various time points between trabeculectomy with MMC and AADI was also computed for each treatment group. A p-value $< 0.05$ was considered statistically significant.

**RESULTS**

A total of 30 eyes of 30 patients with glaucoma secondary to aniridia underwent surgical treatment, including 12 eyes that had a trabeculectomy with MMC and 18 eyes that had AADI implantation. Six additional patients were identified but were exluded from the study because they had less than 12 months of follow-up. The baseline demographic and clinical features of the study population are shown in Table 1. There were no significant differences in baseline characteristics such as age, gender, IOP, BCVA, cup:disc ratio, lens status or concomitant ocular disorders in the trabeculectomy and AADI groups.

Three eyes (25%) in the trabeculectomy group had previous cataract extraction with PCIOL implantation. Four eyes (22%) in the AADI group had undergone previous cataract surgery. Three eyes (75%) had PCIOL implantation, including two (50%) of them also underwent primary posterior capsulorhexis with anterior vitrectomy. One eye underwent simultaneous pars plana lensectomy along with a pars plana vitrectomy and was left aphakic.

Comparisons of IOP, visual acuity (VA), and glaucoma medications at baseline and across follow-up between the trabeculectomy and AADI groups are shown in Table 2. Mean postoperative IOP was significantly lower than baseline in the trabeculectomy and AADI groups throughout the first 2 years of follow-up. However, IOP was not significantly different from the

preoperative level at 3 years and 4 years postoperatively in either treatment group. It is noteworthy that a majority of patients were seen for 2 years after surgery, but follow-up was limited thereafter especially in the AADI group. The mean number of glaucoma medications was similar to the preoperative level in both treatment groups throughout 4 years of follow-up. There was also no significant difference in LogMAR VA from baseline in either treatment group, except for an improvement in VA in the AADI group at 3 months and 6 months.

Mean IOP was similar between both treatment groups at 1 month and 3 months. However, the AADI group had lower mean IOP compared with the trabeculectomy group at 6 months and thereafter, which was statistically significant with the exception of the 4-year time point (Figure 1). This greater IOP reduction was achieved with fewer glaucoma medications in the AADI group than the trabeculectomy group, although the difference was not statistically significant except at 4 years. LogMAR VA was similar between treatment groups throughout follow-up (Figure 2).

The outcomes at 2 years unadjusted for follow-up are presented in Table 3. All patients who completed 2-year follow-up visits and/or experienced a prior failure were included in this analysis. At 2 years, treatment failure had occurred in 7 (58%) eyes in the trabeculectomy group and 2 eyes (11%) in the AADI group ($p = 0.006$). In the trabeculectomy group, 2 eyes (17%) were classified as complete successes, and 3 additional eyes (5/12, 42%) were classified as qualified successes. In AADI group, 15 eyes (83%) were classified as complete successes, and 1 additional eye (16/18, 89%) was qualified successes. The rate of complete success was significantly higher in the AADI group compared with the trabeculectomy group ($p =<0.001$).

Kaplan-Meier survival curves using the primary definition of failure are shown in Figure 3. The cumulative probability of failure at 2 years was 58.3% in the trabeculectomy group (95%

CI=33.5 to 84.8%) and 11.1% in the AADI group (95% CI=2.9 to 37.6%, p = 0.05, log-rank) (HR = 3.88; 95% CI = 1.1 to 18.1, p=0.05). Figure 4 shows failure rates for the two treatment groups using alternative outcome criteria. Patients with persistent hypotony, reoperations for glaucoma or a complication, or loss of light perception of vision were still classified as treatment failures. However, the upper IOP limit distinguishing success from failure was changed. When inadequate IOP reduction was defined as IOP > 18 mmHg or reduced < 30% from baseline on 2 consecutive visits after 3 months, the cumulative probability of failure at 2 years was 75% (95%CI=49-93%) in the trabeculectomy group and 22.7% (95%CI=8-56%) in the AADI group (p =0.01, log-rank); HR = 3.58; 95% CI = 1.1 to 13.2,( p=0.05). When inadequate IOP reduction was defined IOP > 15 mmHg or reduced < 40% below baseline on 2 consecutive visits after 3 months, the cumulative probability of failure at 2 years was 92% (95%CI=69-99%) in the trabeculectomy group and 48.7% (95%CI=26-77%) in the AADI group (p = 0.18 log-rank; HR = 1.62; 95% CI = -0.6 to 4.2, p=0.32).

The complications and reoperations of these eyes are listed in Table 4. The rate of complications in both the groups was comparable (p = 0.6), with one eye (5.5%) in the AADI group experiencing anterior chamber shallowing and one eye (8.3%) in the trabeculectomy group developing a superior ciliary staphyloma. One eye (8.3%) in the trabeculectomy group underwent surgery for retinal detachment, and another needed a bleb needling. There were four eyes (33%) that required a subsequent AADI implantation after the primary trabeculectomy failed. Five eyes (42%) from the trabeculectomy group needed surgery for cataract: one patient underwent cataract extraction, two underwent cataract surgery with PCIOL implantation, one had a lens extraction with a capsular tension ring implantation and the fifth patient had a lens

extraction with anterior vitrectomy. Interestingly, no patients in the AADI group required reoperations, including cataract surgery.

## DISCUSSION

Congenital aniridia is a rare panocular disorder with an incidence between 1 : 64000 and 1 : 100000. It is usually bilateral, and associated with mutations of the PAX6 gene, located in the short arm of chromosome 11 (11p13). The inheritance of aniridia is heterogenous with almost two-thirds being autosomal dominant pattern and the rest sporadic. The latter are usually associated with systemic dosorders. The profibrotic disorder is characterized by iris hypoplasia, but affects the entire anterior segment including the cornea, drainage angle and the lens, as well as the optic nerve and the fovea. Abnormalities in the differentiation of the angle, as well as of progressive synechial angle closure may result in glaucoma.[1,11-12]

Glaucoma associated with aniridia usually cannot be controlled with medical management and surgical treatment is frequently required. While many surgical options are available, trabeculectomy and GDD implantation are the most popular approaches. The AADI may prove to be a cost effective alternative for the more expensive GDDs. Our study is the first case series comparing the results of AADI and trabeculectomy in aniridia patients, and the largest case series comparing trabeculectomy with any GDD in patients with aniridia.

Previous studies have evaluated the outcomes of trabeculectomy and GDD surgery in patients with aniridia. Okada et al performed 17 trabeculectomies and 3 trabeculectomies with MMC in 10 eyes of six patients with aniridia who were less than 40 years of age. They reported good IOP control (IOP < 20 mm Hg with or without glaucoma medications) for a duration of 14.6 months (follow up range 2-54months).[8] In contrast, Nelson et al[1] and Grant et al[13] reported

that IOP remained uncontrolled after trabeculectomy in five of 14 patients, and in nine eyes of seven patients with glaucoma associated with aniridia, respectively. Adachi et al also reported that only one of five eyes treated with trabeculectomy achieved IOP control for 1 year.[6] Of the 12 patients who underwent trabeculectomy with MMC in the current series, six failed within the first six months, and two more failed at the end of three years. At four years, only three of nine patients under follow up demonstrated adequate IOP control.

Molteno et al reported that successful IOP control (defined as IOP < 20 mm Hg without medical treatment) was achieved in all 3 aniridia patients following Molteno shunt implantation.[14] However, the duration of follow-up was not mentioned in the report. Billson et al also reported surgical success and good IOP control during a three year follow up, in both their aniridia patients who underwent a Molteno shunt surgery.[15]

Adachi et al reported surgical success (IOP < 21 mm Hg) in two of six patients with glaucoma associated with aniridia following Molteno shunt implantation.[6] Out of the 17 eyes of 10 patients with aniridia evaluated by Wiggins et al, 11 eyes had good IOP control after an average of 2.8 surgeries. This included one of 11 eyes with trabeculectomy, and five of 20 eyes with cyclocryotherapy. The Molteno implantation, on the other hand, was successful in five of six eyes.[2] Cunliffe et al reported the results of three Molteno implants in patients with aniridia, and reported a partial success (IOP<22mm of Hg on IOP lowering medications) in all three eyes.[16] Almousa et al implanted the Ahmed Glaucoma Valve (AGV) in eight eyes of six aniridia patients, reporting good IOP control in seven eyes over a mean follow up of 37.4 months, with no deleterious effect on visual acuity. One eye went into pthisis bulbi following a traumatic globe rupture not related to the GDD implantation. Another eye had a persistent vitreous hemorrhage, followed by a total retinal detachment.[17] Demirok et al evaluated the results of

AGV implantation in six eyes of six aniridia patients, and reported a surgical success in five eyes at one month, and 4 eyes at one year follow up. At last visit, half the patients had good IOP control (Mean follow up 19 months). One patient had a tube exposure complicated with retinal detachment and vitreous hemorrhage one month after surgery.[18] Arroyave et al implanted the Baerveldt glaucoma implant in eight eyes with aniridia, and found good IOP control in seven eyes over 11 to 39 months of follow up. They reported that one eye developed a retinal detachment, while the vision remained stable in two eyes, and improved in five.[7] In our cohort, we found that the Baerveldt-like AADI group had a significantly higher success rate when compared with the trabeculectomy group across a broad range of IOP criteria defining success and failure.

It is difficult to compare across various studies because of differences in study populations, implant designs, follow-up time, and definitions of success/failure. However, we found a higher rate of surgical success and lower rate of postoperative complications following AADI placement than other studies involving GDDs. Advances in surgical technique and earlier institution of glaucoma medical therapy to ameliorate the hypertensive phase, may have contributed to better outcomes in our study. It is also possible that our study population has clinical characteristics that made them less predisposed to surgical failure. Thirteen (72 %) of the 18 eyes in the AADI group did not undergo any prior intraocular surgery compared to the high percentage (67-100 % ) of eyes in previous studies that had intraocular surgical intervention prior to GDD implantation.[2,6,16,18]

We observed lower mean IOPs in the AADI group relative to the trabeculectomy group at 6 months and thereafter, and these differences were statistically significant with the exception of the 4-year time point. The greater degree of IOP reduction in the AADI group was seen with similar use of glaucoma medications in both treatment groups. It is not surprising that the greater IOP lowering effect of the AADI was not seen until several months postoperatively. The AADI is a nonvalved GDD requiring a temporary restriction of aquous flow at the time of surgical implantation until encapsulation of the end plate develops.

Recent multicenter randomized clinical trials involving trabeculectomy and GDD surgery have reported high incidences of postoperative complications, although most are transient and self-limited. [19-22] A low rate of complications was seen in the present study, and complication rates were similar between the two treatment groups. It has been suggested that retrospective studies generally report lower rates of surgical complications than prospective trials. [19] Complications may be overlooked unless attention is specifically directed toward their detection, such as Seidel testing to identify wound leaks and peripheral fundus examination to detect choroidal effusions. Furthermore, complications may not be documented in the medical record if they are considered insignificant.

While our results with AADI are extremely encouraging, certain challenges exist when implanting a GDD in a patient with aniridia. Some surgeons have advocated the use of a limbus-based rather than a fornix-based conjunctival flap in eyes with limbal stem cell deficiency, including aniridia. [23] This approach avoids destruction of limbal stem cells. The lens is more vulnerable to injury with tube insertion in patients with aniridia, and we recommend positioning the tube peripherally over the lens zonules to avoid inadvertent violation of the lens capsule.

Interestingly, five patients in the trabecuectomy group and no patients in the AADI group required cataract surgery during follow-up in our study.

The present study has several limitations. The small sample size limits the power to detect significant difference between the two surgical procedures that were evaluated. Retrospective comparative case series like our study are subject to selection bias. Although no significant differences were noted between the two treatment groups, there were likely individual patient characteristics that directed the surgeon in selecting a glaucoma procedure. Postoperative interventions and use of glaucoma medications were left to the discretion of the surgeon, and no standard protocols were used to guide postoperative management. All surgical procedures were performed by a single surgeon in India using one type of GDD, and the results may not be generalizable to other patient populations and implant types. The concentration of MMC used in the trabeculectomy group was relatively low (0.2 mg/ml), especially for a cohort of eyes with high risk of fibrosis and in which the mean age is young. This may have reduced the surgical success rate. Limited follow-up was available, particularly after 2 years.

In summary, this study is the largest case series comparing trabeculectomy and GDD surgery in patients with aniridia. Placement of an AADI resulted in lower IOP and a higher rate of surgical success compared to trabeculectomy with MMC in eyes with glaucoma associated with aniridia. Surgical complications were observed with similar frequency after both glaucoma procedures. Cataract extraction was performed more often after trabeculecomty with MMC than AADI implantation.

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**Credit Author Statement**

**Indira Durai**: Conceptualization, Data curation, Formal analysis, Methodology, Writing-review & editing

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Table of Contents Statement

A retrospective comparative analysis of surgical management of eyes with glaucoma associated with aniridia showed that glaucoma drainage device implantation had a higher success rate than mitomycin-augmented trabeculectomy over 2 years.



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**FIGURE LEGENDS**

**Figure 1.** Plot of intraocular pressure (IOP) at baseline and follow-up. Data are presented as mean ± SD.

**Figure 2.** Distribution of change in visual acuity from baseline.

**Figure 3.** Kaplan-Meier curves showing cumulative probability of failure in the trabeculectomy and Aurolab Aqueous Drainage Implant (AADI) groups.

**Figure 4.** Kaplan-Meier curves showing cumulative probability of failure defining inadequate IOP control as (A) IOP > 15 mmHg or reduced < 40% and (B) IOP > 18 mmHg or reduced < 30%.