

Pilot Outcomes of Cataract Extraction with Modified Ahmed ClearPath 250 Retrobulbar/Intraconal Glaucoma Drainage Device Implantation with Inferior Sclerotomy in Patients with Advanced Glaucoma: A 1-year Retrospective Study

Louis Aghanwa BA¹, Laila Abouhasswa OD² and Daniel Laroche MD^{2,3*}

¹Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY

²Advanced Eye Care of New York, Queens Village, NY

³Department of Surgery, Morehouse School of Medicine

*Corresponding author

Daniel Laroche MD, Advanced Eyecare of New York, 49 West 127th Street, NY, NY 10027 and Morehouse School of Medicine, Atlanta, Georgia, USA. dlarochemd@aol.com

Received: September 08, 2026; **Accepted:** September 16, 2026; **Published:** September 30, 2026

ABSTRACT

Aim: This retrospective study aims to evaluate the real-world safety and efficacy of a modified Ahmed ClearPath 250 retrobulbar/intraconal glaucoma drainage device (GDD) placement in patients with advanced primary open-angle glaucoma (POAG) by assessing intraocular pressure reduction, medication burden, and postoperative complications over a 12-month follow-up period.

Methods: This study was conducted at Advanced Eye Care of New York, a private practice located in NY, NY. This was a single-center, retrospective chart review of adult patients with advanced POAG who underwent placement of a modified Ahmed ClearPath 250 retrobulbar/intraconal GDD between 2023 and 2025. De-identified demographic, clinical, and surgical data were extracted from the medical record and organized longitudinally to include baseline and postoperative follow-up at approximately 1, 3, 6, and 12 months. Outcomes assessed included intraocular pressure (IOP), glaucoma medication burden, visual acuity, visual field parameters when available, and postoperative complications at the 6-month and 1-year intervals from baseline measures. Changes in intraocular pressure and medication use over time were analyzed using paired longitudinal comparisons for eyes with available follow-up data.

Results: Twelve eyes underwent surgery, of which 9 had complete longitudinal data and were included in repeated-measures analysis of variance. Mean IOP decreased from 17.78 ± 7.69 mmHg at baseline to 13.44 ± 4.30 mmHg at 12 months (24% $p = 0.030$), with significant reduction achieved by 6 months ($p = 0.008$) and maintained through 12 months. Mean medication burden decreased from 2.22 ± 1.56 at baseline to 1.33 ± 0.71 at 12 months ($p = 0.004$), with significant reductions observed at 1 month ($p = 0.035$) and 6 months ($p = 0.027$). Visual acuity remained stable over the follow-up period ($p = 0.78$). Postoperative complications included transient hypotony in 3 eyes (25%), transient IOP elevation in 2 eyes (17%), hyphema in 1 eye (8%), and fibrin formation in 1 eye (8%). No cases of endophthalmitis, suprachoroidal hemorrhage, choroidal effusions, or retinal detachment were observed.

Conclusion: At 1 year, the modified retrobulbar/intraconal placement of the Ahmed ClearPath 250 GDD achieves substantial intraocular pressure lowering, reduces the need for topical medications. These findings support the short-term feasibility of this promising procedure, while longer-term studies are needed to establish its safety, durability, and clinical role.

Introduction

Glaucoma is a group of progressive optic neuropathies characterized by retinal ganglion cell loss and corresponding visual field deterioration, with elevated intraocular pressure (IOP) representing the most significant modifiable risk factor for disease development and progression. Globally, an estimated 80.5 million individuals aged ≥ 40 years are living with open-angle glaucoma in 2024, representing a prevalence of 2.8%,

and this burden is projected to more than double to 186.6 million by 2060, driven by population aging and rising myopia prevalence.¹ Primary open-angle glaucoma (POAG) accounts for approximately 80% of glaucoma cases in the United States with advanced POAG disproportionately affecting individuals of African ancestry, which is associated with nearly four times the risk of developing POAG, earlier age of onset, and greater disease severity compared with the average global population.^{2,3}

Citation: Louis Aghanwa BA, Laila Abouhasswa OD, Daniel Laroche MD. Pilot Outcomes of Cataract Extraction with Modified Ahmed ClearPath 250 Retrobulbar/Intraconal Glaucoma Drainage Device Implantation with Inferior Sclerotomy in Patients with Advanced Glaucoma: A 1-year Retrospective Study. *J Opto Opt Res*. 2026. 2(3): 1-8. DOI: doi.org/10.61440/JOOR.2026.v2.19

These disparities reflect not only inequities in access to care but also intrinsic biological susceptibility, contributing to the markedly higher rates of POAG-related blindness observed in Black populations. Moreover, because adult-onset POAG is frequently asymptomatic and progresses silently in its early stages, approximately 50% of affected individuals are unaware of their diagnosis, allowing peripheral visual field loss to accrue before central impairment is threatened.⁴

The goal of glaucoma treatment, lowering IOP, has historically relied on two main categories: topical pharmacotherapy and surgical intervention. Topical agents reduce IOP through several mechanisms, including suppression of aqueous humor production (e.g., beta-blockers) and enhancement of outflow (e.g., prostaglandin analogues), but their effectiveness depends on correct, sustained daily use over years. A recent systematic review and meta-analysis found that mean adherence (MPR/PDC) was only 54% at Year 1, with only 44% of patients classified as adherent at one year. In addition, the study found that patient persistence on first-line prostaglandin analogues drops dramatically over time from 75% at 6 months to only 31% at 3 years which underscores the need for surgical alternatives.⁵

Surgical intervention usually comes in the form of trabeculectomy. Trabeculectomy “remains a widely used but imperfect surgery due to failure from scarring, unpredictability, and life-long risk of infection,” despite its great improvement since the 1960s.³ However, the Tube vs. Trabeculectomy Study demonstrated that in eyes with prior ocular surgery, GDDs were associated with a significantly lower probability of failure (29.8% vs. 46.9%) and a lower reoperation rate (9% vs. 29%) compared with trabeculectomy, challenging the assumption that trabeculectomy is uniformly superior for long-term IOP control.⁴ In the prospective, randomized Gold-Standard Pathway Study, only 68.2% of trabeculectomy eyes achieved composite success at 12 months, while 63.6% required office-based postoperative interventions and 50% experienced hypotony at some point during follow-up. Complications related to the subconjunctival filtering bleb created during trabeculectomy, including fibrosis, leakage, and the need for postoperative needling to interrupt fibrotic tissue, reflect the inherent intensive monitoring of biologic fragility of bleb-dependent filtration.⁶ Because long-term success relies on maintaining a functioning subconjunctival reservoir, progressive scarring or dysregulated outflow can compromise sustained aqueous drainage and necessitate additional interventions. These limitations, together with the challenges of chronic topical therapy, underscore the need for durable, bleb-independent surgical strategies, particularly for high-risk populations in whom scarring, adherence barriers, and advanced disease compromise long-term control.

This study builds directly on our prior pilot investigation of combined phacoemulsification and intraconal (retrobulbar) Ahmed ClearPath 250 implantation with inferior sclerotomy in Black and Afro-Latino patients with advanced POAG, which demonstrated favorable short-term efficacy and safety at 6 months, with no cases of bleb formation, diplopia, or induced astigmatism.⁷ The present study extends this foundation to 12 months of follow-up, examining the durability and generalizability of this posterior drainage strategy in a high-risk population.

Methods

This was a single-center, retrospective cohort study conducted at Advanced Eye Care of New York, a private ophthalmology practice serving a predominantly underserved urban population in New York City. The study evaluated consecutive adult patients with advanced POAG who underwent intraconal retrobulbar glaucoma drainage device implantation between January 2023 and December 2025. Clinical data were obtained from the electronic medical record and de-identified prior to analysis. Postoperative follow-up evaluations were conducted at standardized intervals, including postoperative day 1, and months 1, 3, 6, and 12. The study protocol was reviewed and approved by the appropriate institutional review board, and a waiver of informed consent was granted due to the retrospective nature of the investigation. All study procedures were conducted in accordance with the principles outlined in the Declaration of Helsinki.

Eligible patients were adults aged 50 years or older with advanced POAG, defined according to the Hodapp-Parrish-Anderson classification who underwent implantation of an Ahmed ClearPath 250 glaucoma drainage device using a modified retrobulbar/intraconal technique with inferior sclerotomy.⁸

Inclusion criteria consisted of eyes with documented preoperative and postoperative clinical data and a minimum of 12 months of postoperative follow-up. Patients were excluded if they had secondary or non-POAG (including neovascular, uveitic, or congenital glaucoma); prior cyclodestructive procedures; active ocular infection or intraocular inflammation at the time of surgery; significant corneal abnormalities precluding accurate IOP measurement; prior incisional glaucoma surgery within six months before implantation; or incomplete medical records for time intervals observed. Demographic information, baseline ocular characteristics, and prior treatment history were recorded for all included patients (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Value
Number of eyes (n)	12
Age in years, mean	68.9±7.3
Laterality	
Right eye, n (%)	8 (66.6%)
Left eye, n (%)	4 (33.3%)
Baseline IOP, mean (mmHg)	18.67±7.23
Baseline number of glaucoma medications, mean (N)	2.67±pm 1.72
Baseline visual acuity (logMAR)	0.86±1.05

The primary outcome was intraocular pressure at 12 months postoperatively. Secondary outcomes included number of glaucoma medications, best-corrected visual acuity, surgical success rates, and postoperative complications. Surgical success was defined according to World Glaucoma Association and European Glaucoma Society guidelines as follows: complete success was defined as IOP between 5 and 21 mmHg with ≥20% reduction from baseline without glaucoma medications; qualified success was defined as achieving the same IOP criteria

with adjunctive medications. Surgical failure was defined as IOP >21 mmHg or <5 mmHg (hypotony) on two consecutive visits after 3 months, loss of light perception vision, or need for additional glaucoma surgery. As a secondary analysis, disease-specific threshold reflecting the advanced nature of the study cohort, outcomes were additionally assessed against a target IOP range of 8-12 mmHg, consistent with the aggressive IOP targets often pursued in patient with advanced glaucomatous optic neuropathy at high risk of further progression.

Surgical Technique

Device Preparation

The Ahmed ClearPath 250 (New World Medical, Inc., Rancho Cucamonga, CA), a non-valved glaucoma drainage device, was modified for retrobulbar implantation. Axial length was measured preoperatively using A-scan biometry. Tube and plate dimensions were individualized using the Laroche retrobulbar tube equation:

$$\text{Retrobulbar tube length (mm)} = (\pi \times \frac{1}{2} \times \text{axial length}) - 3$$

This formula calculates the optimal length to position the plate between the globe equator and optic nerve while minimizing interference with intraconal structures. The formula derives the arc length along the surface of the globe from the anterior segment to the posterior pole, approximating the eye as a sphere, and subtracts 3mm to account for the optic nerve, ensuring the distal end of the tube and plate are positioned between the equator and the optic nerve, without impinging on the optic nerve. The plate wings were trimmed to facilitate posterior intraconal positioning in between the muscles (Figure 1).

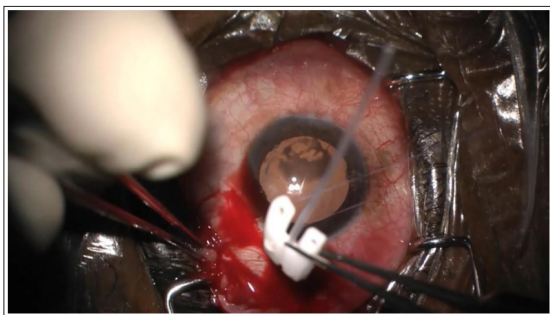


Figure 1: Intraoperative photograph showing the modified Ahmed ClearPath 250 (New World Medical, Inc., Rancho Cucamonga, CA) during retrobulbar/intraconal implantation. The white plate of the glaucoma drainage device is visible above the inferotemporal limbus. The plate wings have been trimmed to facilitate posterior positioning within the intraconal space.

Anesthesia and Exposure

> Following informed consent, patients were prepared and draped in standard sterile fashion. The surgeon (D.L.) was positioned temporally. Topical lidocaine gel was applied, followed by a peribulbar block consisting of 4 mL of 2% preservative-free lidocaine with 0.75% bupivacaine. A superotemporal conjunctival peritomy was performed using Westcott scissors to dissect, and large curved Steven scissors are used to access the retrobulbar space.

> Implantation Procedure

The modified ClearPath plate and tube are measured and trimmed to the calculated length.

The plate is inserted posteriorly into the retrobulbar space, superficial to the sclera and deep to Tenon's capsule, with the complete length of the tube present. After placing the plate into the retrobulbar space, the tube bevel is then trimmed. Clear cornea cataract surgery is performed temporally in the usual and customary manner. A 10-0 nylon suture is used to secure the wound to prevent any leak during the remaining procedure. Viscoelastic is injected into the anterior chamber and ciliary sulcus via an inferior paracentesis.

Using calipers, a point approximately 1.5 mm posterior to the limbus is marked. A 23-gauge needle is used to create a tract into the ciliary sulcus, and the tube is inserted with the bevel oriented downward into the anterior chamber. The tube position in the anterior chamber is confirmed intraoperatively with a cyclodialysis spatula. The tube is secured to the sclera using two 10-0 polypropylene sutures: one at the entry site and a second as far as possible approximately 10 mm posteriorly to enhance stability and prevent anterior migration. At both sites, the surgeon secures using 3-1-1 knots. A large corneoscleral patch graft (Katena Products, Inc.) is trimmed and secured over the full length of the tube with interrupted 8-0 vicryl sutures to prevent the plate from migrating anteriorly. Fibrin glue is applied to secure the graft and advance the conjunctiva over the tube.

Prophylactic Inferior Sclerotomy

Given the target IOP of 8–12 mmHg and associated 30% risk of choroidal effusion, a prophylactic inferior sclerotomy is performed. Through an inferior conjunctival dissection, a full thickness sclerotomy is created 4.5 mm posterior to the limbus using a crescent blade and 0.12 forceps. The conjunctiva was subsequently closed over the sclerotomy with 8-0 vicryl suture.

Postoperative Management

At the conclusion of the procedure, viscoelastic was left in approximately 50% of the anterior chamber. Intracameral antibiotics (moxifloxacin and triamcinolone acetonide) were administered. Postoperatively, patients were treated with topical antibiotics and corticosteroids per standard protocol. Follow-up examinations were conducted on postoperative day 1 and months 1, 3, 6, and 12. Complications were assessed at each visit through slit-lamp examination, IOP measurement, and dilated fundus evaluation.

Data Collection

Clinical data for all patients were obtained through retrospective review of the electronic medical record and de-identified prior to analysis. Collected variables included demographic characteristics, baseline ocular history, prior glaucoma treatments, and longitudinal postoperative outcomes. Outcome measures were recorded at standardized postoperative intervals, including postoperative day 1, 1 month, 3 months, 6 months, and 12 months.

IOP was measured using Goldmann applanation tonometry at each visit. The number of glaucoma medications was defined as the total count of topical IOP-lowering agents in use at each time point. Visual acuity was recorded as Snellen acuity and converted to logarithm of the minimum angle of resolution (logMAR) units for statistical analysis.

Postoperative complications were assessed at each follow-up visit and included hypotony, intraocular pressure spikes, hyphema, fibrin formation, choroidal effusion, suprachoroidal hemorrhage, corneal decompensation, retinal detachment, and endophthalmitis.

Sample Size and Statistical Analysis

This study was designed as a pilot and feasibility investigation of a novel intraocular glaucoma drainage device implantation technique. Of 12 eyes that underwent surgery, 9 had complete longitudinal data across all postoperative time points and were included in the primary repeated-measures analysis; the 3 excluded eyes were lost to follow-up prior to the 12-month visit and did not differ from included eyes in baseline IOP or medication burden. Changes in IOP and medication burden over time were analyzed using repeated-measures analysis of variance (ANOVA). Pairwise comparisons were conducted with Bonferroni correction. A p-value of <0.05 was considered statistically significant for all analyses.

Results

A total of 12 eyes from 12 patients underwent retrobulbar/intraocular Ahmed ClearPath 250 implantation with inferior sclerotomy. Of these, 9 eyes had completed longitudinal data and were included in repeated-measures analyses.

Mean IOP decreased from 17.78 ± 7.69 mmHg at baseline to 13.33 ± 2.92 mmHg at 6 months and 13.44 ± 4.30 mmHg at 12 months (Figure 2). Repeated-measures ANOVA demonstrated a statistically significant effect of time on IOP after correction for violation of sphericity ($p = 0.030$). Pairwise comparisons showed a significant reduction from baseline to 6 months ($p = 0.008$), with no significant change between 6 and 12 months, indicating sustained IOP control over the follow-up period.

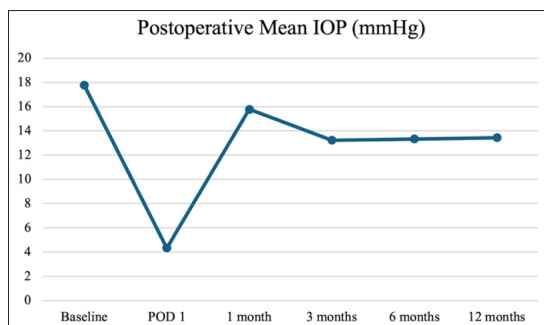


Figure 2: Mean intraocular pressure (IOP) following retrobulbar/intraocular Ahmed ClearPath 250 implantation with inferior sclerotomy. IOP decreased from baseline (17.78 mmHg) to postoperative day 1 (4.22 mmHg), followed by stabilization at 1 month (15.78 mmHg), 3 months (13.11 mmHg), 6 months (13.33 mmHg), and 12 months (13.44 mmHg), demonstrating early postoperative reduction with sustained long-term control.

Mean visual acuity (logMAR) was 0.57 ± 0.64 at baseline and remained stable at 0.58 ± 0.58 at 1 month, 0.46 ± 0.53 at 3 months, 0.54 ± 0.66 at 6 months, and 0.59 ± 0.36 at 12 months. There was no statistically significant effect of time on visual acuity (Greenhouse-Geisser corrected $p = 0.78$), indicating preservation of visual function throughout the postoperative period.

The mean number of topical glaucoma medications decreased from 2.22 ± 1.56 at baseline to 0.56 ± 1.01 at 1 month, followed by 1.22 ± 1.09 at 3 months, 1.11 ± 1.17 at 6 months, and 1.33 ± 0.71 at 12 months (Figure 3). Repeated-measures ANOVA demonstrated a significant effect of time on medication burden (Greenhouse-Geisser corrected $F(2.41, 19.26) = 6.96$, $p = 0.004$). Pairwise comparisons revealed significant reductions from baseline at 1 month ($p = 0.035$) and 6 months ($p = 0.027$). The overall medication burden remained reduced relative to baseline at 12 months.

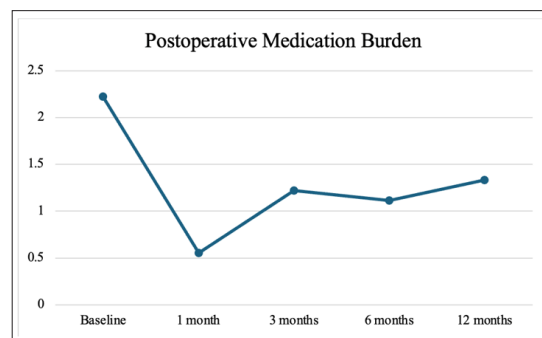


Figure 3: Mean number of topical glaucoma medications following retrobulbar/intraocular Ahmed ClearPath 250 implantation. Medication burden decreased from baseline (2.22 medications) to 1 month (0.56), with a gradual increase at 3 months (1.22), 6 months (1.11), and 12 months (1.33), remaining lower than baseline throughout the follow-up period.

Postoperative complications were documented in 12 eyes during the follow-up period. Early transient hypotony with associated shallow anterior chamber occurred in 3 eyes (25%). Transient postoperative IOP elevation was observed in 2 eyes (17%). Mild hyphema occurred in 1 eye (8%), and fibrin formation causing temporary central visual obscuration was observed in 1 eye (8%). No cases of endophthalmitis, suprachoroidal hemorrhage, persistent corneal decompensation, choroidal effusion, or retinal detachment were identified.

Collectively, these findings demonstrate that retrobulbar/intraocular Ahmed ClearPath 250 implantation with inferior sclerotomy provides sustained IOP reduction and significantly decreases medication burden while preserving visual acuity over 12 months of follow-up.

Discussion

In this single-center retrospective study of 9 eyes with advanced POAG, modified retrobulbar/intraocular Ahmed ClearPath 250 implantation was associated with sustained IOP reduction and a statistically significant decrease in medication burden through 12 months of follow-up. Mean IOP decreased from 17.8 mmHg at baseline to 13.4 mmHg at 12 months, a clinically meaningful reduction that was achieved by 6 months and maintained without significant rebound. Medication burden declined from 2.22 agents preoperatively to 1.33 at 12 months, with the reduction remaining statistically significant relative to baseline at early and intermediate time points despite partial reintroduction of therapy. Visual acuity remained stable over the follow-up interval, indicating preservation of functional vision in this advanced cohort. Taken together, these findings suggest that posterior orbital aqueous humor diversion using a modified retrobulbar technique can provide durable IOP control

while reducing dependence on topical therapy in patients with advanced disease.

Comparison with Traditional Tube Shunt Surgery

The ciliary sulcus placement (Figure 4) of the retrobulbar/intraconal approach offers several potential advantages over conventional anterior chamber GDD placement. A central concern with anterior chamber positioning is progressive corneal endothelial cell loss from chronic GDD tube-cornea proximity. Studies comparing anterior chamber versus alternative tube positions have demonstrated that anterior chamber placement results in approximately 2–3 times greater monthly endothelial cell density loss relative to ciliary sulcus placement, with corneal decompensation rates significantly higher in the anterior chamber group.⁹⁻¹² The exact positioning of the tube in the ciliary sulcus initially followed by securing it in the desired position with the 10-0 prolene suture ensures more accurate placement than inserting the tube after the plate has been secured.

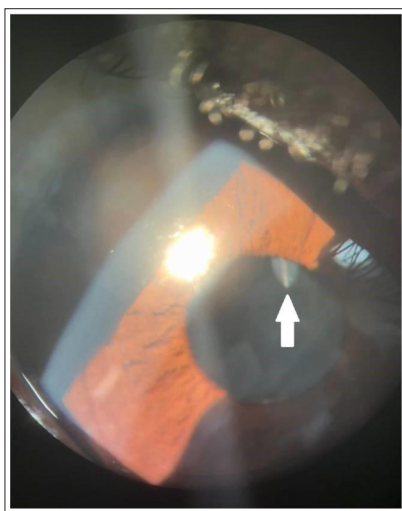


Figure 4: Intraoperative photograph demonstrating ciliary sulcus tube placement of the Ahmed ClearPath 250 drainage tube in the posterior chamber. The white arrow indicates the tube tip positioned in the ciliary sulcus, posterior to the iris and anterior to the intraocular lens, in contrast to the traditional anterior chamber placement in which the tube tip sits anterior to the iris. This posterior chamber positioning distances the tube from the corneal endothelium, circumventing the progressive endothelial cell loss that has been documented with conventional anterior chamber tube placement.

Conventional GDD surgery is also associated with a 12% rate of persistent diplopia, attributable primarily to mechanical restriction from plate positioning near the equatorial sclera and extraocular muscle insertions.¹³ Notably, no cases of diplopia were observed in this series. The intraconal positioning of the plate, posterior to the equatorial plane and removed from the extraocular muscle insertions, may reduce the risk of restrictive strabismus compared with traditional equatorial placement.

The IOP outcomes observed in this series compare favorably with established benchmarks for conventional GDD surgery. The Primary Tube Versus Trabeculectomy Study, a landmark multicenter randomized trial, reported a mean IOP of 13.4 ± 3.5 mmHg at 5 years following traditional Baerveldt implantation, achieved with a mean of 2.2 ± 1.3 adjunctive medications.¹⁴

Our cohort achieved a comparable mean IOP of 13.4 ± 4.3 mmHg at 12 months, but with a meaningfully lower medication burden of 1.33 ± 0.71 agents. While cross-study comparisons must be interpreted cautiously given differences in follow-up duration, patient population, and study design, this difference in medication burden may reflect the absence of progressive fibrotic encapsulation, which has been the dominant long-term failure mechanism of bleb-dependent drainage that frequently necessitates escalating adjunctive pharmacotherapy as conventional GDDs mature.

Bleb-Independent Drainage, Fibrosis Resistance, and Mechanism of Aqueous Absorption

Unlike conventional GDDs that drain to the subconjunctival space, where fibrotic encapsulation remains the principal cause of long-term failure, retrobulbar aqueous diversion bypasses this mechanism entirely. The Ahmed Baerveldt Comparison Study reported overall complication rates of 63–69% at 5 years with traditional GDD placement, including persistent diplopia in 12%, corneal edema in 20%, and GDD tube erosion requiring reoperation in 1–3%.^{13,15} Chronic hypotony, pooled across three randomized trials of conventional GDD surgery, occurred in approximately 4.1% of patients at 5 years, with vision reduction documented in 71% of affected eyes at the time of diagnosis.¹⁶ In contrast, the retrobulbar/intraconal space represents a large, compliant anatomical compartment that does not rely on bleb formation for aqueous drainage. By distributing aqueous humor into orbital tissues rather than a confined subconjunctival reservoir, this approach may reduce dependence on fibrotic encapsulation as the primary determinant of outflow resistance and provide a more stable physiologic backpressure environment. Sponsel and colleagues demonstrated that retrobulbar aqueous diversion maintained a mean IOP reduction from 33.1 to 14.6 mmHg through 24 months with concomitant reduction in medication burden from 2.8 to 0.56, and they proposed that the intrinsic properties of the retrobulbar space may limit the scarring response that characterizes bleb-dependent failure.^{17,18}

The mechanism by which the retrobulbar space accommodates diverted aqueous has been elucidated through laboratory tracer studies demonstrating lacunar distribution throughout the orbital compartment, confirming diffuse posterior diversion and reuptake rather than focal accumulation.¹⁹ The orbital space contains venous drainage pathways with substantial absorptive capacity, which may account for the durable IOP reduction observed in the absence of a filtering bleb. The “uveolymphatic pathway,” the lymphatic vessels within ocular tissues that contribute to aqueous drainage, has been increasingly recognized as a clinically important outflow route, and orbital lymphatics may play a complementary role in retrobulbar aqueous resorption.^{21,22} The exact mechanism of aqueous resorption in the retrobulbar space remains incompletely understood, and further histologic and imaging studies are needed.

Complication Profile

The complication profile of the retrobulbar approach compares favorably with that of traditional GDD surgery across several clinically important categories, as summarized in Table 2. The higher rate of transient hypotony in this series (25%) likely reflects both the low target IOP of 8–12 mmHg and the non-valved design of the Ahmed ClearPath 250, which provides no resistance to

flow in the immediate postoperative period. Notably, no flow-restricting ripcord suture was employed, likely contributing to the higher hypotony rate observed relative to valved devices. All episodes resolved without permanent sequelae. Unlike chronic hypotony, which has been associated with vision reduction in over 70% of affected eyes at the time of diagnosis, transient hypotony of this nature carries a more favorable prognosis when managed conservatively and monitored closely.¹⁶ The absence of corneal edema, persistent diplopia, and GDD erosion represents a meaningful potential safety advantage of the retrobulbar configuration, though prospective comparative data will be required to confirm these early signals.

Table 2: Postoperative Complication Rates Following Retrobulbar/Intraconal Ahmed ClearPath 250 Implantation Compared with Traditional Tube Shunt Surgery

Complications	This Study (Retrobulbar)	Traditional Tube Shunt (ABC Study)
Transient hypotony	25%	4.1% chronic hypotony (Gedde et al.)
IOP elevation	17%	Hypertensive phase common
Hyphema	8%	Similar rates
Diplopia	0%	12% persistent (Budenz et al.)
Corneal edema	0%	20% (Budenz et al.)
Choroidal effusion	0%	18% average (Ying et al.)
Tube erosion	0%	1–3% (Budenz et al.)
Endophthalmitis	0%	~1%

Prophylactic Inferior Sclerotomy

The prophylactic inferior sclerotomy performed in this series represents a technical innovation that is not yet standard practice in conventional glaucoma drainage device (GDD) surgery and warrants dedicated discussion. An inferior sclerotomy can serve as a decompressive drainage procedure for suprachoroidal fluid, which commonly develops in the setting of hypotony after implantation of a non-valved drainage device. In our study, despite a low mean postoperative day 1 IOP of 4.22 mmHg following non-valved device implantation without a ligature technique, no choroidal effusions were observed. This may have allowed the transient hypotony to resolve without further complication. Choroidal effusions complicate GDD implantation in approximately 18% of cases, with recognized risk factors including prior GDD surgery, use of a 350 mm2 Baerveldt implant.²⁰ The underlying mechanism involves disruption of the normal pressure gradient between the intraocular and suprachoroidal spaces: when IOP falls significantly below physiologic levels, the oncotic pressure of plasma proteins within the fenestrated choroidal vasculature exceeds the counterbalancing outward force of IOP, driving transudative fluid accumulation into the potential suprachoroidal space.²²⁻²⁴ Surgical inflammation may further increase vascular permeability, compounding this effect.²⁶ The prophylactic sclerotomy addresses this risk by creating a controlled full-thickness decompression pathway at the time of surgery, allowing any accumulating suprachoroidal fluid to egress before clinically significant effusion develops.

Conventional flow-restrictive strategies were intentionally omitted in this non-valved-device cohort to demonstrate the feasibility of achieving surgical success without complications using this novel technique. The absence of choroidal effusion compares favorably with reports of traditional non-valved techniques performed without sclerotomy.

Limitations include the absence of a control group undergoing non-valved device implantation without sclerotomy. In addition, no imaging modalities such as B-scan ultrasonography, orbital imaging, ultrasound biomicroscopy, or anterior-segment OCT were used to evaluate posterior fluid distribution or detect occult choroidal pathology. Further studies, including controlled comparative investigations with postoperative imaging, are warranted to confirm this proposed mechanism.

Implications for High-Risk Populations

The practice at the center of this investigation primarily serves Black and Latino patients with glaucoma through clinical sites in Harlem and southeast Queens. This local sample is an example of populations that are disproportionately affected by advanced disease and associated visual morbidity. Surgical approaches that reduce medication burden carry relevance in underserved settings, where real-world persistence on first-line prostaglandin analogues falls to approximately 31% at 3 years and chronic preservative exposure commonly contributes to ocular surface disease, further undermining long-term control.^{5,27} In a prospective cohort of POAG patients undergoing trabeculectomy, only 46% achieved success without adjunctive medications at 1 year, and 32% required further intervention within the first postoperative year, underscoring that many patients remain medication-dependent even after filtering surgery.^{28,29} Long-term real-world data further demonstrate that cumulative failure estimates reach 35–45% at 5 years in advanced glaucoma cohorts, reflecting wound healing, scarring, and bleb dysfunction as principal failure mechanisms, with ongoing procedural burden from hypotony management, bleb needling, and revision.²⁵ By bypassing the subconjunctival space altogether, the intraconal/retrobulbar approach may offer a more durable drainage pathway for patients in whom scarring risk, adherence barriers, and advanced baseline disease often converge.

Therefore, the outcomes of this study suggest that intraconal (retrobulbar) GDD implantation may be particularly well-suited as a rescue strategy for patients who have exhausted conventional surgical options or who carry risk factors that compromise the durability of bleb-dependent drainage, including prior conjunctival scarring from failed trabeculectomy or conventional GDDs, significant corneal disease precluding anterior chamber GDD placement, or high fibrotic risk profiles. Previous studies have similarly positioned retrobulbar GDD shunting as a viable intervention in eyes with refractory glaucoma and uncontrolled IOP despite prior surgical treatment, supporting the utility of this approach in a salvage context (Montelongo et al).¹⁸ Prospective comparative trials with standardized patient selection criteria and longer follow-up will be necessary to define its role within the broader surgical glaucoma armamentarium.

Limitations and Future Directions

This study has several important limitations that should be considered when interpreting its findings. First, the retrospective design introduces the potential for selection bias, as patients who

completed 12 months of follow-up may differ systematically from those who did not, and treatment decisions were not standardized prospectively. Second, the primary analysis included only 9 eyes, representing a small sample with limited statistical power. Three eyes were excluded due to incomplete longitudinal data, and we cannot rule out the possibility that these cases differed in clinically meaningful ways. As a pilot and feasibility investigation, this study is underpowered to detect differences in less common outcomes or to support definitive conclusions about efficacy. Third, all procedures were performed by a single surgeon at a single center, which limits the generalizability of both the surgical outcomes and the technical reproducibility of the modified implantation technique. Fourth, because there is no control group, we cannot determine cause and effect. The outcomes likely reflect a combination of the retrobulbar GDD placement, prophylactic inferior sclerotomy, ciliary sulcus positioning, and patient-specific factors, and it is not possible to separate the impact of each one individually. Fifth, although the 12-month follow-up period extends beyond the 6-month follow-up reported in the original pilot study, it remains insufficient to fully characterize long-term device performance, late fibrotic changes, or delayed complications. Sixth, no standardized protocol governed the reintroduction of topical medications postoperatively, which may have influenced medication burden outcomes at later time points.

Limitation: Fibrosis and Long-Term Tissue Response

Although retrobulbar aqueous diversion is designed to avoid a conventional subconjunctival filtering bleb, its long-term relationship to fibrosis remains uncertain. The orbital and intraconal tissues may also mount fibrotic, inflammatory, or encapsulation responses around the posterior plate or along the diversion pathway.

In the absence of dedicated orbital imaging, histopathologic assessment, or extended clinical follow-up, this study cannot establish that the approach is fibrosis-resistant or that it completely bypasses fibrosis-related mechanisms of surgical failure. Accordingly, any potential advantage in providing a more stable physiologic outflow pathway should be interpreted cautiously. Future studies incorporating longitudinal imaging, tissue-response evaluation where feasible, and longer-term outcome data will be necessary to characterize the extent and clinical significance of peri-device fibrosis or encapsulation.

Limitation: Duration of Safety Follow-up

The 12-month follow-up period provides only preliminary information regarding the safety and durability of this novel posterior orbital drainage approach. While no major late adverse events may have been observed during the study interval, this duration is insufficient to exclude delayed complications related to chronic device–tissue interaction or long-term aqueous diversion.

Potential late events that remain incompletely characterized include orbital fibrosis or encapsulation, restrictive strabismus, optic nerve compression, chronic orbital inflammation, persistent hypotony, tube migration, posterior erosion, and delayed orbital cyst formation. Therefore, the present findings should not be interpreted as establishing long-term safety or durability.

Longer-term follow-up in larger cohorts, ideally including standardized orbital examination and imaging where appropriate, will be necessary to define the incidence, timing, and clinical consequences of these potential complications. Long-term follow-up is particularly important because clinically meaningful safety findings may emerge after the formal study period ends.

Limitation: Full-Thickness Inferior Sclerotomy

The potential safety implications of a prophylactic full-thickness inferior sclerotomy warrant further consideration. Although the procedure may facilitate posterior aqueous diversion, creation of a full-thickness scleral opening carries theoretical and procedure-related risks that should be explicitly acknowledged.

Potential complications include retinal or vitreous incarceration at the sclerotomy site, vitreous prolapse, persistent postoperative hypotony and hypotony maculopathy, and the creation of an unintended cyclodialysis-like pathway. Additional concerns include wound-related infection, progressive scleral thinning or weakening, and possible late structural consequences at the sclerotomy site. Vitreous incarceration at a sclerotomy has been associated with altered wound healing and may contribute to hypotony, endophthalmitis risk, and traction-related retinal complications.

Accordingly, the present findings should be interpreted as preliminary, and the safety of prophylactic full-thickness inferior sclerotomy cannot be fully established from the current dataset. Future studies should include careful intraoperative and postoperative assessment of the sclerotomy site, standardized monitoring for hypotony-related complications, retinal examination and imaging where indicated, and longer-term evaluation of scleral integrity and posterior segment safety.

Prospective studies with larger sample sizes are needed to confirm these findings and define the durability of intraconal (retrobulbar) aqueous diversion over extended follow-up. A sample size of approximately 40–50 eyes per group would provide adequate power for prospective comparative trials evaluating this approach against conventional anterior chamber tube surgery. Randomized trials should also incorporate standardized medication protocols, Kaplan-Meier survival analysis for surgical success, and patient-reported outcome measures. Dedicated investigation into the role of prophylactic inferior sclerotomy, including randomized comparison with and without the procedure, and further characterization of orbital aqueous absorption dynamics will be important steps toward optimizing and validating this posterior drainage strategy.

References

1. Wang Z, Xue CC, Li Y, Wu Y, Pan Z, et al. Global glaucoma prevalence: burden and projection to 2060. *Am J Ophthalmol.* 2026. 283: 324-335.
2. Mahabadi N, Zeppieri M, Tripathy K. Open Angle Glaucoma.. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2025. <https://www.ncbi.nlm.nih.gov/books/NBK441887/>
3. Jayaram H, Kolko M, Friedman DS, Gazzard G. Glaucoma: now and beyond. *Lancet.* 2023. 402: 1788-1801.

4. Stein JD, Khawaja AP, Weizer JS. Glaucoma in adults—screening, diagnosis, and management. *JAMA*. 2021. 325: 164-174.
5. Baudouin C, Myers JS, Van Tassel SH, Goyal NA, Martinez-de-la-Casa J, et al. Adherence and persistence on prostaglandin analogues for glaucoma: a systematic review and meta-analysis. *Am J Ophthalmol*. 2025. 275: 99-113.
6. Sheybani A, Vera V, Grover DS, Vold SD, Cotter F, et al. Gel stent versus trabeculectomy: the randomized, multicenter, gold-standard pathway study (GPS) of effectiveness and safety at 12 months. *Am J Ophthalmol*. 2023. 252: 306-325.
7. Laroche D, Calderon I and Nwokeji I A novel retrobulbar/intraconal surgical approach with combined cataract extraction and a modified AHMED ClearPath 250mm2 tube in the ciliary sulcus with an inferior sclerotomy in Black and Afro-Latino patients with advanced glaucoma: a 6-month retrospective study. *Front. Ophthalmol*. 2026. 6: 1738832.
8. Braeu FA, Chuangsuwanich T, Tun TA, Perera SA, Husain R, et al. Three-Dimensional Structural Phenotype of the Optic Nerve Head as a Function of Glaucoma Severity. *JAMA Ophthalmol*. 2023.141: 882-889.
9. Kim JY, Lee JS, Lee T, Seo D, Choi W, et al. Corneal endothelial cell changes and surgical results after Ahmed glaucoma valve implantation: ciliary sulcus versus anterior chamber tube placement. *Sci Rep*. 2021. 11: 12986.
10. Zhang Q, Liu Y, Thanapaisai S, Oatts J, Luo Y, et al. The effect of tube location on corneal endothelial cells in patients with Ahmed glaucoma valve. *Ophthalmology*. 2021. 128: 218-226.
11. Godinho G, Barbosa-Breda J, Oliveira-Ferreira C, Madeira C, Melo A, et al. Anterior chamber versus ciliary sulcus Ahmed glaucoma valve tube placement: longitudinal evaluation of corneal endothelial cell profiles. *J Glaucoma*. 2021. 30: 170-174.
12. Jha UP, Kumar S, Jindal V, Gupta G, Ichhpujani P. Clinical and surgical outcomes of glaucoma drainage device tube in ciliary sulcus versus anterior chamber in North Indian glaucoma patients. *Indian J Ophthalmol*. 2023. 71: 1960-1965.
13. Budenz DL, Feuer WJ, Barton K, Schiffman J, Costa VP, et al. Postoperative complications in the Ahmed Baerveldt Comparison Study during five years of follow-up. *Am J Ophthalmol*. 2016. 163: 75-82 e3.
14. Gedde SJ, Feuer WJ, Lim KS, Barton K, Goyal S, et al. Treatment outcomes in the Primary Tube Versus Trabeculectomy Study after 5 years of follow-up. *Ophthalmology*. 2022. 129: 1344-1356.
15. Christakis PG, Kalenak JW, Tsai JC, Zurakowski D, Kammer JA, et al. The Ahmed versus Baerveldt study: five-year treatment outcomes. *Ophthalmology*. 2016. 123: 2093-2102.
16. Gedde AY, Huertas L, O'Brien R, Christakis PG, Ahmed IIK, et al. Chronic hypotony after tube shunt surgery: a pooled analysis of data from three randomized clinical trials. *Am J Ophthalmol*. 2025. 282: 305-315.
17. Sponsel WE, Groth SL, Ayyala RS. Retrobulbar diversion of aqueous humor: clinical feasibility studies. *J Glaucoma*. 2014. 23: 628-632.
18. Montelongo M, de Ribot FM, Craven ER, Sponsel WE. Retrobulbar tube shunt: anterior chamber to back of the eye (A2B) efficacy in glaucomatous eyes with uncontrolled IOP. *Graefes Arch Clin Exp Ophthalmol*. 2021. 259: 705-714.
19. Batlle OR, Sponsel WE, Swann FB, Margo CE, Groth SL, et al. Retrobulbar diversion of aqueous humor: laboratory studies. *J Glaucoma*. 2014. 23: 624-627.
20. Ying S, Coulon SJ, Lidder AK, Labowsky M, Cheng CP, et al. Choroidal effusions after glaucoma drainage implant surgery: risk factors and surgical management. *Ophthalmol Glaucoma*. 2023. 6: 530-540.
21. Yücel YH, Johnston MG, Ly T, Patel M, Drake B, et al. Identification of lymphatics in the ciliary body of the human eye: a novel “uveolymphatic” outflow pathway. *Exp Eye Res*. 2009.89: 810-819.
22. Costagliola C, dell’Omo R, Agnifili L, Bartollino S, Fea AM, et al. How many aqueous humor outflow pathways are there? *Surv Ophthalmol*. 2020. 65: 144-170.
23. Ying S, Sidoti PA, Panarelli JF. Risk factors and management of choroidal effusions. *Curr Opin Ophthalmol*. 2023. 34: 162-167.
24. Schrieber C, Liu Y. Choroidal effusions after glaucoma surgery. *Curr Opin Ophthalmol*. 2015. 26: 134-142.
25. Wang Q, Thau A, Levin AV, Lee D. Ocular hypotony: a comprehensive review. *Surv Ophthalmol*. 2019. 64: 619-638.
26. Berke SJ, Bellows AR, Shingleton BJ, Richter CU, Hutchinson BT. Chronic and recurrent choroidal detachment after glaucoma filtering surgery. *Ophthalmology*. 1987. 94: 154-162.
27. Kemer ÖE, Mekala P, Dave B, Kooner KS. Managing ocular surface disease in glaucoma treatment: a systematic review. *Bioengineering*. 2024. 11: 1010.
28. Mamidipaka A, Shi A, Addis V, He J, Lee R, et al. Outcomes of trabeculectomy and predictors of success in patients of African ancestry with primary open angle glaucoma. *J Glaucoma*. 2025. 34: 127-135.
29. Qedair J, Schargel K, AlShahwan S, AlObaida I. Xen45 gel stent versus trabeculectomy for glaucoma: A systematic review and meta-analysis of efficacy and safety. *AJO International*. 2025. 2: 100202.