Outcomes of Sutureless Ahmed Glaucoma Valve Surgery: A Retrospective Study

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ABSTRACT

Introduction: This study compared the safety and efficacy of sutureless Ahmed glaucoma valve surgery (AGV standalone) to sutureless AGV plus cataract surgery (AGV-CEIOL) in Black or Hispanic patients.

Methods: Records from Black or non-white Hispanic patients who received either AGV standalone or AGV-CEIOL from 2014 to 2019 at a Bronx, New York practice were reviewed. All surgeries were performed using a sutureless technique with Tisseel fibrin glue. Primary outcomes included failure (defined as intraocular pressure (IOP) > 21 mmHg, ≤ 5 mmHg, or reduced by < 20% after the first 3 months; loss of light perception; or reoperation for glaucoma), hypertensive phase, IOP changes, and medication changes. Secondary outcomes included postoperative complications and interventions.

Results: A total of 203 eyes that received AGV standalone (n = 78) or AGV-CEIOL (n = 125) were analyzed. Mean follow-up duration was 42.2 ± 17.5 months, with similar cohort-specific intervals (P = 0.68). Failure among AGV-CEIOLs (44.8%, n = 56) and AGV standalones (47.4%, n = 37) occurred at similar frequencies; log-rank testing indicated comparable 5-year survival (P = 0.56). Mean IOP among AGV-CEIOLs (15.8 ± 12.1 mmHg) was greater than standalones (8.6 ± 5.1 mmHg) at post-op day 1 (P < 0.001). The AGV-CEIOL group had a 60% lower odds of experiencing a hypertensive phase after adjustment for baseline group differences (P = 0.01). Five-year IOP reduction was similar between groups in the multivariable model (P = 0.45). There were no significant differences in medications (P > 0.05 at all time points) or in total complications (P = 0.28). More standalones required reoperation (39.7%, n = 31) compared to AGV-CEIOLs (21.6%, n = 24; P = 0.007).

Conclusions: Sutureless AGV-CEIOL was non-inferior to sutureless AGV standalone when performed in Black or non-white Hispanic patients. The combined group experienced the hypertensive phase less frequently despite higher day 1 IOP.

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Keywords: Ahmed glaucoma valve; Cataract surgery; Combined surgery; Glaucoma drainage device

Key Summary Points

Why carry out this study?

There is limited information on how the outcomes of Ahmed glaucoma valve surgery combined with cataract surgery (AGV-CEIOL) compare to the outcomes of Ahmed glaucoma valve surgery alone (AGV standalone), particularly when performed using the novel sutureless technique.

In the two landmark prospective trials that studied sutured AGVs, Black or Hispanic patient representation was limited despite the well-documented glaucoma treatment disparities that those two underserved groups face.

What was learned from the study?

In this retrospective comparison of sutureless AGV-CEIOL to sutureless AGV standalone in a Black or non-white Hispanic population, safety and efficacy of the combined approach were comparable to the standalone approach through 3.5 years of mean follow-up, and were also comparable to historical findings from sutured AGVs.

In the context of moderate-to-severe glaucoma co-presenting with cataract in Black or non-white Hispanic patients, sutureless AGV-CEIOL may serve as an effective treatment option without major compromises.

INTRODUCTION

Glucoma drainage devices (GDDs) enable ophthalmologists to substantially reduce intraocular pressure and medication burden for patients with moderate to severe glaucomas [1]. Two commonly used options include the Ahmed glaucoma valve (AGV; New World Medical, Inc, Rancho Cucamonga, CA, USA) and the Baerveldt glaucoma implant (BGI; Abbott Medical Optics, Abbott Park, IL, USA). Both are increasingly becoming the end-stage interventions of choice among American glaucoma specialists [2]. However, when faced with patients who co-present with visually significant cataracts, only 9% of glaucoma surgeons reported that they would perform simultaneous GDD–cataract surgery in a survey published in 2017 [2]. This preference for sequential surgery may reflect concerns regarding the safety and efficacy of the combined approach. In the only prospective comparison of BGI in pseudophakic eyes versus BGI combined with cataract surgery, failure rates at 3 years of follow-up were 22% greater for the combined cohort [3]. No similar study, however, has been published on the AGV. Thus, we sought to address this gap by comparing outcomes of AGV combined with cataract surgery (AGV-CEIOL) to outcomes of AGV standalone. All surgeries were performed with a unique sutureless technique incorporating fibrin sealant that has shown favorable safety and efficacy [4–6].

The next aim of our study was to explore outcomes of the standalone and combined approaches in Black or Hispanic patients. Glaucoma is more prevalent in Black or Hispanic individuals compared to non-Hispanic white patients, and glaucoma may also arise at an earlier age in these populations [7, 8]. A recent large-scale study of Medicare beneficiaries revealed that Black and Hispanic patients were each more likely to undergo glaucoma procedures than non-Hispanic white patients [9]. Black patients have been reported to undergo cataract surgery at around a 30% lower rate than white patients [10]. Cataract removal is itself a form of glaucoma surgery, especially in the context of narrow angles; therefore, less cataract surgery among Black individuals may in part contribute to the greater likelihood of other glaucoma surgeries [11]. Furthermore, despite receiving glaucoma surgeries at a higher rate than white patients, Black patients have
been found to experience worse surgical outcomes following GDD implantation [12].

Yet despite the disparities in glaucoma risk and glaucoma surgery for Black and Hispanic patients, the landmark clinical trials comparing the AGV and BGI included mostly white enrollees and had limited representation from either Black or Hispanic individuals [13, 14]. Consequently, there exists significant need for high-quality data on outcomes after AGV implantation in Black or Hispanic patients. The patients that our (NMR) practice serves in the Bronx, New York primarily identify as Black or non-white Hispanic, providing an opportunity for studying clinical outcomes especially pertinent to underrepresented populations.

METHODS

Study Design

This was a single-center, single-surgeon, retrospective cohort study. Sterling Institutional Review Board (IRB) (Atlanta, GA, USA) ruled that approval was not required for this study. Owing to the retrospective design and deidentified collection of data, informed consent was not required. All study procedures followed the standards set by the Declaration of Helsinki and its amendments as well as the Health Insurance Portability and Accountability Act.

Study Population

Electronic medical records from self-identified non-Hispanic Black or non-white Hispanic patients aged 18 or older who had received either an FP7 Ahmed glaucoma valve only (“AGV standalone”) or an FP7 AGV combined with cataract surgery (“AGV-CEIOL”) in the 2014–2019 period at a private practice in the Bronx, New York were reviewed. All surgeries were performed by author NMR. For AGV-CEIOL eyes, they were only included if capsular bag lens implantation had been performed. White patients were excluded from the study. Eyes that were missing 1-year follow-up data for intraocular pressure (IOP) or glaucoma medications were excluded. Eyes that had previous glaucoma drainage device surgery, received AGV surgery combined with any other procedure besides CEIOL, or lacked light perception vision at baseline also met exclusion criteria. When patients had received AGVs in both eyes, both eyes were included in the analysis. For patients who had multiple AGV surgeries in the same eye, the time of the first surgery was used as reference.

Baseline data were collected including glaucoma type, demographics, eye laterality, previous glaucoma procedures, Snellen visual acuity (VA), and visual field mean deviation (VFMD). Demographic information was determined from the electronic medical record and was originally recorded on the basis of patient self-report. Preoperative IOP measured by Goldmann applanation tonometry and preoperative glaucoma medications were determined by averaging recorded values within 42 days prior to surgery, as recommended by the World Glaucoma Congress guidelines [15]. Glaucoma medications were tallied by the total number of IOP-lowering chemicals, including oral carbonic anhydrase inhibitors. Postoperative visits were recorded at 1 day, 1 week, 1 month, 3 months, 6 months, 9 months, 1 year, and annually thereafter. Changes from baseline were noted up to the most recent follow-up visit.

Surgical Technique

All surgeries were performed using the sutureless approach described in our previous publication [4]. Prior to incision, a retrobulbar block under monitored anesthesia care was utilized. In brief, the key steps of the AGV placement from the initial, superotemporal-preferred conjunctival peritomy to the scleral tunneling were akin to the common maneuvers described in the literature [16]. The key difference occurred after tube positioning. No sutures were used for any part of the surgery, and Tisseel fibrin sealant (Baxter Health Corp., Deerfield, IL, USA) secured the pericardial patch graft to the sclera. The incision was then closed by approximating the wound margins with toothed forceps,
making use of the fibrin sealant to keep the conjunctiva affixed. Dexamethasone and antibiotic medications were subsequently injected near the plate in the subconjunctival space. As for patients who received AGV-CEIOL, routine cataract surgery with phacoemulsification was performed prior to the AGV implantation in all cases. All lenses were placed in the capsular bag. In both surgical groups, tube tips were placed in either the anterior chamber or the ciliary sulcus, on the basis of the operating surgeon’s clinical judgement.

Postoperatively, topical ofloxacin applied four times daily was prescribed for 1 week. Postoperative inflammation was controlled with a standardized regimen of topical prednisolone 1% four times a day, tapered down to three times daily, twice daily, and once daily over the course of 1 month. Glaucoma medications that patients were on preoperatively were generally suspended in the immediate post-op period, then resumed on the basis of need for IOP control.

**Outcome Measures**

Four primary outcomes were studied: failure rate, hypertensive phase occurrence, change in IOP, and change in glaucoma medication use. Failure was defined in accordance with the criteria outlined in the Ahmed Baerveldt Comparison (ABC) study [17]. To paraphrase, failure was met if any of the following occurred: IOP greater than 21 mmHg on two consecutive study visits after 3 months, IOP of 5 mmHg or less on two consecutive study visits after 3 months, reoperation for glaucoma, or loss of light perception vision. Reoperations for glaucoma included any procedures intended to reduce IOP performed in the operating suite, as well as tube shunt removal. To capture early postoperative IOP volatility in the first 3 months, cases of the hypertensive phase were tallied. Per Won and Sung, the hypertensive phase is an IOP spike within the first 3 months of over 21 mmHg after adequate IOP control in the first week and no other clear source of AGV failure [18]. Lastly, when changes in IOP and medications were compiled, readings were censored following a reoperation for glaucoma.

Secondary outcomes included complications and procedures performed during the follow-up period. Postoperative complications attributable to the primary surgery were recorded with categorizations guided by the listings in the Ahmed versus Baerveldt (AVB) and ABC studies [19, 20]. Postoperative slit lamp interventions and reoperations for glaucoma or complications were similarly identified and enumerated.

**Statistical Analyses**

Analyses were performed using Statistical Package for the Social Sciences for Mac (SPSS v. 28.0.0, IBM, Armonk, NY, USA). Inter-eye correlations were accounted for by using generalized estimating equations (GEEs) to compare baseline and follow-up metrics between AGV and AGV-CEIOL groups [21–23]. Linear outcomes such as magnitude of IOP reduction were assessed by using either linear regression or gamma regression GEEs depending on best model fit, while categorical outcomes such as hypertensive phase occurrence were analyzed with logistic model GEEs. Multivariable GEE regressions were subsequently performed for any primary outcomes that differed significantly between groups on univariate analysis; covariates were selected according to baseline differences. Interaction analyses were then computed in order to thoroughly account for any additional modulating effects connecting the surgery type to statistically significant covariates. To limit multiple comparisons, logistic GEE analyses were only performed when at least five cases of the outcome of interest were present in at least one surgical group. Kaplan–Meier survival curves were computed for failure up to 5 years and log-rank testing was used to evaluate the difference in survival between surgical cohorts. Linear findings are reported as mean ± standard deviation (SD), while “n” values for categorical outcomes refer to number of eyes. Statistical significance was set at two-sided $P < 0.05$. 

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### Table 1 Baseline characteristics of eyes that received AGV or AGV-CEIOL

|                          | AGV ($n = 78$) | AGV-CEIOL ($n = 125$) | $P$ value |
|--------------------------|----------------|-----------------------|-----------|
| Age (mean years ± SD)    | 67.97 ± 12.00  | 69.54 ± 10.02         | 0.47      |
| Sex                      |                |                       | 0.93      |
| Female                   | 37 (47.4%)     | 61 (48.8%)            |           |
| Male                     | 41 (52.6%)     | 64 (51.2%)            |           |
| Demographic category     |                |                       | 0.66      |
| Non-white Hispanic       | 47 (60.3%)     | 81 (64.8%)            |           |
| Non-Hispanic Black       | 31 (39.7%)     | 44 (35.2%)            |           |
| Right eye                | 37 (47.4%)     | 67 (53.6%)            | 0.47      |
| IOP (mean mmHg ± SD)     | 31.7 ± 10.5    | 23.8 ± 9.0            | < 0.001   |
| Glaucoma medications (mean ± SD) | 3.8 ± 1.0   | 3.5 ± 1.2            | 0.12      |
| Snellen visual acuity (median) | 20/60     | N/A                  |           |
| Visual field mean deviation (mean ± SD) | −18.94 ± 9.10 | −17.22 ± 9.54 | 0.22      |
| Glaucoma type            |                |                       |           |
| Primary open-angle       | 66 (84.6%)     | 95 (76.0%)            | 0.15      |
| Chronic angle-closure    | 3 (3.8%)       | 17 (13.6%)            | 0.053     |
| Low-tension              | 0 (0.0%)       | 2 (1.6%)              |           |
| Neovascular              | 7 (9.0%)       | 4 (3.2%)              | 0.03      |
| Uveitic                  | 0 (0.0%)       | 1 (0.8%)              |           |
| Mixed-mechanism          | 1 (1.3%)       | 4 (3.2%)              |           |
| Traumatic                | 1 (1.3%)       | 1 (0.8%)              |           |
| Steroid-induced          | 0 (0.0%)       | 1 (0.8%)              |           |
| Previous glaucoma laser  | 33 (42.3%)     | 57 (45.6%)            | 0.57      |
| Previous glaucoma surgery|                |                       |           |
| None                     | 48 (61.5%)     | 116 (92.8%)           | < 0.001   |
| Trabeculectomy           | 10 (12.8%)     | 2 (1.6%)              | 0.003     |
| Micro-invasive glaucoma surgery | 11 (14.1%) | 0 (0.0%)              | < 0.001   |
| Endoscopic cyclophotocoagulation | 15 (19.2%) | 0 (0.0%)              | < 0.001   |
| Transscleral cyclophotocoagulation | 1 (1.3%) | 0 (0.0%)              |           |
| Iridectomy               | 1 (1.3%)       | 7 (5.6%)              | 0.18      |

AGV Ahmed glaucoma valve, AGV-CEIOL Ahmed glaucoma valve combined with cataract surgery

Glaucoma medications were coded on the basis of total number of IOP-lowering chemicals, including oral agents. $P$ values were calculated using linear or logistic regressions with generalized estimating equations (GEEs). To limit multiple comparisons for categorical outcomes, logistic GEE analyses were only performed when at least five cases of the outcome of interest were present in either surgical group.
Follow-up data to at least 1 year was available for 203 eyes from 164 non-Hispanic Black or non-white Hispanic patients. Eyes that received AGV standalone comprised 38.4% \((n = 78)\) of the sample, while eyes that received AGV-CEIOL comprised 61.6% \((n = 125)\). Uncensored data to 2 years was available for 166 eyes, to 3 years for 137 eyes, to 4 years for 97 eyes, and to 5 years for 64 eyes. Average length of follow-up was 42.2 ± 17.5 months, and mean follow-up times were similar between groups \((P = 0.68)\). Baseline information is shown in Table 1. Demographic distributions were similar \((P > 0.05)\). However, certain metrics of glaucoma severity differed between groups. The AGV standalone cohort had a higher baseline mean IOP of 31.7 ± 10.5 mmHg, versus 23.8 ± 9.0 mmHg in the AGV-CEIOL group \((P < 0.001)\). A history of prior glaucoma surgery was present in 38.5% \((n = 30)\) of eyes that received only an AGV compared to 7.2% \((n = 9)\) of those that received AGV-CEIOL \((P < 0.001)\). Eleven eyes had a primary diagnosis of neovascular glaucoma (NVG), seven of which were in the standalone cohort \((P = 0.03)\). Otherwise, differences in preoperative VFMD \((P = 0.22)\) and glaucoma medication burden \((P = 0.12)\) did not meet statistical significance. Most eyes that received only an AGV were pseudophakic at the time of surgery (75.6%, \(n = 59)\).

Key Treatment Outcomes

By the time of the last follow-up visit, failure rate for the overall sample was 45.8% \((n = 93)\). The proportion of eyes that met failure criteria in the AGV standalone cohort (47.4%, \(n = 37)\) was similar to the AGV-CEIOL cohort (44.8%, \(n = 56)\). When stratified by glaucoma diagnosis, failure rate was lowest in the primary open-angle glaucoma group (POAG, 44.6%, \(n = 72)\), and highest in the “other” group (54.5%, \(n = 6)\) consisting of low-tension, uveitic, mixed-mechanism, traumatic, and steroid-induced glaucomas (Supplemental Table 1). The Kaplan–Meier survival curves plotted up to

Fig. 1  \(P\) value calculated from log-rank test. AGV Ahmed glaucoma valve, AGV-CEIOL Ahmed glaucoma valve combined with cataract surgery.
5 years for AGV standalones and AGV-CEIOLs are depicted in Fig. 1. Per log-rank testing, the difference in survival functions did not meet statistical significance ($P = 0.56$). Differences in survival functions when stratified by type of glaucoma diagnosis did not meet significance either ($P = 0.88$; Supplemental Fig. 1). The survival curve for NVG eyes appears lowest at 5 years in part due to dropout; all NVG eyes had either failed (45.4%, $n = 5$) or were lost to follow-up (54.6%, $n = 6$) by 5 years.

The most common criterion that triggered failure in the standalone group was reoperation for glaucoma (20.5%, $n = 16$), while for the combined group it was IOP reduction of less than 20% for two consecutive visits after 3 months (27.2%, $n = 34$) (Table 2). Reoperation for glaucoma triggering failure ($P = 0.04$) and IOP greater than 21 mmHg triggering failure ($P = 0.04$) were each more frequent in the AGV standalone group. In contrast, AGV-CEIOLs were more likely to fail as a result of the percentage reduction requirement ($P = 0.003$). Reasons for failure did not differ significantly between groups on the basis of glaucoma type (Supplemental Table 1).

For each of the three failure rules in which outcomes differed between surgical cohorts, multivariable logistic regressions using GEEs were compiled to adjust for baseline covariates that differed at $P < 0.05$ (Table 3). Those covariates included preop IOP, previous glaucoma surgery, and neovascular glaucoma. Upon full adjustment, AGV surgery type was no longer significantly associated with any of the three failure causes ($P > 0.05$). However, higher preop IOP was significantly associated with increased failure rate due to reoperation (odds ratio = 1.07 [1.03, 1.12]; $P < 0.001$), and decreased failure rate due to insufficient percentage reduction (OR = 0.73 [0.66, 0.81]; $P < 0.001$). Interaction analyses were subsequently performed. The interaction between AGV combination and preop IOP did not meet statistical significance for the reoperation ($P = 0.73$) or the less than 20% reduction ($P = 0.40$) criteria. However, a significant interaction effect was observed between AGV combination and preop IOP when the outcome was failure due to IOP greater than 21 mmHg ($P = 0.03$). Per the interaction analysis, receiving AGV-CEIOL amplified the effect of preop IOP on increasing failure rate due to IOP greater than 21 mmHg after 3 months (OR = 1.10 [1.01, 1.20]) when compared to AGV standalone (OR = 0.97 [0.93, 1.02]).

The early postoperative phenomenon of a hypertensive phase occurred in 65.4% ($n = 51$) of the AGV standalone group and 38.4% ($n = 48$) of the combined group ($P < 0.001$).

### Table 2 Reasons for failure in AGV standalone and AGV-CEIOL groups

|                | AGV standalone ($n = 78$) | AGV-CEIOL ($n = 125$) | $P$ value |
|----------------|--------------------------|------------------------|-----------|
| IOP > 21 mmHg for two consecutive visits after 3 months | 9 (11.5%) | 6 (4.8%) | 0.04 |
| IOP reduced by < 20% for two consecutive visits after 3 months | 5 (6.4%) | 34 (27.2%) | 0.003 |
| IOP 5 mmHg or less for two consecutive visits after 3 months | 2 (2.6%) | 1 (0.8%) | 0.003 |
| Reoperation for glaucoma | 16 (20.5%) | 13 (10.4%) | 0.04 |
| Loss of light perception | 5 (6.4%) | 2 (1.6%) | 0.09 |

*AGV* Ahmed glaucoma valve, *AGV-CEIOL* Ahmed glaucoma valve combined with cataract surgery, *IOP* intraocular pressure

$P$ values were calculated using logistic regressions with generalized estimating equations (GEEs). To limit multiple comparisons, logistic GEE analyses were only performed when at least five cases of the outcome of interest were present in either surgical group.
Multivariable logistic regression using GEE with the same three covariates previously described was performed (Table 3). Upon full adjustment, the AGV-CEIOL group had a 60% lower odds of experiencing a hypertensive phase \((P = 0.01)\). Additionally, a 1 mmHg increase in preop IOP was associated with a 5% increase in the odds of the phase occurring \((P = 0.004)\). The interaction between AGV combination and preop IOP was not statistically significant for the hypertensive phase outcome \((P = 0.99)\).

### Table 3  Multivariable logistic regressions comparing efficacy outcomes between AGV standalone and AGV-CEIOL groups

| Term                                      | Odds ratio | 95% confidence interval | \(P\) value |
|-------------------------------------------|------------|--------------------------|-------------|
| IOP > 21 mmHg for two consecutive visits after 3 months |            |                          |             |
| AGV combination\(^a\)                    | 0.52       | 0.09, 3.16               | 0.48        |
| Preop IOP                                 | 1.01       | 0.96, 1.05               | 0.85        |
| Previous glaucoma surgery                 | 1.79       | 0.31, 10.42              | 0.52        |
| Neovascular glaucoma                      | 2.72       | 0.47, 15.69              | 0.26        |
| IOP reduced by < 20% for two consecutive visits after 3 months |            |                          |             |
| AGV combination\(^a\)                    | 1.70       | 0.31, 9.51               | 0.54        |
| Preop IOP                                 | 0.73       | 0.66, 0.81               | < 0.001     |
| Previous glaucoma surgery                 | 1.43       | 0.26, 7.80               | 0.68        |
| Neovascular glaucoma                      | 4.83       | 0.56, 41.57              | 0.15        |
| Reoperation for glaucoma                  |            |                          |             |
| AGV combination\(^a\)                    | 0.51       | 0.21, 1.21               | 0.13        |
| Preop IOP                                 | 1.07       | 1.03, 1.12               | < 0.001     |
| Previous glaucoma surgery                 | 0.34       | 0.09, 1.30               | 0.12        |
| Neovascular glaucoma                      | 0.14       | 0.02, 1.26               | 0.08        |
| Hypertensive phase                        |            |                          |             |
| AGV combination\(^a\)                    | 0.40       | 0.19, 0.81               | 0.01        |
| Preop IOP                                 | 1.05       | 1.02, 1.09               | 0.004       |
| Previous glaucoma surgery                 | 0.62       | 0.29, 1.34               | 0.23        |
| Neovascular glaucoma                      | 1.32       | 0.30, 5.69               | 0.71        |

\(^a\)AGV standalone was the reference category

Intraocular Pressure

Changes in IOP from preop to 5 years post-op are depicted in Fig. 2. There were statistically significant differences between groups in mean IOP at post-op day 1 \((P < 0.001)\), month 1 \((P = 0.001)\), and month 3 \((P < 0.001)\). Mean IOP in the AGV standalone group \((8.6 \pm 5.1\ mmHg)\) was lower than the combined group \((15.8 \pm 12.1\ mmHg)\) at day 1. The trend reversed at months 1 and 3, when mean IOPs in the standalone cohort were \(20.1 \pm 9.1\ mmHg\).
and 17.9 ± 5.3 mmHg, respectively, compared to 16.6 ± 5.9 mmHg and 15.3 ± 4.2 mmHg among the combined (Fig. 2). At all other time points, inter-group IOP differences were small \((P > 0.05)\). By 5 years, the 46 eyes that were not censored or lost to follow-up had a mean IOP of 15.3 ± 4.07 mmHg, which was a statistically significant 34.8% reduction compared to baseline \((P < 0.001)\). Stratified by surgical combination, mean magnitude of IOP reduction by 5 years was 14.6 ± 15.1 mmHg among AGV standalones compared to 6.2 ± 8.7 among AGV-CEIOLs \((P = 0.04)\). Multivariable gamma regression with log-link function using GEE was computed for the IOP reduction outcome (Table 4). After adjustment for baseline covariates, preop IOP was the only term that significantly correlated with magnitude of IOP reduction. In the gamma regression GEE multivariable model, an increase of 1 mmHg of preop IOP was associated with a 6% increase in the magnitude of IOP reduction by 5 years post-op \((P < 0.001)\). No significant interaction effect was observed between AGV combination and preop IOP \((P = 0.28)\). When stratified by glaucoma diagnosis, there were no statistically significant differences in IOP reads at each postoperative time point \((P > 0.05); Supplemental Fig. 2)\.

**Glaucoma Medications**

Changes in postoperative IOP-lowering medications stratified by surgery type are depicted in Fig. 3. Both groups had a considerable medication burden prior to surgery \((3.6 ± 1.1 overall)\). Differences in medication burden between groups were non-significant at all studied time points \((P > 0.05)\). Five years after surgery, the average eye was using approximately one fewer glaucoma medication versus baseline, a statistically significant improvement \((31.2\% \text{ reduction, } P < 0.001)\). Magnitude of medication reduction from baseline did not differ significantly between surgical groups \((P = 0.39)\). When stratified by glaucoma diagnosis, there were no statistically significant differences in

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\(n\) values indicate total eyes available for analysis at each time point after censorship and dropout. Asterisks (*) indicate statistical significance at \(P < 0.05\). AGV Ahmed glaucoma valve, AGV-CEIOL Ahmed glaucoma valve combined with cataract surgery, IOP intraocular pressure.
Table 4 Multivariable gamma regression comparing magnitude of IOP reduction 5 years after AGV standalone or AGV-CEIOL

| Term                        | Exp (β) | 95% confidence interval | P value |
|-----------------------------|---------|-------------------------|---------|
| AGV combination<sup>a</sup> | 1.13    | 0.83, 1.53              | 0.45    |
| Preop IOP                   | 1.06    | 1.04, 1.07              | < 0.001 |
| Previous glaucoma surgery   | 1.18    | 0.92, 1.51              | 0.19    |
| Neovascular glaucoma<sup>b</sup> | N/A     | N/A                     | N/A     |

<sup>a</sup>AGV standalone was the reference category  
<sup>b</sup>There were zero cases of eyes with neovascular glaucoma that were eligible for analysis at 5 years due to censoring and drop-out

Postoperative Complications

Table 5 identifies the complications experienced throughout follow-up. Cumulative complication rate for all primary surgeries was 36.5% (n = 74). Complications among eyes that had received AGV-CEIOL occurred at a rate of 33.6% (n = 42) compared to 41.0% (n = 32) among AGV standalones (P = 0.28). The most common event overall was a shallow or flat chamber, which occurred in 10.3% (n = 21) of the full sample. Corneal complications occurred at a higher rate in the AGV-CEIOL group, though the difference was non-significant (P = 0.23). Three corneal complications in the standalone group were corneal edema cases persisting beyond 3 months, while two complications were corneal decompensation. The AGV-CEIOL cohort experienced two instances of corneal ulcer and a single occurrence of corneal decompensation; the remaining nine cases were persistent edema. The standalone group had a higher rate of tube–cornea touch and corresponding tube trimming procedures (P = 0.04). Conjunctival erosions occurred only four times in total (2.0%). Tube occlusions occurred at the same rate and were observed only in the AGV-CEIOL group. Migration of the AGV occurred in 3.4% (n = 7) of the sample. There were no cases of endophthalmitis, retinal detachment, suprachoroidal hemorrhage, vitreous hemorrhage, or phthisis bulbi attributable to the primary surgery.

Loss of light perception occurred in 3.4% (n = 7) of the sample, with five of the seven cases occurring in the standalone group (P = 0.09); 9.1% (n = 1) of NVG eyes became NLP, compared to 3.7% (n = 6) of POAG eyes. Among the 64 eyes that had uncensored follow-up to 5 years, loss of two Snellen lines of vision or more occurred in 28.1% (n = 18). This outcome was experienced by 38.1% (n = 8) of the standalone group, compared to 23.3% (n = 10) of the combined group (P = 0.20). Median best-corrected visual acuity at 5 years was 20/40 in AGV standalones and 14.97 ± 9.36 in AGV-CEIOLs, which was a non-significant difference (P = 0.35).

Postoperative Procedures

By the end of follow-up, reoperation for glaucoma had been performed in 21.7% (n = 44) of the sample, while reoperation for complications had occurred in 9.4% (n = 19). Table 5 outlines the types and frequencies of procedures performed. Twelve eyes received a combination of...
surgeries simultaneously. Overall operating room intervention rate was higher in the standalone group (39.7%, \(n = 31\)) compared to the combined group (21.6%, \(n = 27\); \(P = 0.007\)). The most common reoperation was transscleral cyclophotocoagulation (TSCPC), occurring at a rate of 13.8% (\(n = 28\)). Twelve eyes had a second GDD placed, which included the AGV, BGI, or Ahmed ClearPath (New World Medical, Inc, Rancho Cucamonga, CA, USA). Four eyes received micro-invasive glaucoma surgery (MIGS). They consisted of the XEN45 gel stent (Allergan, an Abbvie company, Irvine, CA, USA), Kahook Dual-Blade (New World Medical, Inc, Rancho Cucamonga, CA, USA), and the Hydrus microstent (Ivantis, Inc, Irvine CA, USA). Of the two eyes from which tubes were removed, one had dysesthesia from conjunctival erosion, while the second had uncontrolled choroidal effusion. Slit lamp interventions related to the AGV surgery were uncommon, with rates (6.4%) identical between cohorts (\(P = 1.00\)).

**DISCUSSION**

With an increasing number of patients who co-present with glaucoma and cataracts, evidence-based guidance on the safety and efficacy of concomitant AGV-CEIOL is needed. Moreover, surgical results for Black and Hispanic patients are of particular importance given the disparities they face in glaucoma frequency, severity, and treatment outcomes [9, 12, 24, 25]. This study presents findings on short-term, intermediate-term, and long-term outcomes of sutureless AGV-CEIOL in non-Hispanic Black or non-white Hispanic patients. We found that sutureless AGV-CEIOL was noninferior to sutureless AGV standalone in this population for most outcomes, including failure per the ABC study criteria, IOP, glaucoma medications, complications, and reoperations.

A few statistically significant differences in metrics related to IOP were observed between groups. At post-op day 1, AGV-CEIOLs were less successful at reducing IOP than standalones...
Table 5  Postoperative complications, slit lamp interventions, and reoperations

| Complications of primary surgery | AGV (n = 78) | AGV-CEIOL (n = 125) | P value |
|----------------------------------|-------------|---------------------|---------|
| None                             | 46 (59.0%)  | 83 (66.4%)          | 0.28    |
| Choroidal effusion               | 6 (7.7%)    | 5 (4.0%)            | 0.27    |
| Conjunctival erosion             | 3 (3.8%)    | 1 (0.8%)            |         |
| Corneal edema¹, ulcer, or decompensation | 5 (6.4%) | 13 (10.4%)        | 0.23    |
| Iritis                           | 5 (6.4%)    | 4 (3.2%)            | 0.32    |
| Cystoid macular edema            | 1 (1.3%)    | 2 (1.6%)            |         |
| Loss of light perception         | 5 (6.4%)    | 2 (1.6%)            | 0.09    |
| Shallow or flat anterior chamber | 9 (11.5%)   | 12 (9.6%)           | 0.60    |
| Tube migration                   | 3 (3.8%)    | 4 (3.2%)            |         |
| Tube–cornea touch                | 5 (6.4%)    | 1 (0.8%)            | 0.04    |
| Tube occlusion                   | 0           | 4 (3.2%)            |         |
| Visually significant hyphema     | 3 (3.8%)    | 3 (2.4%)            |         |
| Diplopia                         | 1 (1.3%)    | 1 (0.8%)            |         |

| Slit lamp intervention           | AGV (n = 78) | AGV-CEIOL (n = 125) | P value |
|----------------------------------|-------------|---------------------|---------|
| None                             | 73 (93.6%)  | 117 (93.6%)         | 1.00    |
| Anterior chamber reformation     | 4 (5.1%)    | 1 (0.8%)            |         |
| Paracentesis                     | 1 (1.3%)    | 1 (0.8%)            |         |
| Steroid injection                | 1 (1.3%)    | 1 (0.8%)            |         |
| Tube repositioning               | 1 (1.3%)    | 4 (3.2%)            |         |
| Tube unclogging                  | 0           | 2 (1.6%)            |         |

| Reoperation for glaucoma or complications | AGV (n = 78) | AGV-CEIOL (n = 125) | P value |
|-------------------------------------------|-------------|---------------------|---------|
| None                                      | 47 (60.3%)  | 98 (78.4%)          | 0.007   |
| Anterior chamber reformation              | 0           | 1 (0.8%)            |         |
| Conjunctival erosion repair                | 3 (3.8%)    | 1 (0.8%)            |         |
| DSEK                                       | 1 (1.3%)    | 1 (0.8%)            |         |
| Endoscopic cyclophotocoagulation          | 3 (3.8%)    | 0                   |         |
| Glaucoma drainage device                  | 6 (7.7%)    | 6 (4.8%)            | 0.40    |
| Micro-invasive glaucoma surgery           | 2 (2.6%)    | 2 (1.6%)            |         |
| Prophylactic tube trimmingb               | 2 (2.6%)    | 0                   |         |
| Transscleral cyclophotocoagulation        | 15 (19.2%)  | 13 (10.4%)          | 0.07    |
| Tube removal                               | 1 (1.3%)    | 1 (0.8%)            |         |
| Tube repositioning                        | 2 (2.6%)    | 0                   |         |

¹ Adis
were. This likely reflects the frequently reported, transient IOP elevation after cataract surgery that may be attributable to factors such as retained viscoelastic and inflammation [26]. In contrast, the AGV-CEIOL group experienced fewer hypertensive phases within the first 3 months, even after multivariable adjustment for baseline differences in glaucoma severity. This finding may suggest that the cataract surgery alters bleb formation morphology, such that the fibrosis that has been implicated in the hypertensive phase may be less potent [27]. An alternative explanation is that cataract surgery itself facilitates aqueous outflow, lowering the odds of a later spike [28]. Though a history of prior glaucoma surgery was adjusted for in the multivariable analyses, previous procedures that manipulated the sub-Tenon’s space may have still contributed to the increased incidence of the hypertensive phase in the standalone cohort. In sum, it appears that the weaker post-op day 1 IOP reduction following AGV-CEIOL is not sustained, and in fact the combined approach may have a somewhat more favorable profile overall in the short term.

Regarding long-term IOP control, AGV-CEIOLs were at a disadvantage on univariate analysis. However, this disadvantage subsided after multivariable adjustment for baseline covariates that differed significantly between groups; preop IOP was the main factor associated with IOP reduction. The one significant interaction effect observed between AGV combination and preop IOP may also warrant attention. Though AGV combination did not predict failure due to IOP greater than 21 mmHg after 3 months, the interaction effect suggests that conducting AGV-CEIOL on eyes with higher preop IOPs may correlate with weaker long-term pressure reductions compared to AGV surgery alone. This may be a select consideration for patients who have both cataract and glaucoma and present with markedly elevated IOPs.

Our findings compared reasonably well to the landmark clinical trials involving sutured AGVs [20, 29]. The total number of eyes with 1-year follow-up in our study exceeded the number of AGV eyes that had achieved 1-year follow-up in the ABC (n = 132) or AVB (n = 110) studies [17, 30]. Of note, our study’s full sample included more Black and Hispanic patients than the Ahmed treatment arms of the ABC and AVB studies combined [13, 14]. At baseline for the ABC study, the AGV group consisted of 43 (30%) eyes from Black patients and 12 (8%) from Hispanic patients; in the AVB study, the numbers were 15 (12%) and 5 (4%), respectively [13, 14]. Race is a social construct, not a biological determinant. In spite of this, there is considerable evidence of Black and Hispanic patients experiencing worse glaucoma outcomes, including after glaucoma surgeries like the AGV [24, 25].

The overall failure rate observed in our study (45.8%) in a sample with mean follow-up of 3.5 years was similar to the failure rate of AGV eyes in the ABC trial at 5 years (44.7%), but...
higher than the rate at 3 years (31.3%) [29, 31]. Interestingly, a pooled post hoc analysis of both the AVB and ABC studies found that lower prep IOP and neovascular glaucoma were each independent risk factors for failure [32]. In our sample, the AGV standalone group had higher prep IOP and more neovascular cases. However, both the clinical and statistical magnitudes of difference in prep IOP between groups were greater than the NVG differences. Thus, prep IOP may have been more impactful, which is supported by the multivariable analyses previously described. This may lend further support for the AGV-CEIOL approach in terms of failure given its cohort’s significantly lower starting IOPs.

We used the same failure criteria as El Wardani and colleagues, who reported greater failure rates in eyes that received combined phacoemulsification and BGI implantation (PBT) versus BGI alone (BT) [3]. There are multiple possible explanations for differences in our two studies of combined GDD approaches. First, in El Wardani’s study, there were no failures due to reoperation for glaucoma in either group. In contrast, reoperation for glaucoma in the present study was the primary reason for failure in AGV standalones and the second most common reason for ACV-CEIOLs. This aligns with the documented disadvantage AGVs have versus BGIs in terms of IOP control [33]. The hypertensive phase in particular is a mostly AGV-specific phenomenon, and the advantage we observed for AGV-CEIOLs in this regard may have had unique downstream effects that reduced failure rates [34]. Furthermore, there are key baseline differences in our samples. Failure rates may have been higher in El Wardani et al.’s combined cohort as a result of the PBT group being 8 years younger than the BT group (P = 0.01), as younger age is an independent risk factor for GDD failure [32]. Furthermore, in their study, racial/ethnic data was not reported and follow-up time was limited to 3 years. It is possible that differences in racial/ethnic distributions and length of observation may have also contributed to the differences in survival between our two studies.

The safety profiles for both sutureless AGV and sutureless AGV-CEIOL in Black and Hispanic patients were similar to prior research of AGV outcomes [19, 20]. Surgeons who have not used the sutureless technique may be particularly interested in complications related to plate fixation. We found that rates of both tube migration and conjunctival erosion were each under 4%, similar to the AGV and ABC studies [19, 20]. Rates of diplopia were lower, possibly because of less mechanical obstruction in the absence of sutures [19, 20, 35]. For comparison, a recent study of outcomes for a small sample of sutureless AGVs that did not use Tisseel sealant did not disclose any cases of diplopia [36]. The decreased rates of tube–cornea touch in the AGV-CEIOL cohort compared to the standalone cohort may be due to deepening of the anterior chamber from cataract removal, enabling the tube to rest more posteriorly. That same mechanism may also explain the higher rate of tube clogging in the combined group. With the tube lying closer to the iris in a deepened chamber, obstruction from iris pigments may have been more likely. Corneal complications like decompensation may have been further reduced by placing the tubes exclusively in the ciliary sulcus, as recent research has found that corneal endothelial cell loss is less with sulcus tubes [37].

Our study has limitations. The retrospective design may have contributed to the baseline differences between surgical cohorts. Baseline IOP was greater in AGV standalone eyes, and around one-third of standalones had a prior glaucoma surgery versus around a tenth of AGV-CEIOLs, limiting the ability to compare outcomes on univariate analysis. The multivariable analyses were performed in order to specifically mitigate for such baseline differences. Data that was recorded in the electronic medical record may not have been as thoroughly logged compared to a prospective study. Hispanic patients in particular can come from a wide variety of sociocultural backgrounds, and in our study, many of them may have held multiple racial identities that were not thoroughly captured by our basic clinic demographics questions. Furthermore, though we excluded white patients, some patients who self-identified as non-white may indeed fit other socio-ethnic definitions of white, such as
northern European ancestry. We did not examine the effect of tube location (anterior chamber or ciliary sulcus) in this study. Furthermore, there was dropout by each annual visit after 1 year, limiting statistical power for long-term outcome comparisons.

Though the sutureless approach provides a novel perspective, we were unable to compare directly against sutured outcomes in our patient population given the operating surgeon's minimal use of the sutured technique. This single-surgeon design allows for consistency; however, the lack of data from other surgeons also presents a gap in understanding the interoperability of the sutureless approach. The sutureless technique is not popular or widely adopted, may have a different complication profile based on the operating surgeon, and carries a greater risk of tube migration if the glue mixture is defective—all further limiting the applicability of the results. We excluded non-bag implantations of intraocular lenses from our AGV-CEIOL group in order to minimize confounding from rare yet complicated procedures. This decision helped to better isolate the independent effects of standalone versus combined status under common circumstances, but provides less insight into how the outcomes of the combined technique may change in extreme cases. For instance, if an eye had a posterior capsule rupture that required vitrectomy and sulcus intraocular lens placement, it may have undergone a greater inflammatory response that could have increased post-op IOP. Our study did not explore the effects of AGV-CEIOL on refractive outcomes, which have been shown to be somewhat less favorable compared to CEIOL alone in a small retrospective cohort [38]. Moreover, our study did not investigate factors related to structural racism, such as intergenerational inequities in health care access, that may contribute to glaucoma disparities [9, 39].

A 2017 Cochrane review found no strong evidence to select tube shunts over trabeculectomy, or vice versa [40]. During the time that the current study’s surgeries were performed (2015–2019), high-quality 5-year data from the tube versus trabeculectomy study (TVT) supported the use of tube shunts over trabeculectomy from the standpoint of surgical success, particularly in eyes that had prior intraocular intervention [41]. In our specific practice’s experience, patients have generally responded well to tube shunts, which have the advantage of fewer early postoperative complications but greater corneal risks compared to trabeculectomy [42]. The sutureless technique in particular has been a patient-centric choice, given that many of our patients have commented on the discomfort caused by abrasive ocular sutures. However, recently published 5-year results from the primary tube versus trabeculectomy study revealed a decreased glaucoma medication burden in the trabeculectomy group [43]. As such, some surgeons may prefer trabeculectomy over tube shunt, especially in the context of a primary surgery. It is possible too that trabeculectomy–CEIOL may hold advantages over sutureless AGV-CEIOL that are yet to be elucidated.

CONCLUSIONS

Our results showed that sutureless AGV-CEIOL had similar safety and efficacy outcomes versus sutureless AGV standalone when performed in non-Hispanic Black or non-white Hispanic patients. Failure rates, glaucoma medications, complications, and most IOP metrics were comparable between surgical cohorts. Multivariable analyses adjusting for baseline differences found the AGV-CEIOL cohort to be better at avoiding the hypertensive phase, while the standalone cohort responded better to high preop IOPs. Overall outcomes of the sutureless technique were similar to previously reported findings from major studies of the sutured approach. This study provides timely information for surgeons regarding the utility of both sutureless AGV and sutureless AGV-CEIOL for patient populations in need of higher-quality glaucoma care. Future randomized controlled trials comparing the sutureless technique to the sutured approach, as well as the AGV-CEIOL to AGV standalone, are warranted. Such trials should make efforts to include more Black and Hispanic participants, and it is crucial for structural causes of differences in glaucoma outcomes to be explored.
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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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