Combined Pars Plana Glaucoma Drainage Device Placement and Vitrectomy Using a Vitrectomy Sclerotomy Site for Tube Placement: A Case Series

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Abstract

**Background:** The purpose of this study is to report the safety and efficacy of pars plana (PP) glaucoma drainage devices (GDDs) with pars plana vitrectomy (PPV) using one of the vitrectomy sclerotomy sites for tube placement in patients with refractory glaucoma.

**Methods:** Retrospective case series of 28 eyes of 28 patients who underwent combined PP GDD and PPV between November 2016 and September 2019 at Massachusetts Eye and Ear. Main outcome measures were intraocular pressure (IOP), glaucoma medication burden, best corrected visual acuity (BCVA), and complications. Statistical tests were performed with R and included Kaplan-Meier analyses, Wilcoxon paired signed-rank tests, and Fisher tests.

**Results:** Mean IOP decreased from 22.8 mmHg to 11.4 mmHg at 1.5 years ($p = 0.009$), and mean medication burden decreased from 4.3 to 1.7 at 1.5 years ($p = 0.009$). Both IOP and medication burden were significantly lower at all follow-up time points. The probability of achieving $5 \leq \text{IOP} \leq 18$ mmHg with at least 20% IOP reduction from preoperative levels was 77.7% at 1 year and 45.8% at 1.5 years. At their last visit, four eyes (14.3%) achieved complete success with IOP reduction as above without medications, and 13 eyes (46.2%) achieved qualified success with medications. Visual acuity was unchanged or improved in 23 eyes (82.1%) at their last follow-up. Two patients had a visual acuity decrease of >2 lines. Two eyes required subsequent PPV for tube obstruction, and one eye had transient hypotony.

**Conclusions:** The results of pars plana GDD and vitrectomy using one of the vitrectomy sclerotomy sites for tube placement are promising, resulting in significant IOP and medication-burden reductions through postoperative year 1.5 without additional risk of postoperative complications. Inserting GDDs into an existing vitrectomy sclerotomy site may potentially save surgical time by obviating the need to create another sclerotomy for tube placement and suture one of the vitrectomy ports.

**Background**

Glaucoma drainage devices (GDDs) are increasingly used in the treatment of glaucoma refractory to medical therapy or after unsuccessful trabeculectomy or laser procedures. Between 1995 and 2004, the use of GDDs increased by 184% in Medicare patients alongside a 53% decrease in the number of trabeculectomies in eyes without scarring [1]. GDDs may be inserted into the anterior chamber, sulcus, or pars plana depending on comorbid ocular pathology that may preclude placement in a particular location or if a vitrectomy is needed for retinal pathology. Namely, tube placement in the anterior chamber may not be recommended in the setting of some corneal diseases, iridocorneal angle abnormalities, or peripheral anterior synechiae amongst other pathologies [2]. In these cases, tube placement in the pars plana (PP) may be considered to prevent postoperative anterior chamber complications [3]. PP GDD insertion requires concurrent or prior pars plana vitrectomy (PPV) to prevent vitreous occlusion of the tube. In the
combined PPV and PP GDD surgery, treatment of concurrent posterior segment diseases may also be performed, minimizing the need for multiple separate surgical procedures.

During combined PPV and pars plana GDD placement, the GDD tube may be inserted into a new sclerotomy or an existing sclerotomy used for one of the vitrectomy ports [4, 5]. With prior 20-gauge sclerotomies for PPV, concerns regarding the risk of hypotony from leakage around the tube led to greater adoption of creating a new sclerotomy for the tube. In fact, tube insertion into sclerotomies larger than 21-gauge were suggested to be associated with higher leakage rates [6]. Thus, the vitrectomy sclerotomies were closed with suturing to allow for a watertight closure, and a new, separate sclerotomy was created for the GDD tube.

With modern small-gauge (ie. 23- and 25-gauge) PPVs, however, there may be a lower risk of hypotony from leakage around a tube inserted into a preexisting sclerotomy [3, 7]. Utilizing an existing sclerotomy also likely saves surgical time by eliminating the need to create another sclerotomy and suture one of the port sites, which may result in less inflammation by minimizing the amount of suture material in the sclera. In this study, we evaluate the surgical outcomes and complication rates of pars plana GDD placement with tube insertion into one of the existing 23- or 25-gauge vitrectomy sclerotomy sites in patients with refractory glaucoma.

**Methods**

**Study Design**

This is a retrospective study of consecutive adult glaucoma patients who underwent PP GDD insertion with PPV using one of the vitrectomy sclerotomy sites for tube insertion. After receiving approval from the Mass General Brigham Institutional Review Board, medical records of patients who underwent the procedure between April 2016 and November 2019 at Massachusetts Eye and Ear were identified and reviewed. GDD insertion was performed by 9 different providers, and PPV was performed by 8 different providers. Data collection abided by the Declaration of Helsinki and the Health Portability and Accountability Act. Patients were included if they met the following criteria: (1) diagnosis of glaucoma; (2) concurrent PP GDD surgery and PPV with tube insertion into one of the vitrectomy sclerotomy sites; (3) at least 3 months of follow-up; and (4) age ≥ 18 years. If patients had undergone procedures in both eyes, the left eye was included in our study.

Demographic and preoperative data included patient age, gender, glaucoma diagnosis and stage, previous ocular surgeries, IOP, number of glaucoma medications, and visual acuity (VA). Glaucoma stages were defined as circumpapillary retinal nerve fiber layer thinning on optical coherence tomography with Humphrey visual field findings of no abnormalities for mild glaucoma; a single corresponding inferior or superior deficit for moderate glaucoma; or a combination of paracentral or superior and inferior defects for severe glaucoma [8]. An indeterminate stage was defined if visual field testing could not be performed reliably or if the patient had light perception or no light perception vision. IOP was measured
with Goldmann applanation tonometry. Preoperative IOP, medication burden, and VA were calculated as an average of the values from two consecutive visits prior to the procedure. Postoperative data were collected at 1 day (POD1), 2 weeks (POW2), 6 weeks (POW6), 3 months (POM3), 6 months (POM6), 1 year (POY1), and 1.5 years (POY1.5) after surgery. At each time point, the IOP, number of glaucoma medications, VA, duration of follow-up, subsequent IOP-lowering procedures, and the presence of postoperative complications such as inflammation in the anterior chamber, hypotony, corneal edema, cystoid macular edema (CME), vitreous hemorrhage, and tube obstruction were recorded.

**Surgical Procedure**

The procedures were performed by multiple glaucoma and retina specialists. All patients underwent either Ahmed or Baerveldt GDD implant placement with 23- or 25-gauge vitrectomy. The type of glaucoma implant and vitrectomy gauge were at the surgeons’ discretion. A retrobulbar block was placed by anesthesia and the operative eye was prepared in the standard ophthalmic fashion. A superotemporal conjunctival peritomy was created, and sub-Tenon's space was accessed. The GDD implant was placed into the superotemporal quadrant and secured to the sclera with 2 interrupted 8 − 0 Nylon sutures. For the vitrectomy, trocars were used to place cannulas in the inferotemporal, superotemporal, and superonasal quadrants through the pars plana in a beveled fashion. A 4 mm infusion cannula was placed through the inferotemporal cannula, and a complete standard three-port PPV was performed. The inferotemporal and superonasal sclerotomies were sutured using 7 − 0 Vicryl in an interrupted fashion, and the conjunctiva was closed in conjunction with the sclerotomy closure. The superotemporal sclerotomy was then used for GDD tube placement. The tube was then cut at the appropriate length, bevel down. The superotemporal trocar was then removed. If an Ahmed glaucoma drainage device was placed, Viscoat was injected into the pars plana to prevent hypotony. The tube was then inserted into the pars plana. A VisionGraft corneal patch graft was used to cover the tube and secured to the sclera with 2 interrupted 7 − 0 Vicryl sutures. The overlying Tenon's and conjunctiva were secured at the limbus using interrupted and running 8 − 0 Vicryl sutures. A sample video of the surgical procedure is included in the references [9].

**Outcome Measures**

Primary outcome measures were IOP reduction, glaucoma medication burden, VA, and cumulative success probabilities from Kaplan-Meier (KM) analyses. Success criteria were obtained from the Tube Versus Trabeculectomy Study [10], with the addition of a more-stringent IOP criteria as follows. Success was defined as an IOP reduction ≥ 20% from preoperative IOP without hypotony and (Criteria 1) IOP ≤ 21 mmHg; (Criteria 2) IOP ≤ 18 mmHg; or (Criteria 3) IOP ≤ 14 mmHg. Hypotony was defined as IOP ≤ 5 mmHg. A failure was recorded if a patient did not meet the specified success criteria on two consecutive follow-up visits after 3 months, required additional glaucoma surgery or laser procedure, or developed no light perception (NLP) vision. Patients who required an additional non-glaucoma procedure were censored from survival analysis. Secondary outcome measures included complication rates and need for additional glaucoma surgery.
Patients were recorded as a complete success if they satisfied Criteria 1 without medications; qualified success if they satisfied Criteria 1 with medications; and qualified failure if they did not meet the above criteria for success but did not require additional glaucoma surgery or develop NLP vision at their last visit.

**Statistical Analysis**

Statistical analyses were performed using R (version 4.0.2). A p value < 0.05 was considered statistically significant. Average and standard deviation (SD) were calculated for IOP, medication burden, and VA. Bar graphs of average values were generated with error bars representing standard deviation. Comparisons with preoperative values were conducted with Wilcoxon paired signed-rank tests. Kaplan-Meier analyses were used to generate cumulative success probabilities, with success criteria as defined above. Hazard ratios for preoperative and demographic characteristics were obtained from Cox proportional hazard regression analyses. Snellen visual acuities were converted to logarithm of minimum angle of resolution (LogMAR) equivalents, with values of 2 and 3 representing count fingers and hand motion vision respectively. Patients with light perception or no light perception vision were not converted to logMAR equivalents and excluded from mean calculations and paired Wilcoxon testing.

**Results**

A total of 28 eyes of 28 glaucoma patients were included in this study. Patient demographic and preoperative data are presented in Table 1. Mean ± SD age was 61.9 ± 20.2 (range 18–90), and 53.6% of the patients were female. Most patients (53.6%) had severe glaucoma, and the most common glaucoma type was chronic angle-closure glaucoma (32.1%) followed by mixed mechanism (25.0%) and primary open angle glaucoma (21.4%). Mean preoperative IOP was 22.8 ± 7.3 mmHg (range 10.5–38 mmHg) with a medication burden of 4.3 ± 1.0 (range 2–6). Mean follow-up time was 14.2 ± 8.1 (range 3.1–35.5 months). The most common surgical indications for the combined procedure were chronic angle-closure glaucoma with synechiae (32.1%), aphakia with vitreous in anterior chamber (21.4%), and an anterior chamber intraocular lens (17.9%). The GDD was inserted into an existing sclerotomy site used for the vitrectomy in all eyes.
### Table 1
Demographic and Ocular Data

| Parameters                                      | Parameters                               | Prior Glaucoma Laser, N (%)                                      |
|------------------------------------------------|------------------------------------------|----------------------------------------------------------------|
| **Demographics**                               | **Prior Glaucoma Laser, N (%)**          |                                                                |
| Eyes                                           | None                                     | 8 (28.6)                                                       |
| Female Eyes, N (%)                             | ALT                                      | 1 (3.6)                                                        |
| Age (years)                                    | LTP                                      | 1 (3.6)                                                        |
| Mean ± SD                                      | LPI                                      | 5 (17.9)                                                       |
| Range                                          | MPCPC/CWCPC                              | 10 (35.7)                                                      |
|                                                 | SLT                                      | 3 (10.7)                                                       |
| **Glaucoma Stage, N (%)**                      | **Preoperative Baseline**                 |                                                                |
| Mild                                           | Mean ± SD                                | 22.8 ± 7.3                                                     |
| Moderate                                       | Range                                    | 10.5–38                                                        |
| Severe                                         |                                          |                                                                |
| Indeterminate                                  |                                          |                                                                |
| # of Glaucoma Medications                      |                                          |                                                                |
| **Glaucoma Type, N (%)**                       | **Surgical Indication, N (%)**           |                                                                |
| Aphakic                                        | Mean ± SD                                | 4.3 ± 1.0                                                      |
| Chronic angle closure                          | Range                                    | 2–6                                                            |
| Mixed mechanism\(^{a}\)                       | Mean ± SD                                | 0.94 ± 0.96                                                    |
| Neovascular                                    | Range                                    | 0–3                                                            |
| Primary open angle                             |                                          |                                                                |
| Pseudoexfoliation                              |                                          |                                                                |
| **Prior Surgeries, N (%)**                     | **Aphakia**                              | 6 (21.4)                                                       |
| None                                           | ACIOL                                    | 5 (17.9)                                                       |
| Chronic angle-closure glaucoma                 | Chronic angle-closure glaucoma            | 9 (32.1)                                                       |
| AGI                                            | DSEK/DSAEK                               | 4 (14.3)                                                       |
| Anterior vitrectomy                            | KPro                                     | 3 (10.7)                                                       |
| DSEK/DSAEK                                      | Vitreous prolapse                        | 3 (10.7)                                                       |

\(^{a}\) Mixed mechanism refers to a combination of glaucoma types, not a specific type.
The type of implant and PPV gauge are listed in Table 1. Twenty-four eyes (85.7%) received an Ahmed glaucoma implant, and the remaining 4 eyes (14.3%) received a Baerveldt glaucoma implant. A 25G vitrectomy was performed in 19 eyes (67.9%) and 23G vitrectomy in 9 eyes (32.1%).

Postoperative intraocular pressure, medication burden, and visual acuity outcomes are summarized in Table 2. Line graphs of postoperative outcomes are shown in Fig. 1. IOP was significantly decreased at all follow-up time points compared to preoperative levels, with an average reduction of 8.5 ± 5.9 mmHg at POY1.5 (p = 0.009). Medication burden was also significantly decreased at all time points with an average of 1.7 ± 1.0 at POY1.5 (p = 0.009). VA was unchanged from preoperative levels at all time points after POD1. VA was the same or improved at the last follow-up visit for 23 eyes (82.1%), with the remaining 5 eyes (17.9%) experiencing decreased vision. One eye experienced VA loss by 1 line, 2 eyes by 2 lines, and 2 eyes by >2 lines. One eye that experienced VA loss of >2 lines had previously undergone placement of a Boston keratoprosthesis type 1 with a postoperative course complicated by

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| Parameters                        | Parameters                        |
|-----------------------------------|-----------------------------------|
| KPro 3 (10.7)                     | Lens fragment in vitreous 2 (7.1) |
| iStent 1 (3.6)                    |                                   |
| Phaco 20 (71.4)                   | Type of Procedure, N (%)          |
| PKP 1 (3.6)                       | AGI / PPV 24 (85.7)               |
| PPV 8 (28.6)                      | BGI / PPV 4 (14.3)                |
| Trabeculectomy 4 (14.3)           |                                   |
| Other (OGI repair, GSL, EL) 7 (25.0) | PPV Gauge, N (%)                  |
|                                   | 23G 9 (32.1)                      |
|                                   | 25G 19 (67.9)                     |

N = number of eyes; SD = standard deviation; IOP = intraocular pressure; mmHg = millimeters of mercury; LogMAR = logarithm of the minimum angle of resolution; AGI = Ahmed glaucoma implant; BGI = Baerveldt glaucoma implant; PPV = pars plana vitrectomy; ALT = argon laser trabeculoplasty; LTP = laser trabeculoplasty; LPI = laser peripheral iridotomy; MPCPC = micropulse cyclophotoagulation; CW CPC = continuous wave cyclophotoagulation; SLT = selective laser trabeculoplasty; PRP = panretinal photoagulation; YAG = YAG capsulotomy; DSEK = Descemet stripping endothelial keratoplasty; DSAEK = Descemet stripping automated endothelial keratoplasty; KPro = keratoprosthesis; Phaco = phacoemulsification; PKP = penetrating keratoplasty; OGI = open globe injury; GSL = goniosynechialysis; EL = endolaser; ACIOL = anterior chamber intraocular lens

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a Mixed mechanism glaucoma includes a combination of primary open angle, chronic angle closure, steroid response, pseudoexfoliative, traumatic, uveitic, and neovascular glaucoma as well as glaucoma secondary to an iris melanoma or corneal transplantation.

b iStent Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L, Glaukos Corporation, San Clemente, California); and iStent inject® Trabecular Micro-Bypass System (Model G2-M-IS, Glaukos Corporation, San Clemente, California)
endophthalmitis and chronic angle-closure glaucoma. The other eye with VA loss of > 2 lines underwent Descemet stripping epithelial keratoplasty after the tube insertion surgery.
Table 2
Postoperative Outcomes Data

|                     | IOP (mmHg) | Medications | VA (LogMAR) |
|---------------------|------------|-------------|-------------|
| **Preoperative (n = 28)** |            |             |             |
| Mean (SD)           | 22.8 (7.3) | 4.3 (1.0)   | 0.94 (0.96) |
| **1 day (n = 27)**  |            |             |             |
| Mean (SD)           | 10.1 (4.9) | 0.0 (0.0)   | 1.32 (0.80) |
| Decrease from baseline | 12.2 (8.9) | 4.3 (1.0)   | -0.39 (0.86) |
| *p value*           | < 0.001*   | < 0.001*    | 0.031*      |
| **2 weeks (n = 27)**|            |             |             |
| Mean (SD)           | 12.6 (5.2) | 0.7 (1.2)   | 1.06 (0.89) |
| Decrease from baseline | 10.3 (9.7) | 3.6 (1.4)   | -0.20 (0.96) |
| *p value*           | < 0.001*   | < 0.001*    | 0.280       |
| **6 weeks (n = 27)**|            |             |             |
| Mean (SD)           | 14.3 (6.5) | 1.4 (1.5)   | 0.75 (0.69) |
| Decrease from baseline | 8.9 (7.8)  | 2.9 (1.5)   | 0.21 (0.75) |
| *p value*           | < 0.001*   | < 0.001*    | 0.211       |
| **3 months (n = 25)**|            |             |             |
| Mean (SD)           | 13.2 (4.4) | 1.7 (1.5)   | 0.80 (0.82) |
| Decrease from baseline | 10.4 (7.9) | 2.6 (1.3)   | 0.17 (0.84) |
| *p value*           | < 0.001*   | < 0.001*    | 0.486       |
| **6 months (n = 21)**|            |             |             |
| Mean (SD)           | 12.6 (3.2) | 1.8 (1.4)   | 0.79 (0.77) |
| Decrease from baseline | 9.7 (7.2)  | 2.4 (1.3)   | 0.29 (0.97) |
| *p value*           | < 0.001*   | < 0.001*    | 0.268       |
| **1 year (n = 16)** |            |             |             |

IOP = intraocular pressure; mmHg = millimeters of mercury; VA = visual acuity; LogMAR = logarithm of the Minimum Angle of Resolution; n = number of eyes; SD = standard deviation

*Patients with LP or NLP at these time points were excluded in mean and *p value* calculations due to a lack of a validated LogMAR equivalent.
|                          | IOP (mmHg) | Medications | VA (LogMAR) |
|--------------------------|------------|-------------|-------------|
| Mean (SD)                | 13.5 (4.2) | 1.5 (1.2)   | 0.68 (0.65) |
| Decrease from baseline   | 6.3 (5.7)  | 2.5 (1.4)   | 0.27 (1.11) |
| p value                  | 0.002*     | < 0.001*    | 0.485       |

1.5 years (n = 9)

|                          | IOP (mmHg) | Medications | VA (LogMAR) |
|--------------------------|------------|-------------|-------------|
| Mean (SD)                | 11.4 (2.0) | 1.7 (1.0)   | 0.34 (0.35) |
| Decrease from baseline   | 8.5 (5.9)  | 2.5 (1.2)   | 0.59 (1.05) |
| p value                  | 0.009*     | 0.009*      | 0.151       |

IOP = intraocular pressure; mmHg = millimeters of mercury; VA = visual acuity; LogMAR = logarithm of the Minimum Angle of Resolution; n = number of eyes; SD = standard deviation

*Patients with LP or NLP at these time points were excluded in mean and p value calculations due to a lack of a validated LogMAR equivalent.

Cumulative success probabilities derived from Kaplan-Meier analyses for all three success criteria are shown in Table 3, with corresponding Kaplan-Meier curves depicted in Fig. 2. For success defined as IOP ≤ 21 mmHg or 18 mmHg (Criteria 1 and 2, respectively) as above, success probabilities were both 77.7 ± 10.2% at 1 year and 45.8 ± 13.8% at 1.5 years. For an even stricter success criteria of IOP ≤ 14 mmHg (Criteria 3), success probability was 60.0 ± 11.2% at 1 year and 32.4 ± 12.0% at 1.5 years.
|                          | Cumulative Success (%) ± SE (95% Confidence Interval) |
|--------------------------|--------------------------------------------------------|
| IOP reduction ≥ 20% with IOP > 5 mmHg and |                                                       |
| IOP ≤ 21 mmHg           | IOP ≤ 18 mmHg                                         | IOP ≤ 14 mmHg                                         |
| 3 months                 | 100.0 ± 0.0                                           | 100.0 ± 0.0                                          | 100.0 ± 0.0                                          |
| (n = 24)                 | (100.0, 100.0)                                        | (100.0, 100.0)                                       | (100.0, 100.0)                                       |
| 6 months                 | 91.3 ± 5.9                                            | 91.3 ± 5.9                                           | 81.7 ± 8.3                                           |
| (n = 20)                 | (80.4, 100.0)                                         | (80.4, 100.0)                                        | (66.9, 99.7)                                         |
| 1 year                   | 77.7 ± 10.2                                           | 77.7 ± 10.2                                          | 60.0 ± 11.2                                          |
| (n = 14)                 | (60.1, 100.0)                                         | (60.1, 100.0)                                        | (41.6, 86.4)                                         |
| 1.5 years                | 45.8 ± 13.8                                           | 45.8 ± 13.8                                          | 32.4 ± 12.0                                          |
| (n = 9)                  | (25.3, 82.8)                                          | (25.3, 82.8)                                         | (15.7, 67.0)                                         |

SE = standard error; IOP = intraocular pressure

Last follow-up visit outcomes are listed in Table 4. Four eyes (14.3%) achieved complete success and 13 eyes (46.4%) achieved qualified success under Criteria 1. Five eyes (17.9%) were a qualified failure and 6 eyes (21.4%) required additional glaucoma surgery, as detailed below.
Table 4
Last Follow-up Outcomes Data

|                      | IOP (mmHg) | Medications | VA (LogMAR) |
|----------------------|------------|-------------|-------------|
| **Total** (n = 22)   |            |             |             |
| Mean ± SD            | 12.4 ± 3.4 | 2 ± 1.4     | 0.77 ± 0.82 |
| Range                | 7–23       | 0–4         | 0–3         |
| **Complete success** (n = 4) |          |             |             |
| Mean ± SD            | 9.5 ± 2.1  | 0 ± 0       | 0.61 ± 0.24 |
| Range                | 7–12       | 0           | 0.40–0.88   |
| **Qualified success** (n = 13) |        |             |             |
| Mean ± SD            | 11.9 ± 2.4 | 2.3 ± 1.0   | 0.73 ± 0.87 |
| Range                | 8–17       | 1–4         | 0–3         |
| **Qualified failure** (n = 5) |          |             |             |
| Mean ± SD            | 15.8 ± 4.2 | 2.8 ± 1.6   | 0.94 ± 0.98 |
| Range                | 13–23      | 0–4         | 0–2         |

IOP = intraocular pressure; mmHg = millimeters of mercury; VA = visual acuity; LogMAR = logarithm of the Minimum Angle of Resolution; n = number of eyes; SD = standard deviation

1 Excluding eyes that underwent additional procedures after the initial combined procedure and were categorized as failures.

For success as IOP ≤ 21 mmHg (Criteria 1) or IOP ≤ 18 mmHg (Criteria 2), the hazard ratio for preoperative medication burden was 0.3643 with a 95% confidence interval of 0.1528–0.8686 (p = 0.02). Otherwise, hazard ratio for preoperative medication burden was not significant for Criteria 3, and hazard ratios for age, race, sex, glaucoma stage, family history of glaucoma, type of glaucoma implant, vitrectomy cannula gauge, and preoperative IOP were not significant for any of the three success criteria.

Complication rates are shown in Table 5. The most common complications prior to 3 months postoperatively were inflammation in 13 eyes (46.4%), corneal edema in 9 eyes (32.1%), and cystoid macular edema (CME) in 5 eyes (17.9%). Late complications after 3 months included CME in 5 eyes (23.8%), corneal edema in 3 eyes (14.3%), and inflammation in 1 eye (4.8%). Five eyes developed CME after surgery, which resolved in two eyes at 3 months and 9 months respectively. In two eyes, CME developed at 1.5 months and 2 months respectively and persisted through their last follow-up. In one eye, CME resolved after 2 months but reappeared at the following visit.
Table 5
Complication Rates

| N (%)                  | AC Inflammation | Hypotony | Corneal edema | Cystoid macular edema | Vitreous hemorrhage | Tube obstruction |
|------------------------|-----------------|----------|---------------|-----------------------|---------------------|------------------|
| Total (n = 28)         | 14 (50.0)       | 1 (3.6)  | 9 (32.1)      | 5 (17.9)              | 6 (21.4)            | 2 (7.1)          |
| Early\(^a\) (n = 28)  | 13 (46.4)       | 1 (3.6)  | 9 (32.1)      | 5 (17.9)              | 4 (14.3)            | 2 (7.1)          |
| Late\(^b\) (n = 21)   | 1 (4.8)         | 0 (0.0)  | 3 (14.3)      | 5 (23.8)              | 0 (0.0)             | 0 (0.0)          |

N = number of eyes in group; n = total number of eyes; AC = anterior chamber

\(^a\)Complications present up to 3 months postoperatively, not including preoperative findings.

\(^b\)Complications present after 3 months postoperatively.

Hypotony was noted in 1 patient (3.6%) and self-resolved after 2 weeks. Vitreous hemorrhage was present in three eyes prior to surgery which resolved with surgery in two eyes. Vitreous hemorrhage was found in 4 eyes postoperatively and self-resolved after 2 weeks. Two eyes (7.1%) required subsequent PPV for tube obstruction with vitreous or blood. No eyes developed choroidal detachment, retinal tears, retinal detachment, endophthalmitis, or diplopia postoperatively.

Six patients had additional glaucoma surgeries after the combined surgery. Two patients received a combination of augmented Micropulse transscleral cyclophotocoagulation (MP-TSCPC) [11] and continuous wave transscleral cyclophotocoagulation at 15 months and 16 months respectively. Another two patients underwent MP-TSCPC only at 2.5 months after surgery. Finally, one patient underwent PPV at 1 month for vitreous occluding the tube, and another patient underwent PPV at 2 months for blood occluding the tube.

**Discussion**

This study is the largest study to date that examines outcomes of pars plana GDD insertion through an existing vitrectomy sclerotomy site. In this study, the mean IOP and medication burden were significantly reduced at all postoperative time points compared to preoperative levels. Four eyes achieved complete success and 13 eyes achieved qualified success at their last follow-up visit, for a total success rate of 60.7% (17/28 eyes) under Criteria 1. This success rate is slightly lower than total success rates reported by prior studies ranging from 67–100%, as seen in Tables 6–8. However, given that our mean preoperative IOP was lower than that of other studies, our lower success rate may instead reflect a lower
magnitude of IOP reduction secondary to a lower starting IOP. For every 1-unit increase in preoperative medication burden, the hazard of failure to achieve IOP ≤ 18 mmHg (Criteria 2) also decreased by 63.6%, suggesting that a higher preoperative medication burden results in higher likelihood of postoperative success. Vitrectomy gauge was not a predictive factor for failure, as demonstrated by the nonsignificant hazard ratio. Average visual acuity was unchanged from preoperative levels at all follow-up visits after POD1, and no patients experienced > 2 lines of visual acuity loss due to the combined PP GDD and vitrectomy. Overall, the final postoperative IOP, postoperative medication burden, and visual acuity findings in this study were similar to prior studies evaluating outcomes of combined pars plana GDD insertion and vitrectomy (Tables 6–8).
Table 6
Selection of retrospective studies of pars plana glaucoma drainage device placement in a new sclerotomy separate from the vitrectomy sclerotomy sites.

| Author, year | Publication | Glaucoma type | GDD type | Sclerotomy for tube insertion | PPV gauge | F/U (months) | # of eyes | % Complete / qualified success<sup>a</sup> | IOP (mean preop / final (mmHg)) | # of Meds (mean preop / final) | # VA decline | # eyes with complications |
|--------------|-------------|---------------|----------|-----------------------------|-----------|-------------|-----------|--------------------------------|-----------------------------|-----------------------------|----------------|--------------------------|
| Tarantola et al., 2011 [13] | Retina | Uncontrolled CACG | Baerveldt | Different | 20 (endoscope-assisted) | Mean 62 (range 10–106) | 19 | 26 / 47 | 31.3 / 11.4 | 3.4 / 1.3 | 1 (5.3%) | 5 (26.3%) |
| Shaikh et al., 2014 [14] | BMJ Ophthalm | Mixed | - | Different | 20, 23, 25 (endoscope-assisted) | Median 18 (range 12–28) | 13 | - | 23.0 / 12.0 | 3.1 / 0.3 | - | 0 (0%) |
| Varma et al., 1995 [15] | AJO Ophthalm | OAG and ACG | Baerveldt | Different | - | Mean 12.1 (range 0-31.8) | 13 | 47 / 41 | 35 / 13 | - / 0.8 | 4 (30.8%) | - |
| Sidoti et al., 2001 [16] | J Glaucoma | Mixed | Ahmed, Baerveldt, Molteno, Krupin | Different | - | Mean 38.4 (range 6–86) | 34 | - | 17.9 / 15.1 | - | 5 (15%) | 20 (30%) |
| Witmer et al., 2010 [17] | - | Mixed | Baerveldt | Different | - | - | 51 | - | 26.9 / 13.5 | - | 16 (31.4%) | - |

CACG = chronic angle closure glaucoma; OAG = open angle glaucoma; ACG = acute-closure glaucoma; vTB = vitreal tube blockage; sTB = swollen Soemmering’s ring blocking tube; SR = shunt retraction; CD = choroidal detachment; hCD = hemorrhagic choroidal detachment; LEM = limited eye movement; D = diplopia; vTB = vitreal tube blockage; H = hypotony, as defined by IOP < 6 mmHg; ScH = suprachoroidal hemorrhage; Hy = hyphema; CGF = corneal graft failure; U = uveitis; ERM = epiretinal membrane; I = iritis; CEf = choroidal effusion; CME = cystoid macular edema; RD = retinal detachment

<sup>a</sup>Complete success was defined as IOP between 6–21 mmHg without medications. Qualified success was defined as IOP between 6–21 mmHg with medications.
| Author, year | Tarantola et al., 2011 [13] | Shaikh et al., 2014 [14] | Varma et al., 1995 [15] | Sidoti et al., 2001 [16] | Witmer et al., 2010 [17] |
|-------------|----------------------------|-------------------------|-------------------------|--------------------------|--------------------------|
| **Select complications (%)** | vTB – 5; sTB – 5; SR – 5; hCD – 5 | - | LEM – 15 | CGF – 50; H – 3; CD – 12; CME – 3; RD – 6; vTB – 9; bTB – 3; VH – 6; U – 6; Hy – 3; ScH – 6 | I – 10; RD – 6; D – 6; vTB – 4; H – 4; ERM – 4; CEF – 4 |
| **# of glaucoma reoperations** | 5 (26.3%) | 3 (23.1%) | 2 (15.4%) | - | - |

CACG = chronic angle closure glaucoma; OAG = open angle glaucoma; ACG = acute-closure glaucoma; vTB = vitreal tube blockage; sTB = swollen Soemmering’s ring blocking tube; SR = shunt retraction; CD = choroidal detachment; hCD = hemorrhagic choroidal detachment; LEM = limited eye movement; D = diplopia; vTB = vitreal tube blockage; H = hypotony, as defined by IOP < 6 mmHg; ScH = suprachoroidal hemorrhage; Hy = hyphema; CGF = corneal graft failure; U = uveitis; ERM = epiretinal membrane; I = iritis; CEF = choroidal effusion; CME = cystoid macular edema; RD = retinal detachment

*Complete success was defined as IOP between 6–21 mmHg without medications. Qualified success was defined as IOP between 6–21 mmHg with medications.*
Table 7
Selection of retrospective studies of pars plana glaucoma drainage device placement in either a new sclerotomy or existing vitrectomy sclerotomy site.

| Author, year              | Publication       | Glaucoma type   | GDD type        | Sclerotomy for tube insertion | PPV gauge | F/U (months)               | # of eyes | % Complete / qualified success<sup>a</sup> | IOP (mean preop / final (mmHg)) | # of Meds (mean preop / final) | # VA decline | # eyes with complications |
|---------------------------|-------------------|-----------------|-----------------|-------------------------------|-----------|--------------------------|-----------|--------------------------------|--------------------------------|-----------------------------|----------------|--------------------------|
| de Guzman et al., 2006    | Clin Exp Ophthal  | Mixed           | Baerveldt, Molteno | Both                          | -         | Mean 30.2 (range 6–77)   | 33        | 49 / 42                         | 33.1 / 13.4                     | 3.6 / 0.6                   | 13 (39.4%)  | -                        |
| Qin et al., 2018          | J Glaucoma        | Mixed NVG       | Ahmed, Baerveldt | Both                          | -         | Mean 43.5 (range 2–66)   | 57        | -                              | 29.0 / 15.1                     | 2.9 / 1.1                   | 22 (38.6%)  | 16 (28.1%)               |
| Kolomeyer et al., 2015    | Retina Oman J Ophthal | Mixed          | Baerveldt      | Both                          | 20, 23, 25| Mean 19.9 (range 2–66)   | 89        | 30 / 37                         | 37.2 / 15.9                     | 2.8 / 1.21                  | 34 (38%)    | 8 (47.1%)                |
| Kolomeyer et al., 2012    | Ophthal           | Mixed NVG       | Molteno        | Both                          | 20, 23    | Mean 33.7 (range 4–71)   | 39        | 21 / 54                         | 31.9 / 13.2                     | 3.8 / 1.7                   | 14 (36%)    | -                        |
| Kaynak et al., 1998       | Br J Ophthal      | Mixed (no NVG)  | Baerveldt      | Unspecified                   | -         | Mean 30.3 (range 4–71)   | 17        | -                              | -                              | -                          | 2 (11.8%)   | -                        |
| Luttrull et al., 2000     | Ophthal           | Mixed           | Baerveldt      | Unspecified                   | -         | Mean 18 (range 3–41)     | 50        | 56 / 28                         | -                              | -                          | 14 (28%)    | -                        |

NVG: neovascular glaucoma; VH = vitreal hemorrhage; CD = choroidal detachment; CE = corneal edema; U = uveitis; LEM = limited eye movement; CGF = corneal graft failure; vTB = vitreal tube blockage; iTB = iris blocking tube; ERM = epiretinal membrane; CEf = choroidal effusion; D = diplopia; H = hypotony, as defined by IOP < 6 mmHg; TE = tube erosion; OH = ocular hypertension; Hy = hyphema; RD = retinal detachment; TB = tube blockage; En = endophthalmitis; SrH = subretinal hemorrhage; RH = retinal hemorrhage; CED = corneal endothelial decompensation; CEf = choroidal effusion; CH = choroidal hemorrhage

<sup>a</sup>Complete success was defined as IOP between 6–21 mmHg without medications. Qualified success was defined as IOP between 6–21 mmHg with medications.
| Author, year | de Guzman et al., 2006 [18] | Qin et al., 2018 [19] | Kolomeyer et al., 2015 [6] | Kolomeyer et al., 2012 [20] | Kaynak et al., 1998 [21] | Luttrull et al., 2000 [22] |
|-------------|-----------------------------|------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| **Select complications (%)** | VH/H – 12; CD – 27; CE – 30; U – 3; LEM – 3; CGF – 15; vTB – 6; iTB – 3; ERM – 3; C Ef – 3 | D – 16; H – 9; VH – 2; TE – 2 | OH – 92; H – 22; Hy – 21; CE – 19; VH – 16; C ME – 15; CD – 12; RD – 4; TB – 3; En – 3; SrH – 1; ERM – 2 | H – 23; CD – 26; OH – 13; RH – 10; VH – 5; C ME – 5; C Ef – 3 | H – 12; VH – 6; CD – 12; RD – 12; CED – 29 | C Ef – 36; C ME – 4; D – 6; RD – 8; CH – 4; VH – 2 |
| **# of glaucoma reoperations** | 13 (39.4%) | 8 (14.0%) | 9 (10%) | 5 (13%) | 1 (5.9%) | - |

NVG: neovascular glaucoma; VH = vitreal hemorrhage; CD = choroidal detachment; CE = corneal edema; U = uveitis; LEM = limited eye movement; CGF = corneal graft failure; vTB = vitreal tube blockage; iTB = iris blocking tube; ERM = epiretinal membrane; C Ef = choroidal effusion; D = diplopia; H = hypotony, as defined by IOP < 6 mmHg; TE = tube erosion; OH = ocular hypertension; Hy = hyphema; RD = retinal detachment; TB = tube blockage; En = endophthalmitis; SrH = subretinal hemorrhage; RH = retinal hemorrhage; CED = corneal endothelial decompensation; C Ef = choroidal effusion; CH = choroidal hemorrhage

\(^a\)Complete success was defined as IOP between 6–21 mmHg without medications. Qualified success was defined as IOP between 6–21 mmHg with medications.
Table 8
Selection of retrospective studies of pars plana glaucoma drainage device placement in an existing vitrectomy sclerotomy site.

| Author, year       | Reichstein et al., 2011 [7] | Kolomeyer et al., 2012 [5] | Present study |
|--------------------|------------------------------|-----------------------------|---------------|
| Publication        | Ophthal                      | Eur J Ophthal               | -             |
| Glaucoma type      | Mixed                        | Mixed                       | Mixed         |
| GDD type           | Ahmed, Baerveldt            | Baerveldt                   | Ahmed, Baerveldt |
| Sclerotomy for tube insertion | Same                        | Same                        | Same          |
| PPV gauge          | 25                           | 23                          | 23, 25        |
| F/U (months)       | >12                          | Mean 12.1 (range 6–27)      | Mean 14.2 (range 3.1–35.5) |
| # of eyes          | 10                           | 8                           | 28            |
| % Complete / qualified success<sup>a</sup> | -                           | 25 / 75                     | 14 / 46       |
| IOP (mean preop / final (mmHg)) | 31 / 16.1                  | 29.1 / 13.8                | 22.8 / 12.4   |
| # of Meds (mean preop / final) | 2.5 / -                     | 3.9 / 1.9                   | 4.3 / 2.0     |
| # VA decline       | 3 (30%)                      | 3 (37.5%)                   | 7 (25%)       |
| # eyes with complications | -                           | -                           | 14 (50%)      |
| Select complications (%) | CE – 20                     | H – 38; DR – 25; VH – 13; IRH – 25; CE – 13; CH – 13; CD – 25 | ACI – 50; H – 4; CE – 32; CME – 18; VH – 21; vTB – 4; bTB – 4 |
| # of glaucoma reoperations | 0 (0.0%)                    | 1 (12.5%)                   | 6 (21.4%)     |

CE = corneal edema; H = hypotony, as defined by IOP < 6 mmHg; DR = decompression retinopathy; VH = vitreal hemorrhage; IRH = intraretinal hemorrhage; CH = choroidal hemorrhage; CD = choroidal detachment; ACI = anterior chamber inflammation; vTB = vitreal tube blockage; bTB = blood tube blockage

<sup>a</sup>Complete success was defined as IOP between 6–21 mmHg without medications. Qualified success was defined as IOP between 6–21 mmHg with medications.
The most common complication encountered in this study was transient anterior chamber inflammation in 14 out of 28 eyes (50%), which resolved in all cases after 2 weeks except for one eye, where inflammation was present intermittently and resolved after 1 year. Corneal edema was present in 2 eyes preoperatively and developed in 7 eyes postoperatively. Edema was present in 3 eyes by 6 weeks and resolved in all eyes after 1 year. Corneal edema was likely due to the prolonged surgical insult from the combined PPV and GDD surgeries, and prolonged corneal edema has also been shown to result from PPV alone [23, 24]. These complication rates were comparable to that of prior studies, as seen in Tables 6–8.

Previously, GDD tube insertion in an existing vitrectomy sclerotomy was thought to result in a higher risk of hypotony due to aqueous leakage around the tube, particularly when sclerotomies larger than 21-gauge were used for vitrectomy [3, 6]. Scott et al. demonstrated a higher incidence of hypotony in their eyes with GDD tubes inserted into sclerotomies created by 20-gauge needles (0/8 eyes) compared to 23-gauge needles (5/18 eyes, 28%) [3]. In a study of neovascular glaucoma patients, Kolomeyer et al. also noted a significantly higher rate of transient hypotony in 20-gauge versus 23- or 25-gauge PPV eyes (p = 0.021), with tube insertion into an existing sclerotomy for the 23- and 25-gauge PPV [6]. In comparison, for 25-gauge PPV, Reichstein et al. found no hypotony amongst the 10 eyes studied also with GDD tube placement in a vitrectomy sclerotomy [7]. In our study, hypotony was noted in 1 eye (3.7%) and self-resolved after 2 weeks, similar to the low rates of hypotony noted in prior studies with small-gauge PPV regardless of sclerotomy status. Thus, tube insertion in an existing sclerotomy site from 23- or 25-gauge PPV may result in a lower risk of hypotony compared with 20-gauge PPV, and creating an additional sclerotomy for the GDD tube may not be necessary.

Vitreous hemorrhage was found in a total of 6 eyes (21.4%) and was present in 3 eyes prior to surgery. Three additional eyes developed vitreous hemorrhage postoperatively, which resolved after 2 weeks. Of the eyes that had vitreous hemorrhage preoperatively, two resolved with surgery, and one resolved after 2 weeks. Two eyes (7.1%) experienced tube occlusion with either blood or vitreous requiring subsequent PPV. These findings of a 12% (3/25 eyes) incidence of vitreous hemorrhage are within the range of findings from prior studies of PP GDD placement and PPV (Tables 6–8). A higher incidence of vitreous hemorrhage has also been noted in studies of patients with neovascular glaucoma, with Kolomeyer et al. reporting 14 out of 89 eyes (16%) and Campagnoli et al. reporting 25 out of 43 eyes (58.1%) with vitreous hemorrhage on postoperative day 1 persisting through 1 year in 16 eyes [6, 12].

The incidence of CME was slightly higher in our study than in prior studies. Five eyes (17.9%) developed CME postoperatively with resolution in 2 eyes prior to 1 year, with prior studies of pars plana GDD insertion and vitrectomy demonstrating rates between 3–15% (Tables 6–8). Given that Massachusetts Eye and Ear is a tertiary-care center, it is possible that the patients in our study were sicker and more complex than patients at non-tertiary-care centers, resulting in our higher rate of CME compared to other studies. Other retinal complications from pars plana vitrectomy, including retinal detachment, retinal tears, and retinal dialyses, were not observed in our study.
Limitations of this study include its retrospective design, small sample size, lack of a comparison group of tube insertions in a separate sclerotomy, and short follow-up time period for patients who had undergone surgery more recently, particularly as expected follow-up visits were displaced by COVID-19. This study is likely not generalizable to surgeries that were not Ahmed valves or if the implant were placed in a location other than the superotemporal quadrant. As children were not included in our study, this study is not applicable to that population. Smaller sample sizes at later time points may have affected the significance of statistical testing. Given that multiple glaucoma and retina surgeons performed the procedure, it is less likely that bias from a single surgeon affected the results of our study. Despite extensive efforts to identify a comparison group with tube insertions in a new sclerotomy separate from the vitrectomy sclerotomy sites, we could not identify a sufficient number of cases to form a suitable comparison group for this study. Thus, we relied on comparisons with prior studies of pars plana GDD insertion and vitrectomy to evaluate our results. Finally, there may be a referral bias as patients in our study were treated at a tertiary-care center, which may limit the generalizability of our results.

Conclusions

In summary, our results demonstrate that inserting a GDD tube into an existing vitrectomy sclerotomy site during combined pars plana GDD insertion and small-gauge vitrectomy likely does not increase the risk of complications. Specifically, there does not appear to be an increased risk of hypotony through leakage around the tube when an existing vitrectomy sclerotomy is utilized. We found similar functional outcomes and complication risk compared to prior studies of the same combined surgery, regardless of tube placement in existing or new sclerotomies. Minimizing the number of sclerotomies created during surgery may potentially reduce the risk of hypotony or tissue trauma and decrease operative time. Thus, GDD placement in a vitrectomy sclerotomy can be safely considered in cases that utilize small-gauge pars plana vitrectomy.

Abbreviations

PP
pars plana; GDD = glaucoma drainage device; PPV = pars plana vitrectomy; IOP = intraocular pressure; BCVA = best-corrected visual acuity; VA = visual acuity; POD1 = postoperative day 1; POW2 = postoperative week 2; POW6 = postoperative week 6; POM3 = postoperative month 3; POM6 = postoperative month 6; POY1 = postoperative year 1; POY1.5 = postoperative year 1.5; CME = cystoid macular edema; NLP = no light perception; SD = standard deviation; LogMAR = logarithm of minimum angle of resolution; MP-TSCPC = Micropulse transscleral cyclophotocoagulation

Declarations

Ethics approval and consent to participate: This retrospective chart review study was approved for exempt status by the Mass General Brigham Institutional Review Board and abided by the tenets of the
Declaration of Helsinki. Informed consent was not required for participation.

Consent for publication: Consent for publication was not required.

Availability of data and materials: The data that support the findings of this study are available on request from the corresponding author DS. The data are not publicly available due to them containing information that could compromise research participant privacy.

Competing interests: The authors declare that they have no competing interests.

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Author's contributions: EKC was involved in project design, data collection, analysis, and manuscript drafting and revision. SG and MC assisted with data collection and manuscript drafting. JBM and TCC were involved in project design and manuscript drafting, and DS was involved in project design, analysis, manuscript drafting, and revision. All authors read and approved the final manuscript.

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