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GLAUCOMA

Implantation of a second glaucoma drainage device

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Abstract
Purpose To evaluate success rates in controlling intraocular pressure (IOP) after implantation of a second glaucoma drainage device (GDD) with a Baerveldt glaucoma implant in patients with refractory glaucoma, with a secondary aim of reducing the need for postoperative glaucoma medications.
Material and methods This retrospective, noncomparative, interventional study included patients undergoing a second GDD for uncontrolled glaucoma from a tertiary care glaucoma service. Data were obtained from the medical records for the preoperative period and after the 1st, 15th, and 30th day, 3, 6, and 12 months, and then yearly until the last postoperative visit. Visual acuity, IOP, and number of glaucoma medications (NGM) from the follow-up visits were compared to baseline. Success and failure criteria were analyzed based on IOP level or need of glaucoma medications.
Results Forty-nine patients were studied, with a mean follow-up time of 25 ± 21 months. The mean preoperative IOP was 23.7 ± 8.2 mmHg, and decreased to 14.8 ± 4.0 mmHg after 1 year, 14.4 ± 3.9 mmHg after 2 years, and 16.6 ± 8.5 mmHg after 3 years. The mean preoperative NGM was 3.4 ± 1.3, and decreased to 2.0 ± 1.8 after 1 year, 2.5 ± 1.6 after 2 years, and 2.8 ± 2.0 after 3 years. Absolute success was 9% after 1 year for a postoperative IOP between 5 and 18 mmHg, and 76% for a postoperative IOP between 5 and 21 mmHg. The qualified success was 88% at the first and second years and 83% at the third year.
Conclusion With up to 3 years of follow-up, a second glaucoma drainage device was successful in reducing IOP to below 21 mmHg, but not as successful below 18 mmHg. The success rate is improved with the use of glaucoma medications with up to 3 years of follow-up.

Keywords Sequential · Glaucoma implants · Refractory glaucoma · Outcome · Complications

Introduction

The concept of the glaucoma shunt device with a plate placed at the equator and away from the limbus was introduced by Molteno almost four decades ago [1–3]. This became the prevalent design of glaucoma drainage devices (GDD), with subsequent models from different companies. GDDs are normally indicated for the management of refractory glaucomas after a previous filtering surgery has failed [4–6]. However, their use has expanded to include primary surgery in patients with conjunctival scarring or with a high risk for trabeculectomy failure [4].

A number of studies have reported intraocular pressure (IOP) control and a decrease in the number of glaucoma medications after the implantation of GDDs [4, 7–12]. The advantages of a GDD are the possibility of implantation regardless of the state of the conjunctiva, previous failed surgeries or quadrant of the eye and also the fact that they are easily combined with other procedures without major effects on their efficacy [5, 6, 10, 13–18].

However, GDDs can fail to control glaucoma, and after a period of time may have their IOP-lowering effect decreased due to further scarring and thickening of the fibrous capsule

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around the plate [7, 19–22]. A second shunt implantation is a commonly entertained option for these challenging cases [23–27]. Several studies have reported the results of a second GDD, with variable success. However, it is unclear from prior studies as to the success of attaining certain IOP goals, and also if success is absolute (no glaucoma medications) or qualified (with the use of glaucoma medications).

The goal of this study was to evaluate the success rates of a second GDD in patients with uncontrolled glaucoma in the presence of a functional first GDD. In addition, we considered success rates depending on the level of IOP attained and whether there was a continued need for glaucoma medications.

Methods

This is a retrospective, non-randomized, medical chart review study, comprising consecutive patients with an existing glaucoma shunt, receiving the second shunt due to failure of the first shunt (IOP level incompatible with maintenance of optic nerve health despite maximum tolerated medication).

Records were obtained from the Doheny Eye Institute, Keck School of Medicine, University of Southern California (Los Angeles, CA, USA) after approval by the Los Angeles County/ University of Southern California Medical Center Institutional Review Board. Since this was a retrospective study, the requirement for informed consent was waived. The study was in compliance with the Health Insurance Protection and Portability Act (HIPPA) and the Declaration of Helsinki for research on human subjects.

All of the evaluations and surgeries were performed at the Doheny Eye Institute (DEI) by trained glaucoma specialists. The implants used were the Baerveldt implant 250 or 350 (Abbott Medical Optics, Santa Ana, CA, USA).

The surgical procedure consisted of a limbal conjuctival incision (one quadrant), and placement and suturing of the plate at 8–10 mm posterior to the limbus and posterior to the rectus muscle insertions. A 23-gauge needle was used to enter the anterior chamber near the limbus, and the tube inserted into the anterior chamber. The tube was covered with pericardium or sclera donor graft tissue, and the conjunctiva sutured.

All eyes with minimum of 6 months follow-up after the implantation of the second device were included in the study. One eye was randomly selected per patient if both met the inclusion criteria. The review consisted of gathering data from the preoperative visit when the surgery was planned, and follow-up data from the 1st, 15th and 30th day, 3, 6, and 12 months, and then yearly until the last visit.

Demographic data such as age, gender, and ethnicity were obtained. Preoperative data (baseline) consisted of diagnosis, visual acuity, Goldmann IOP, number of glaucoma medications, cup/disc ratio. When available, visual field mean deviation (MD) and pattern standard deviation (PSD) were described. In general, patients with visual acuity worse than 20/100 did not have visual field data. Postoperatively, visual acuity, IOP, and number of medications were compared to baseline.

Five definitions of surgical success were analyzed to assess IOP control. Criteria one and two defined success as a postoperative IOP between 5 and 18 mmHg or between 5 and 21 mmHg respectively, without the use of glaucoma medications. Criteria three and four were defined by IOP between 5 and 18 or between 5 and 21 mmHg respectively, with the use of medications. The last criteria, the "qualified success", defined by IOP between 5 and 21 mmHg controlled with or without medications.

Failure was defined as an IOP less than 5 mmHg or more than 21 mmHg on two consecutive readings, less than 20% reduction of IOP from baseline, loss of light perception secondary to glaucoma, phthisis bulbi, additional glaucoma surgery, or a combination thereof. Hypotony was defined as an IOP of less than 6 mmHg on two consecutive measurements after the surgery, only if hypotony, maculopathy, and/or lens/IOL corneal touch were present.

Paired test was used to evaluate the IOP variation, and signed rank sum test for the variation in the glaucoma medications, between baseline and follow-ups. P values of less than 0.05 were considered statistically significant.

Visual acuity progression was evaluated based on the visual acuity conversion chart published by Holladay [28].

The Kaplan–Meier life-table (survival) analysis was used to determine cumulative success rates at specified time periods, based on the surgical success definitions and failure exclusion. SAS V9.2 (SAS Inst., Cary, NC, USA) programming language was used for all analyses.

Results

We reviewed the charts of 68 patients who had received a second GDD over the period 2006 to 2010. After eliminating those with inadequate follow-up, we examined 49 patients, age 60.6 ± 15.6 (mean ± SD), 20 females (40.8%) and 29 males (59.2%) (Table 1). In cases where both eyes met criteria, we randomly chose one eye per patient. Caucasian (51%) and Hispanic (26.5%) were the most prevalent ethnicities in the population studied.

The mean follow-up after the second GDD surgery was of 25 ± 21 months (range 6–72). The initial cohort of eyes were 30 with 1 year of follow-up, 20 with 2 years of follow-up, and 15 with 3 years of follow-up.

Table 1 Demographic and preoperative data

	$N = 49$ patients
Age (years; mean ± SD)	60.6 (15.6)
Range	27–88
Gender	
Female	20 (40.8%)
Male	29 (59.2%)
Race	
Asian	9 (18.4%)
Black	2 (4.1%)
White	
Hispanic	13 (26.5%)
Non-Hispanic	25 (51.0%)
Glaucoma diagnosis	
POAG	18 (36.7%)
CACG	9 (18.4%)
Secondary — traumatic	1 (2.0%)
Secondary — inflammatory	9 (18.4%)
Steroid glaucoma	1 (2.0%)
Juvenile open-angle glaucoma	2 (4.1%)
Congenital glaucoma	1 (2.0%)
Neovascular glaucoma	8 (16.3%)
Preoperative IOP (mmHg; mean ± SD)	23.7 ± 8.2
Preoperative number of glaucoma medications; mean ± SD	3.4 ± 1.3
Median (range)	4 (0–5)
Preoperative visual acuity; median (range)	20/300 (20/25–LP)
Cup-to-disc ratio, $n = 40$	0.95 ± 0.66
Visual field MD, $n = 23$	−17.23 ± 8.68
Visual field PSD, $n = 23$	6.75 ± 3.07

MD: mean deviation

PSD: pattern standard deviation

LP: light perception

The most prevalent diagnosis was primary open-angle glaucoma (POAG), comprising 36.7% of all cases, followed by chronic angle-closure glaucoma (CACG) and inflammatory glaucoma, with 18.4%. All other diagnoses are represented with their respective percentage in Table 1. Prior surgeries, including previous glaucoma procedures, are listed in Table 2.

The cup/disc (C/D) ratio was evaluable in 40 patients and the baseline mean was 0.95 ± 0.66. Visual field (n= 23), mean deviation was −17.23 ± 8.68 with a pattern standard deviation of 6.75 ± 3.07.

The mean preoperative IOP was 23.7 ± 8.2 mmHg, with the use of 3.4 ± 1.3 glaucoma medications (range 1–5) (Table 3). In the post-op follow-up, IOP was 14.5 ± 5.7 mmHg after 3 months, 15.0 ± 6.5 mmHg after 6 months, 14.8 ± 4.0 mmHg after 1 year, 14.4 ± 3.9 mmHg after 2 years, and 16.6 ± 8.5 mmHg after 3 years. The percentage IOP reduction compared with the preoperative IOP was 38.8 ± 13.0% after 3 months, 36.7 ± 20.6% after 6 months, 37.6 ± 60.7% ($p < 0.05$) after 1 year, 39.2 ± 27.8% (p= 0.001) after 2 years, and 30.0 ± 33.4% ($p < 0.01$) after 3 years (Table 3).

The mean preoperative number of glaucoma medications was 3.4 ± 1.3, and decreased to 2.0 ± 1.8 after 1 year, 2.5 ± 1.6 after 2 years, and 2.8 ± 2.0 after 3 years.

The preoperative visual acuity ranged from 20/25 to no light perception (LP), with a mean of 20/300. The mean visual acuity at 3 months was 20/200 (range 20/25–LP), at 6 months 20/250 (range 20/25–LP), at 1 year counting fingers (CF) (range 20/20–LP), at 2 years CF (range 20/20–LP), and at 3 years CF [(range 20/20–hand motion (HM)].

The cumulative success rate varied with the different criteria adopted (Table 4). Using the most stringent criteria of absolute success (1: IOP ≤ 18 mmHg without glaucoma medications), the success at 1, 2 , and 3 years is 9%, 0%, and 0% respectively. Using the most lenient criteria of

Table 2 Previous surgeries

	$N = 49$ patients
Number of previous surgeries, median (range)	3 (1–5)
Type of previous surgeries (number of patients)	
Baerveldt implant	33 (67.4%)
Ahmed valve	13 (26.5%)
Molteno implant	3 (6.1%)
Trabeculectomy	11 (22.4%)
Tube shunt revision	1 (2.0%
Argon laser trabeculoplasty	1 (2.0%)
Laser peripheral iridotomy	4 (8.2%)
Pars plana vitrectomy	13 (26.5%)
Phacoemulsification cataract extraction	26 (53.1%)
Penetrating keratoplasty	12 (24.5%)
Strabismus surgery	1 (2.0%)
Anterior chamber intraocular lens	1 (2.0%)
Panretinal retinal photocoagulation	4 (8.2%)
Pars plana lensectomy	5 (10.2%)
Intraocular lens exchange	1 (2.0%)
Lasik refractive surgery	1 (2.0%)
Scleral buckle	1 (2.0%)
Silicone oil	1 (2.0%)

qualified success (5: IOP ≤ 21 mmHg with or without medications), the success at 1, 2, and 3 years is 88%, 88%, and 82% respectively. The Kaplan–Meier plot is illustrated in Fig. 1.

The safety and complication data is contained within Table 5. High IOP was the most frequent postoperative complication in the first day, and at the first, third, and sixth months, present in 57% of our subjects in the first day. At 12 months, 13% of the eyes had corneal edema (Table 5).

Discussion

The results of this study agree with previous publications regarding the effectiveness of second GDD [23–27]. However, when comparing the results for different criteria that included or excluded the use of glaucoma medication, it became notable that in this series almost all patients required additional medical treatment to maintain IOP at acceptable levels. This finding indicates that the second GDD alone is not sufficient to provide glaucoma control. Surgeons should consider that these patients have a strong possibility of requiring glaucoma medications at some point of the postoperative period.

Several studies have reported the results of second GDD. Shah et al. [24] showed that after a failed tube shunt surgery, an additional tube shunt offers better IOP control than surgical revision by excision of an encapsulated bleb. They reported 42% of qualified success (25% IOP reduction with or without medication) in surgically revised patients, versus 62% in second GDD cases after a mean follow-up of 25.5 months. Burgoyne et al. [23] described that a second tube shunt did not cause "higher-than-expected complication rates" and provided satisfactory IOP control, but ten of 22 patients had corneal endothelial complications. Godfrey et al. [25] identified 18 patients who had a second GDD and reported 89%, 83%, 63%, and 37% surgical success at 6 months, 1 year, 2 years and 3 years respectively, with a mean follow-up of 19.6 ± 13.6 months. They considered success as an IOP below 21 mmHg regardless of the use of glaucoma medications, and at least 20% reduction in IOP without the need of additional procedures. Anand et al. [27] studied 43 eyes with mean follow-up of 32.6 ± 21.6 months. They found success rates of 93%, 89%, and 83% at 1, 2, and 3 years respectively (success was defined as IOP <21 mmHg with at least 25% IOP reduction with no prolonged hypotony) without any increase in number of medications or visual loss. When they considered a maximum IOP of 17 mmHg, success rates were 83% at 1 year, and 75% at 2 and 3 years.

In our study, the cumulative success rate can vary depending on which criterion is used. Using more strict criteria, such as IOP < 18 mmHg with no medications, the success rate is considered low, going from 18.2% in the first 6 months, 9.1% at 1 year, and zero in the following years. On the other hand, if the target IOP is 21 mmHg, with or without medications, the success rates can increase up to 82.7%, even 3 years after the surgery. Previous studies report success rates up of 73.7% when using this last criterion [26]. As with our study, these were all retrospective analyses with limited numbers.

The number of medications used increased in the first year of follow-up, and then decreased after that. Nevertheless, the second shunt in our study was associated with lower IOP in the follow-ups. The IOP decrease ranged from 36% at 6 months to 33% at the second year. The patients undergoing a second implant in this study had very advanced glaucoma, with a very advanced C/D ratio and visual field damage. Despite achieving lower IOP with this second intervention, the mean visual acuity decreased in the follow-up period.

Previous studies have described corneal decompensation as the most significant complication following sequential tubes. Earlier series report a 25% to 45% incidence of corneal decompensation following second aqueous shunts [25, 29–31]. Considering the number of previous surgical procedures, laser procedures, and poor IOP control, it is not surprising that a substantial number of corneas decompensated. In our study, cornea decompensation was also the most prevalent complication following a second GDD. Interestingly, the highest incidence in our study was seen at 12 months and then decreased. This could be explained by the use of hyperosmolar drops or be due to loss to follow-up.

Table 3 Postoperative data

Follow-up (months)			
Median (range)	12 (3–72)		
Mean ± SD	25 ± 21		
IOP mmHg (*n*, mean ± SD)	49 23.7 ± 8.2	Decrease	% decrease
3 months	47 14.5 ± 5.7	9.2 ± 9.9***	38.8 ± 13.0
6 months	43 15.0 ± 6.5	8.7 ± 11.1***	36.7 ± 20.6
1 year	30 14.8 ± 4.0	8.9 ± 8.3***	37.6 ± 22.7*
2 years	20 14.4 ± 3.9	9.3 ± 7.7***	39.2 ± 27.8***
3 years	15 16.6 ± 8.5	7.1 ± 9.5*	30.0 ± 33.4**
Postoperative glaucoma medications		Decrease	
Median (range)	4 (0–5)	Median; mean ± SD	
3 months	2 (0–4)	2 1.6 ± 1.8***	
6 months	2 (0–5)	2 1.4 ± 1.6***	
1 year	2 (0–4)	1 1.5 ± 1.8***	
2 years	3 (0–5)	1 0.9 ± 1.6*	
3 years	3 (0–5)	0 0.6 ± 2.0	
Visual acuity, median (range)			
3 months	20/200 (20/25–LP)		
6 months	20/250 (20/25–LP)		
1 year	CF (20/20–LP)		
2 years	CF (20/20–LP)		
3 years	CF (20/20–HM)		

Statistically significant difference *** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$.

HM: Hand motion; LP: Light perception

The limitations of this study are its retrospective design and possible selection bias. The treating surgeons may have chosen patients with better prognosis for a second GDD rather than other procedures such as transscleral cyclophotocoagulation. The subjects that were excluded due to insufficient follow up may have not returned due to poor results. Finally, the complications were based on observations in the medical record but were not necessarily looked for at each visit.

In conclusion, a second GDD procedure can help control refractory glaucoma without hypotony and phthisis over the long term in highly complicated glaucomatous eyes. Although corneal decompensation and vision loss occured in this study, a sequential tube shunt procedure can be considered a viable approach for refractory glaucoma when an initial tube shunt has failed to control IOP. Patients should be counseled about the risk of corneal decompensation and vision loss. According to our results, surgeons should expect that glaucoma medications will be required even after a second GDD.

Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964

Table 4 Kaplan–Meier success analysis for 5 criteria following second glaucoma drainage device surgery

Surgical success criteria	Cumulative success % 6 months	Cumulative success % 1 year	Cumulative success % 2 years	Cumulative success % 3 years
1: IOP ≤ 18 mmHg without meds	18.2 ± 5.7	9.1 ± 5.4		
2: IOP ≤ 21 mmHg without meds	18.2 ± 5.7	13.6 ± 5.8	13.6 ± 5.8	13.6 ± 5.8
3: IOP ≤ 18 mmHg with or without meds	82.8 ± 5.5	76.2 ± 6.8	76.2 ± 6.8	70.3 ± 8.4
4: IOP ≤ 21 mmHg with meds	80.7 ± 5.8	77.5 ± 6.4	77.5 ± 6.4	77.5 ± 6.4
5: IOP ≤ 21 mmHg with or without meds (qualified success)	91.4 ± 4.1	88.2 ± 5.0	88.2 ± 5.0	82.7 ± 7.1

IOP: intraocular pressure

Meds: medications

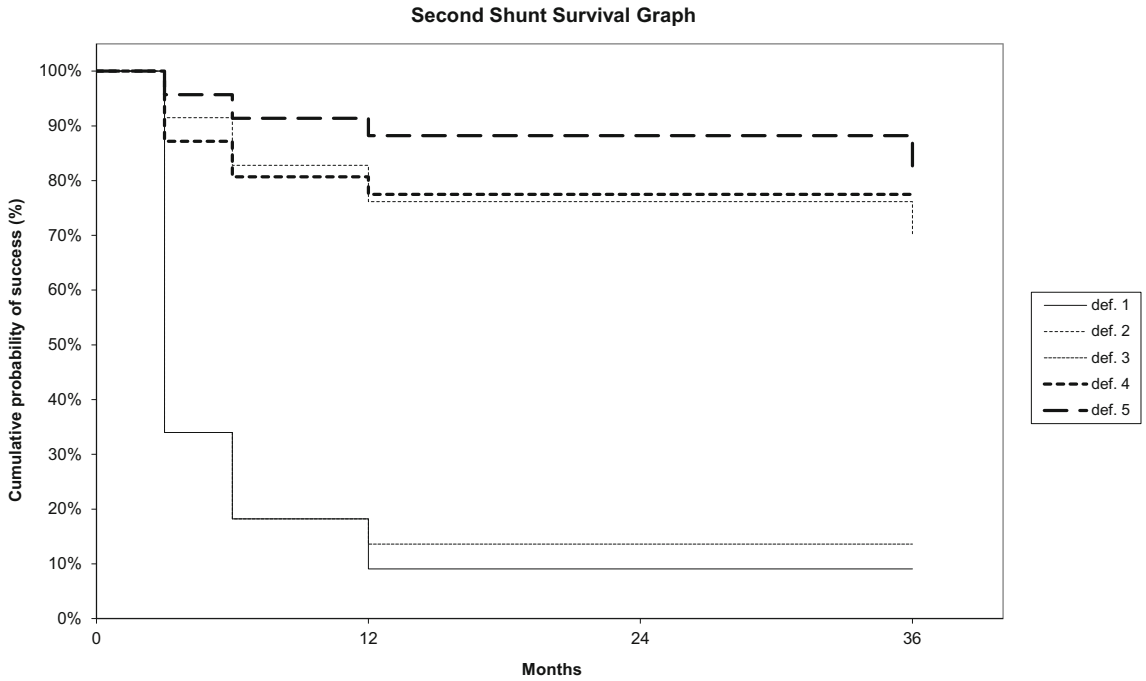

Fig. 1 Kaplan–Meier illustration plot for second shunt survival graph. Def 1: The success as a postoperative IOP between 5 and 18 mmHg without the use of glaucoma medications. Def 2: The success as a postoperative IOP between 5 and 21 mmHg without the use of glaucoma medications. Def 3: The success as a postoperative IOP between 5 and 18 with or without the use of medications. Def 4: The success as a postoperative IOP between 5 and 21 mmHg with the use of medications. Def 5: The "qualified success", as a postoperative IOP between 5 and 21 mmHg controlled with or without medications.

Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent For this type of study, formal consent is not required.

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Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Table 5 Safety and complications of second glaucoma drainage device surgery

Complication	Post-op (1 day)	Month 1	Month 3	Month 6	Month 12	Month 24	Month 36
Hypotony	3 (6%)	4 (8%)	1 (2%)	3 (7%)	1 (3%)	0	0
High intraocular pressure	28 (57%)	12 (24%)	6 (13%)	4 (9%)	2 (7%)	1 (5%)	0
Inflammation	0	2 (4%)	4 (9%)	0	1 (3%)	0	0
Choroidal detachment	0	3 (6%)	0	1 (2%)	0	0	0
Bleb leak	1 (2%)	0	0	1 2%)	0	0	0
Shallow anterior chamber	2 (4%)	1 (2%)	0	0	1 (3%)	0	0
Posterior synechiae	0	1 (2%)	0	0	0	0	0
Strabismus	0	0	0	0	0	1 (5%)	0
Cataract	0	1 (2%)		0	0	0	0
Eyelid edema	1 (2%)	0	0	0	0	0	0
Vitreous hemorrhage	0	0	0	2 (5%)	1 (3%)	0	0
Corneal edema	4 (8%)	2 (4%)	1 (2%)	0	4 (13%)	0	0

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