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Comparison of Non-staged (Complete) versus Two-Stage Baerveldt Aqueous Shunt Implantation in Patients with Advanced Glaucoma

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Abstract

Purpose: To compare Intraocular Pressure (IOP) control and complications associated with the non-staged, complete Baerveldt implantation (CBVI) vs. two-stage Baerveldt implantation (SBVI) in patients with advanced glaucoma.

Design: Retrospective, comparative, parallel group, interventional study.

Subjects: Sixty-seven eyes that underwent CBVI were matched with 66 eyes that underwent SBVI based on glaucoma diagnosis and age.

Methods: The study included a 24-month follow-up of 67 eyes that underwent CBVI with temporary ligature vs. 66 eyes that underwent SBVI for advanced glaucoma.

Main Outcome Measures: The criterion for surgical success was reduction of IOP of greater than or equal to 20% from baseline, with postoperative IOP from 6 mmHg to 21 mmHg on two or more consecutive measurements with or without the use of glaucoma medications and without loss of light perception or necessity for further surgical intervention for complications or high IOP.

Results: 67 eyes of 67 patients who underwent the CBVI and 66 eyes of 66 patients who had the SBVI were included in the analysis. After the CBVI, the cumulative probability of success by the Kaplan-Meier life-table analysis was 72% and 68% at 12 and 24 months respectively. The cumulative probability of success in the SBVI group was 82% and 80% at 12 and 24 months respectively (P=0.18). In the CBVI group, the median preoperative IOP of 27.1 (± 11.9) mmHg decreased to 14.9 mmHg (± 7.2) and the number of IOP lowering medications decreased from three to one. In the SBVI group, the median preoperative IOP of 25.9 (± 9.5) mmHg decreased to 14.0 mmHg (± 5.1) and the medications decreased from four to two. Visual acuity remained within one Snellen line or improved in 64% of the CBVI group, and 59% of the SBVI group (P=0.77). Corneal edema was the most common complication in both groups, with 25% and 32% in the CBVI and SBVI groups, respectively (P=0.45). Hypotony was the second most common complication, 24% and 18% in the CBVI and SBVI groups, respectively (P=0.52).

Conclusions: Staged BVI and complete BVI showed similar efficacy and rate of complications in the surgical treatment of advanced glaucoma.

Keywords: Baerveldt implantation; Complete baerveldt implantation; Staged baerveldt implantation; Glaucoma surgery; Aqueous shunt implantation; Intraocular pressure

Abbreviations

BVI: Baerveldt Implantation; CBVI: Complete Baerveldt Implantation; SBVI: Staged Baerveldt Implantation; IOP: Intraocular pressure; AC: Anterior Chamber; SCE: Supra Choroidal Effusion; SCH: Supra Choroidal Hemorrhage

Introduction

Implanted aqueous drainage devices, such as the Baerveldt glaucoma implant (Abbott Medical Optics, Santa Ana, CA), are often used to treat glaucoma refractory to medical therapy. The Baerveldt 350 implant consists of a nonvalved silicone tube connected to a 350 mm^2 silicone end plate [1,2]. It does not restrict the flow of aqueous from the opening of the tube in the anterior chamber to the episcleral plate [1]. The resulting free flow of aqueous may lead to hypotony, which can then lead to other complications, including, a flat anterior chamber (AC), suprachoroidal effusion (SCE), and suprachoroidal hemorrhage (SCH). Therefore, modifications in the technique used to implant the Baerveldt device have been developed to delay the flow of aqueous until a capsular bleb has formed over the plate. Such modifications have included temporary ligation of the silicone tube, or insertion of the implant in two distinct stages [3-7].

The complete insertion of the Baerveldt implant requires fixation of the episcleral plate and insertion of the tube into the anterior chamber

with temporary ligation of the tube within one procedure. The advantages of a complete Baerveldt insertion include a one-time risk of surgery and anesthesia. However, it may be associated with complications secondary to a sudden drop in intraocular pressure (IOP) with opening of the ligature approximately 6 weeks after insertion of the tube [1-3,8]. In addition to the sudden drop of IOP associated with the complete BVI, it has been hypothesized that the early flow of aqueous humor through the plate may induce a thicker capsule which then leads to a hypertensive phase as well as a chance of higher IOP and possible failure of the implant [7,8].

Molteno et al. introduced the two-stage implantation [7] in an effort to reduce complications associated with a sudden drop in IOP. The rationale of the two stage surgery was that after the episcleral plate was inserted at stage I, a capsule was allowed to form around the plate over a 6-week period. The capsule provides resistance to aqueous outflow. Subsequently, when the silicone tube is inserted into the anterior chamber (stage II) 6 weeks after stage I, there is a more controlled decrease in the IOP. The staged procedure thus may decrease the risk of hypotony and its associated complications [7-19]. While staging the procedure can delay immediate IOP control, this delay is also seen with insertion of the complete Baervedlt implant, because the tube is ligated for a period of approximately 4 to 6 weeks to allow a fibrous capsule to form around the episcleral plate [1,2].

A retrospective study done by Tong et al. [9] of 19 eyes that underwent the two-stage Baerveldt implantation with a median follow-up of 17 months showed that the two-stage Baerveldt implantation was effective in reducing IOP, had few complications, and preserved visual acuity in more than two thirds of eyes with advanced glaucomatous damage. Another study, by Budenz et al [16], of [10] eyes with Sturge-Weber syndrome reported the two-stage Baerveldt implantation was a safe and effective method to reduce IOP in this patient population [20]. These studies compared the results from the two-stage Baerveldt implantation to previously published reports on the one-stage Baerveldt implantation. However, the differences in study design, number of patients and types of patients limited the ability to make a conclusive comparison.

In this retrospective, parallel group comparison study, we examined the two-stage and the complete one stage BVI in age matched eyes with advanced glaucomatous damage, in terms of IOP control, preservation of visual acuity, and the incidence of postoperative complications.

Materials and Methods

We reviewed the medical records of all glaucoma patients who underwent either the two-stage or the complete insertion of the Baerveldt implant between January 1995 and July 2008 at the Doheny Eye Institute, University of Southern California, Los Angeles, California. All eyes with a minimum of 6 months of follow-up were included in the study. In patients who underwent bilateral BVI, only the first eye to undergo surgery was included in the study. Eyes that failed before 6 months were also included in the study.

Informed written consent was obtained for all patients before the Baerveldt implantation. All surgeries were performed at the Doheny Eye Institute by a fellowship-trained glaucoma specialist. Both the two-stage and complete BVI insertion techniques were performed by the same set of surgeons, without substantial modification of technique during the timeframe of the study. This retrospective review was approved by the Los Angeles County/University of Southern California Medical Center Institutional Review Board.

The Baerveldt implant was indicated for patients with advanced glaucomatous damage as shown by a severely excavated optic disc (C/D ratio ≥ 0.9), advanced glaucomatous visual field loss (MD ≥ 12 dB on Humphrey Visual Field testing 24-2 algorithm, SITA standard), or both. Informed written consent was obtained for all patients before the operation. The decision of whether to perform two-stage vs. complete BVI was made by the surgeon.

Surgical procedure:

The two-stage BVI was initiated by stage I, where a fornix- or limbus-based conjunctival flap was raised in the superotemporal quadrant. The Baerveldt implant was irrigated and inspected before fixation to the episclera with two 8-0 nylon sutures. The plate was fixed 8 to 10 mm from the limbus with the lateral edges under the superior and lateral rectus muscles. The tube was then tucked beneath the plate and sutured to the episclera using an 8-0 black silk marker. The conjunctiva and Tenon's capsule were closed with 8-0 polyglactin sutures using a blood vessel needle.

Stage II was performed at least 3 weeks later, with the median interval between stages I and II being 8 weeks. The decision to perform the second stage was based on the IOP not being medically controlled. During stage II, the conjunctiva and Tenon's capsule were opened. The black silk marker was used to localize the position of the previously placed tube. The subconjunctival tissue from around the tube was dissected to expose the tube. The marking suture was excised and the tube was released from beneath the episcleral plate. Care was taken to not disrupt the capsule surrounding the plate. The tube was then trimmed and inserted through a 23-gauge needle track into the anterior chamber.

The complete insertion of the Baerveldt implant requires fixation of the episcleral plate and insertion of the tube into the anterior chamber with temporary ligation of the tube with 7-0 vicryl in one procedure.

Postoperative medications consisted of antibiotic drops for 1 week and corticosteroid drops starting at four times a day and tapering as the postoperative inflammation resolved. Hypotensive medications were used as needed to control IOP after BVI. In the two-stage group, patients were examined on postoperative days 1, 7, and 21. Patients were then either scheduled for stage II of the implant insertion or followed up every 2 to 3 months. After the BVI was completed, patients were examined on postoperative day 1, week 1, week 2, and subsequently every month for the first 6 months. Follow-up visits thereafter were scheduled for every 3 to 4 months.

For the purpose of comparison, our definition of surgical success and failure was similar to that used in previous studies [9-11]. Surgical success was defined as a postoperative IOP 6 mmHg or more and 21 mmHg or less, with or without the use of hypotensive medications. Failure was defined as an IOP less than 6 mmHg or more than 21 mmHg on two consecutive readings, loss of light perception secondary to glaucoma, phthisis bulbi, additional glaucoma surgery, or a combination thereof. The criterion for hypotony was an IOP of 5 mmHg or less on two consecutive measurements after stage II of the Baerveldt implant insertion or after the complete BVI. The visual acuity progression was evaluated based on the visual acuity conversion chart published by Holladay [12].

The Kaplan-Meier life-table (survival) analysis was used to determine cumulative success rates at specified time periods. This allowed us to compare our results with those of other studies. Depending on whether the assumption of normality was satisfied, either two-sample *t* tests or Wilcoxon rank sum tests were used to compare preoperative and postoperative continuous data. Chi-square and Fisher's Exact tests were used to compare categorical data between the two groups. Cumulative success rates were calculated at each failure time. *P* values of less than 0.05 were considered statistically significant. SAS V9.2 (SAS Inst., Cary NC) programming language was used for all analyses.

Results

One hundred and twenty five patients underwent the first stage of the BVI, of whom 82 completed the second stage based on medical necessity. Sixteen patients who did not complete at least 6 months of follow up were excluded. The remaining 66 patients with staged BVI were matched based on diagnosis and age with 67 patients who underwent complete BVI. Demographics for both groups are further illustrated in Table 1.

	CBVI (n=67)	**Staged BVI (n=66)**	**p-value***
Age (yrs),			0.75
mean(sd)	67.7 (17.4)	68.6 (17.5)	
median(range)	72 (10-92)	73.5 (8-92)	
Gender			0.54
Male	32 (47.8%)	35 (53.0%)	
Female	35 (52.2%)	31 (47.0%)	
Race			0.09
Asian	13 (19.4%)	18 (27.3%)	
Black	5 (7.5%)	7 (10.6%)	
Hispanic	13 (19.4%)	21 (31.8%)	
White	31 (46.3%)	16 (24.2%)	
Other	5 (7.5%)	4 (6.1%)	
Glaucoma diagnosis			1.00
Angle closure	6 (9.0%)	7 (10.6%)	
Open angle	52 (77.6%)	50 (75.7%)	
Uveitic	3 (4.5%)	3 (4.6%)	
Neovascular	3 (4.5%)	3 (4.6%)	
JOAG/Congenital	3 (45.%)	3 (4.6%)	
Lens status			0.39
Aphakic	3 (4.5%)	7 (10.6%)	
Phakic	20 (29.9%)	20 (30.3%)	
Pseudophakic	44 (65.7%)	39 (59.1%)	
Previous surgeries			
Cataract extraction	48 (71.6%)	43 (65.2%)	0.42
Trabeculectomy	24 (35.8%)	24 (36.4%)	0.95
Needling	2 (3.0%)	1 (1.5%)	1.00
Trabectome	2 (3.0%)	0	0.50
Tube	5 (7.5%)	6 (9.1%)	0.73
Glaucoma laser	6 (9.0%)	9 (13.6%)	0.39
Penetrating keratoplasty	10 (14.9%)	10 (15.2%)	0.97
DSEK	1 (1.5%)	0	1.00
Peripheral iridotomy/ iridectomy	13 (19.4%)	25 (37.9%)	0.02
Number of previous surgeries, median (range)	2 (0-5)	2 (0-10)	0.28

*Independent samples t-test and Wilcoxon Rank sum tests for continuous variables, Chi-Square and Fisher's Exact tests for categorical variables.
CBVI : Complete BVI; SBVI: Staged (two-stage) BVI

Table 1: Demographics.

In the complete BVI group, the median preoperative IOP of 27.1 (± 11.9) mmHg decreased to a median postoperative IOP of 14.9 (± 7.2) mmHg at 2 years and the number of glaucoma medications was reduced from a preoperative median of three to a postoperative median of one. In the two-stage BVI group, the median preoperative IOP of 21.8 (± 10.2) mmHg decreased to 14.0 (± 5.1) mmHg, postoperatively after the final stage. The number of glaucoma medications was reduced from four to two. There was no significant difference between the two groups.

Based on our previously described definitions of success and failure, twenty eyes failed from the complete BVI group and thirteen eyes failed from the staged BVI group. After the complete BVI, the cumulative probability of success was 72% and 68% at 12 and 24 months, respectively. The cumulative probability of success in the two-stage BVI group was 82% and 80% at 12 and 24 months, respectively (Table 2, Figure 1) (P=0.18).

	CBVI	**Staged BVI**	**p-value***
Follow-up, months median (range)	25 (7-96)	30 (7-135)	0.02
Time between stage I and II (weeks), median (range)		8 (3-116)	
IOP, mmHg	n mean (sd)	n mean (sd)	
Preop (stage I for staged BVI)	67 27.1 (11.9)	66 21.8 (10.2)	0.007
Preop (stage II for staged BVI)		66 25.9 (9.5)	0.52
1 day	66 21.0 (12.5)	64 10.2 (7.3)	<0.001
1 month	64 14.4 (7.7)	64 14.5 (6.7)	0.93
3 months	63 14.6 (7.0)	62 13.5 (5.2)	0.33
6 months	60 13.6 (6.2)	59 13.0 (5.1)	0.58

1 year	57 14.2 (10.5)	57 12.5 (3.9)	0.25
2 years	44 14.9 (7.2)	38 14.0 (5.1)	0.50
Glaucoma medications	n median (range)	n median (range)	
Preop	67 3 (0-5)	66 4 (0-5)	0.87
1 day	67 3 (0-5)	64 0 (0-5)	<0.001
1 month	65 3 (0-5)	64 0.5 (0-5)	<0.001
3 months	63 2 (0-5)	62 1.5 (0-4)	0.99
6 months	63 2 (0-5)	59 2 (0-4)	0.80
1 year	58 2 (0-4)	57 2 (0-5)	0.93
2 years	46 1 (0-5)	37 2 (0-5)	0.74
Visual acuity			0.77
Improved (≥2 Snellen lines)	19 (28%)	19 (29%)	
Same (±1 Snellen lines)	24 (36%)	20 (30%)	
Worse (≤2 Snellen lines)	24 (36%)	27 (41%)	
Life table analysis			0.18
Success (12 months)	72.4%	81.7%	
Success (24 months)	67.9%	79.5%	

*Independent samples t-test and Wilcoxon Rank sum tests for continuous variables, Chi-Square and Fisher's Exact tests for categorical variables, Log-rank test for life table analysis.
CBVI: Complete BVI; SBVI: Staged (two-stage) BVI

Table 2: Preoperative and postoperative data for the complete and two-stage Baerveldt implantation groups.

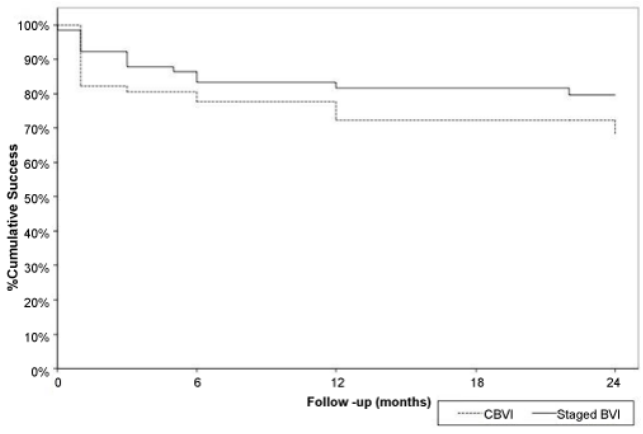

Figure 1: The cumulative success of the two-stage (straight line) and the complete one stage (dotted line) of the 350-mm^2 Baerveldt implantation over a 24-month period. The life-table analysis for the complete BVI includes 67 eyes at baseline, 49 eyes at 12 months, and 47 eyes at 24 months. The life-table analysis for the two-stage BVI includes 66 eyes at baseline, 54 eyes at 12 months, and 53 eyes at 24 months.

The median interval between stages I and II of the two-stage BVI was 8 weeks (range, 3–116 weeks; Table 2). However, the surgeons opted to perform stage 2 early after stage 1 of the BVI if the eyes were intolerant to the IOP-lowering medications and a thickened capsule had formed around the plate. In several eyes, the stage II procedure was performed after a longer interval than the customary 6-week period. These were in cases where intraocular pressures were well controlled on medications, the patients had stable visual field and funduscopic examinations, or if there was a possibility of increasing corneal edema if the tube was introduced in the anterior chamber at an earlier timeframe.

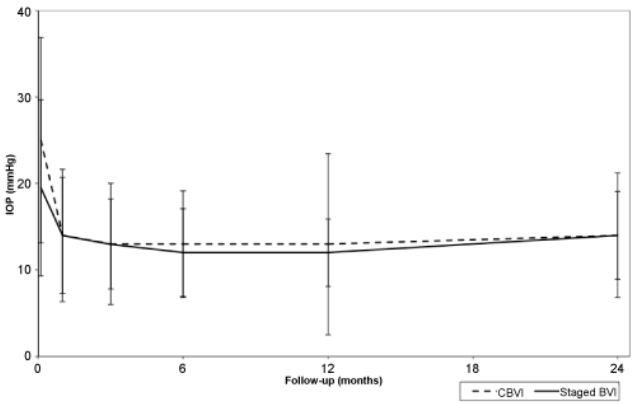

Figure 2: Median intraocular pressure (IOP) (± standard deviation) after stage II and complete Baerveldt implantation (n = 66, 67 respectively).

The preoperative best-corrected visual acuity compared with the postoperative best-corrected visual acuity improved or stayed within one Snellen line in 43 (64%) of 67 eyes in the complete BVI group, and 39 (59%) of 66 eyes in the staged BVI group (P=0.18).

Corneal edema was the most common corneal complication in both groups (25% in the complete BVI, and 32% in the two-stage BVI; P=0.45). Sustained hypotony occurred in 16 eyes (24%) of the complete BVI group, and 12 eyes (18%) of the two-stage BVI group (P=0.52). Choroidal complications including SCE occurred in four eyes (6%) of each group. One eye (2%) progressed to SCH in the two-stage BVI group. A flat anterior chamber occurred in 7 eyes (10%) of the complete BVI group, and in 6 eyes (9%) of the two-stage BVI group. A detailed list of complications is shown in table 3.

Complication		CBVI (N =67)		SBVI (N =66)		
		Number of Eyes	Percent	Number of Eyes	Percent	Fisher's Exact p-value
Hypotony	Hypotony	16	24%	12	18%	0.52
	Flat anterior chamber	7	10%	6	9%	1.00
	Suprachoroidal effusion	4	6%	4	6%	1.00
	Suprachoroidal hemorrhage	0	0	1	2%	0.50

	Phthisis bulbi	2	3%	1	2%	1.00
Corneal complications	Corneal edema	17	25%	21	32%	0.45
	Corneal ulcer	1	2%	0	0	1.00
	Graft failure	6	9%	5	8%	1.00
	Corneal decompensation	2	3%	0	0	0.50
Tube function and placement	Tube erosion	2	3%	3	5%	0.68
	Tube blockage	2	3%	1	2%	1.00
	Tube corneal touch	3	5%	3	5%	1.00
	Tube iris touch	3	5%	3	5%	1.00
Other	Irido-corneal touch	1	2%	8	12%	0.02
	Peripheral anterior synechiae	1	2%	4	6%	0.37
	Cataract	3	5%	1	2%	0.62
	Central macular edema	1	2%	0	0	1.00
	Hyphema	1	2%	4	6%	0.21
	Retinal detachment	1	2%	1	2%	1.00
	Vitreous hemorrhage	5	8%	1	2%	0.21
CBVI: Complete BVI; SBVI: Staged (two-stage) BVI						

Table 3: Post-Surgical Complications.

Discussion

Overall, the life-table success rates for the complete BVI were 72.4% at 12 months and 67.9% at 24 months. The success rates for the two-stage BVI were 81.7% at 12 months and 79.5% at 24 months. There was no statistically significant difference between the two groups (P=0.18). Our study results are comparable with previously reported success rates for the complete and two-stage Baerveldt implant procedures [9-11].

Siegner et al. [10] reported 24-month success rates of 60% during an early experience with the complete BVI, using four different sizes (200 mm^2, 250 mm^2, 350 mm^2, and 500 mm^2). Thereafter, Britt et al. [11] reported 12- and 24-month life table success rates of 98 and 93 % with the complete insertion of 350-mm^2 Baerveldt plate. Tong et al. [9] reported life-table success rates of 89% at both 12 and 24 months with the two-stage BVI.

In the complete BVI group, the median preoperative IOP of 27.1 (± 11.9) mmHg decreased to a median postoperative IOP of 14.9 (± 7.2) mmHg. The number of glaucoma medications was reduced from a preoperative median of three to a postoperative median of one. In the two-stage BVI group, the median preoperative IOP of 21.8 (± 10.2) mmHg decreased to a median postoperative IOP of 14.0 (± 5.1) mmHg and the number of glaucoma medications was reduced from four to two. The IOP of patients undergoing the first stage may have been lower than the IOP prior to undergoing the second stage (21.8 vs. 25.9 mmHg, respectively) but the first stage of the two stage BVI was generally performed based on advancement of fields and optic nerve damage. These patients were not considered medically controlled based on their their stage of advanced glaucoma. For this reason, the patient underwent the first stage in anticipation that the second stage will likely be performed. While the IOP may not have been quite as high as the complete BVI patients, it was high enough to be causing optic nerve damage, deeming them appropriate surgical candidates by the surgeon. Both groups demonstrated adequate IOP control and medication reduction by our definition of surgical success and there was no significant difference between the two groups. These results were comparable to recently published studies which showed a preoperative IOP of 30 mmHg reduced to 13 mmHg postoperatively [11] and the number of postoperative medications were reduced to one in the complete BVI approach. Other studies of the SBVI showed a similar reduction of IOP from 21 mmHg to 12 mmHg and a medication reduction down to one [9]. In our study, the preoperative IOP (27.1 mmHg) in the complete BVI group was higher than the preoperative IOP in the staged BVI group (21.8 mmHg) which was comparable to other previously published studies [9,11,20].

Visual acuity remained within one Snellen line or improved in 64% of the complete BVI group, and 59% of the two-stage BVI group (P=0.77). These results suggest that neither the two-stage nor the one stage insertion of the Baerveldt implant were associated with an increased rate of progressive visual acuity loss.

Corneal edema occurred in 25% of the complete BVI eyes and 32% of the two-stage BVI eyes (P=0.45). Britt et al. reported an 8% to 20% yearly incidence rate of corneal complications with the complete BVI [11]. Tong et al. reported corneal complications in 11% of the two stage BVI [9]. Our study reported corneal graft failure in 9% of the complete BVI and 8% of the two-stage BVI group.

A transient hypertensive phase, which usually occurs 3 to 6 weeks after aqueous tube shunt implantation and resolves after 12 to 16 weeks, has been described in several published studies. This was not observed in our study in either the CBVI or SBVI groups. However, in the two-stage BVI, the pre-stage 1 mean IOP of 22 mmHg increased to 26 mmHg pre stage 2. Molteno et al. encountered similar phenomenon with both the complete and two-stage Molteno implant procedures [7,14,15]. However, Siegner et al. did not observe this hypertensive phase with the complete one-stage Baerveldt implant [10]. Tong et al. experienced the hypertensive phase in 3 out of 19 eyes that underwent the two-stage BVI, while Schmidt et al. [19] suggested that a two-stage procedure avoided a hypertensive state [9]. These differences may be related to an individual surgeon's postoperative management, particularly with regard to steroid use and glaucoma medications. The differences amongst the studies can also be related to the rate at which the capsule around the bleb matures. Alternatively, the reduced prevalence of a hypertensive phase with the Baerveldt implant may reflect the larger implant size, as Siegner et al. hypothesized [10].

Sustained hypotony occurred in 24% of the complete BVI group, and 18% of the two-stage BVI group (P=0.52). Choroidal complications including SCE occurred in 4 eyes (6%) of each group. One eye (2%) progressed to SCH in the two-stage BVI group. A flat AC occurred in 10% of the complete BVI group, and in 9% of the two-stage BVI group (P=1.00). Our study shows no significant difference in terms of complications between the complete and two-stage BVI groups, except for irido-corneal touch, which was 2% in CBVI and 12% in SBVI (p=0.02). Our reported rates of hypotony, flat AC, and choroidal complications were comparable to previously published data [9,10,16].

The strengths of our study include the inclusion of a matched control group of complete BVI for comparison to two-stage BVI based on age and glaucoma diagnosis. However, because the study data was collected retrospectively, and is therefore not randomized, there are possible confounding variables. For example, the baseline IOP is lower in the staged BVI group. This may impact the ability to compare the two groups.

In summary, the complete and two-stage BVI groups both demonstrated improved IOP control, reduction in medication number and preservation of vision. The success and complication rates for the complete and the two-stage Baerveldt implantation were also not significantly different. Thus, in our population, staged BVI did not appear to offer additional benefits compared to complete BVI. The added medical cost and the risks of anesthesia associated with two separate surgeries are additional issues that should be weighed when choosing between a two-stage versus a complete implantation. The decision to place a complete or staged Baerveldt can then be based on the patient's clinical profile and the surgeon's preference for the individual patient.

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