

## Short-Term Clinical Outcomes Following Baerveldt Glaucoma Implantation Performed via the Inferonasal Pars Plana Route

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### Abstract

The study aimed to examine short-term clinical outcomes following Baerveldt glaucoma implantation (BGI) via the inferonasal pars plana route. It was a retrospective, comparative study of patients who underwent BGI via the inferonasal pars plana route. The postoperative follow-up period was longer than 12 months in all cases. Intraocular pressure (IOP) was examined before and after surgery. Thirteen eyes in 12 subjects (5 men, 7 women,  $60.9 \pm 15.1$  years old) were examined. Eight eyes were diagnosed with neovascular glaucoma, 1 with pseudoexfoliation glaucoma, 2 with late-onset glaucoma, and 2 with uveitis-related-glaucoma. Subjects were followed-up for  $15.3 \pm 4.2$  months. The mean IOP was significantly lower at each of the 1-month, 3-month, and final follow-up visits ( $16.6 \pm 7.2$ ,  $18.4 \pm 5.9$ , and  $14.0 \pm 7.1$  mmHg, respectively) than at the preoperative visit ( $37.2 \pm 9.5$  mmHg,  $P < 0.05$ ). These results support the conclusion that a BGI via the inferonasal pars plana route could effectively reduce IOP over the short-term in eyes with various types of glaucoma.

**Keywords:** Glaucoma Implantation; Pars Plana; Intraocular Pressure

### Introduction

Tube shunt surgery reduces intraocular pressure (IOP) by increasing aqueous out flow using implantation of a glaucoma drainage device (GDD). Aqueous liquid flows from the anterior chamber (AC) via the inserted tube that oozes out around to the plate sutured onto the posterior sclera. This surgery is generally performed to treat eyes with refractory glaucoma, which usually have a scarred conjunctiva from prior intraocular surgery.

Complications, including a shallow AC and corneal endothelial decompensation, have been reported following GDD tube insertion into the AC [1-5]. On the other hand, the pars plana GDD is designed to avoid these complications [4]. However, regarding the pars plana GDD, it is necessary to thoroughly resect the vitreous by vitrectomy to avoid occluding the tube with vitreous. Therefore, if the patient has not already undergone a vitrectomy, a combined vitrectomy/GDD insertion procedure must be performed. The Hoffmann elbow needs to be covered by a lamellar scleral flap or by preserved sclera to avoid exposure to conjunctiva. A conventional vitrectomy includes making three ports, one each in the superotemporal, inferotemporal, and superonasal quadrants. Making a scleral flap in these quadrants for a Baerveldt glaucoma implant (BGI) is often difficult because a 3-port vitrectomy causes scleral and/or conjunctival damage in these quadrants. Unfortunately, preserved sclera is not always easy to obtain in Japan.

Most glaucoma filtration surgeries utilize the superotemporal quadrant, because during surgeries in the inferonasal quadrant, it is difficult to secure a surgical field, and the risk for infection following glaucoma surgery increases [6]. However, the risk of infection does not increase following tube shunt surgery via the inferonasal quadrant that does not leave the tube or plate exposed to the conjunctiva [7]. Most of the literature on GGD implants focuses on procedures performed in the superotemporal quadrant. Unfortunately, the sclera and/or conjunctiva is often scarred from prior superotemporal surgeries in eyes with refractory glaucoma. However, the procedure would still be easy to perform in the surgically-naïve inferonasal quadrant. This study examines the surgical outcomes and complication rates of GDDs implanted in the inferonasal quadrant.

## Materials and Methods

The protocol for this retrospective study was approved by the ethics committee at Toho University Sakura Medical Center (approval number: No.S16047). All study conduct adhered to the tenets of the Declaration of Helsinki. In accordance with the clinical research guidelines of the Japanese Ministry of Health, Labour, and Welfare, the study design was explained to subjects using the hospital's website. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research.

### Study Subjects

The medical records of consecutive patients who underwent BGI surgery via the pars plana route in the inferonasal quadrant were retrospectively reviewed. All patients underwent surgery at Toho University Sakura Medical Center between June 2015 and June 2016 and were followed for at least 12 months after surgery.

### Baerveldt Glaucoma Implant Surgery

Sub-Tenon's anesthesia was administered, and a conjunctival incision was made along the corneal limbus to expose the inferior rectus and medial rectus muscles. A 6 × 6 mm fornix-based lamellar scleral flap was created, and a 25-gauge (G) infusion line was placed in the inferotemporal quadrant. The Baerveldt implant tube was knotted using 8-0 polyglactin suture thread, because aqueous flow through the device must be restricted until plate encapsulation and insertion beneath the medial rectus and inferior rectus muscles in the inferonasal quadrant is completed. The anterior edge of the plate was then anchored to the sclera using 5-0 polyester suture thread. Next, a sclerotomy was made 3.5 mm to the limbus under the scleral flap using a 20-G V-lance. The Hoffmann elbow was inserted through the sclerotomy and fixed in place with 8-0 nylon thread. The Hoffmann elbow was then covered by the scleral flap, which was sutured closed using 10-0 nylon thread. A Sherwood slit was made using a micro blade to avoid early postoperative IOP elevation. Lastly, the infusion cannula was removed, and a continuous suture was used to close the conjunctival incision.

### Data Analyses

The IOP (measured using a Goldmann Applanation Tonometer), visual acuity, and number of hypotensive medications at the 1-month, 3-month, and final visits were compared to values from the preoperative visit. A previous study has shown that the effect of a combination medication drug is equal to that of an oral hypotensive drug [8]. Thus, in our study, the number of hypotensive medications was counted using the following method: single medication drop = 1 medication, combination medication drop = 2 medications, and oral hypotensive agent = 2 medications. The BGI surgery was considered successful if the IOP was normal (6–22 mmHg) without the use of oral hypotensive medications, visual acuity at the final visit was light perception or better, and further glaucoma surgeries were not needed.

All statistical analyses were performed using Statcel (OMS, Saitama, Japan) statistical software. Paired t-tests were used to compare IOP values and the number of hypotensive medications before and after surgery. Statistical significance was defined as  $P < 0.05$ .

## Results

Thirteen eyes of 12 subjects (5 male, 7 female) with an average age of  $60.9 \pm 15.1$  years were included in this study. Subjects were followed for  $15.3 \pm 4.2$  months after surgery. Subjects underwent BGI surgery to treat neovascular (8 eyes), pseudoexfoliation (1 eye), late-onset developmental (2 eyes of 1 subject), and uveitis-related (2 eyes) glaucoma. Eleven eyes did not have vitreous and underwent BGI alone because of vitrectomized eyes. All eyes were pseudophakic. The remaining 2 eyes (cases 6 and 11) underwent a combined vitrectomy/BGI procedure (Table 1). Additional filtration surgery was required in one subject (case 10) 6 months after BGI surgery because IOP increased to 32 mmHg in spite of treatments for hypertensive IOP. Additionally, 1 eye (case 4) developed phthisis bulbi 18 months after BGI surgery because of PDR progression.

Case	Sex	Age (years)	Glaucoma type	Vitreous status	Prior intraocular surgeries	Preoperative visit			Final postoperative visit			Follow-up period (months)
						LogMAR VA	IOP (mmHg)	Number of hypotensive drugs	LogMAR VA	IOP (mmHg)	Number of hypotensive drugs	
1	M	45	NVG	—	4	2.30	37	6	1.70	20	5	18
2	M	58	NVG	—	1	1.22	40	5	0.52	22	5	18
3	F	43	NVG	—	2	2.00	44	6	1.85	5	0	22
4	F	63	NVG	—	1	2.80	60	6	2.80	0	0	22
5	F	63	NVG	—	1	2.80	40	5	2.80	17	3	18
6	F	89	PEG	+	1	1.05	46	1	0.10	9	0	14
7	F	46	Develop.	—	2	1.30	40	6	0.10	22	4	16
8	F	67	NVG	—	3	1.70	31	3	1.70	20	5	14
9	M	62	NVG	—	2	2.30	30	5	2.30	10	4	14
10	F	46	Develop.	—	2	0.10	30	4	0.22	32	4	6
11	M	65	Uveitis	+	1	1.85	23	5	2.00	10	0	13
12	M	42	NVG	—	1	0.30	32	5	0.30	17	2	12
13	F	88	Uveitis	—	1	1.40	30	7	1.70	16	0	12
Mean		60.9	----	----	1.9	1.625	37.2	4.9	1.392	15.4	2.5	15.3
SD		15.1	----	----	1.0	0.847	9.5	1.6	0.973	8.1	2.1	4.2

**Table 1:** Characteristics of eyes and patients who underwent Baerveldt glaucoma implant surgery via the inferonasal quadrant.

M: Male; F: Female; NVG: Neovascular Glaucoma; PEG: Pseudoexfoliation Glaucoma; develop.: Late-Onset Developmental Glaucoma; Uveitis: Uveitis-Related Glaucoma; Logmar VA: Logarithm of the Minimum Angle Of Resolution Visual Acuity; IOP: Intraocular Pressure; SD: Standard Deviation.

The mean IOP was  $37.2 \pm 9.5$  mmHg at the preoperative visit and  $16.6 \pm 7.2$ ,  $18.4 \pm 5.9$ , and  $14.0 \pm 7.1$  mmHg at the 1-month ( $P = 0.00005$ ), 3-month ( $P = 0.00003$ ), and last follow-up ( $P = 0.00014$ ) visits, respectively (all comparisons to preoperative value, paired-t test; Table 2). Surgery significantly reduced the number of hypotensive medications used from  $4.9 \pm 1.6$  medications before surgery to  $2.3 \pm 2.2$  medications after surgery (final visit,  $P = 0.0067$ , paired-t test; Table 3). Regarding IOP values at the final visit, one case was excluded because of an additional operation 6 months later (case10). Visual acuity was stable or improved in 9 of 12 eyes (75.0%) followed for at least 1 year (excluding Case10), and all included eyes had a visual acuity better than light perception at the final follow-up visit. Therefore, we classified BGI surgery as successful in 9 of 13 cases (69.2%).

Case	Intraocular pressure (mmHg)			
	Before surgery	1 month	3 months	Final visit
1	37	15	22	20
2	40	30	29	22
3	44	19	20	5
4	60	13	16	0
5	40	20	20	17
6	46	5	13	9
7	40	21	19	22
8	31	16	20	20
9	30	20	9	10
10	30	23	20	----
11	23	11	8	10
12	32	4	25	17
13	30	19	18	16
Mean	37.2	16.6	18.4	14.0
SD	9.5	7.2	5.9	7.1
P-value*	----	0.00005	0.00003	0.00014

**Table 2:** Intraocular pressure before and after Baerveldt glaucoma implant surgery via the inferonasal quadrant.

\*comparison to preoperative value, performed using a paired t-test. SD: Standard Deviation.

Case	Number of hypotensive drugs used	
	Preoperative visit	Final postoperative visit
1	6	5
2	5	5
3	6	0
4	6	0
5	5	3
6	1	0
7	6	4
8	3	5
9	5	4
10	4	-----
11	5	0
12	5	2
13	7	0
Mean	4.9	2.3
SD	1.6	2.2

**Table 3:** The number of hypotensive drugs used before and after Baerveldt glaucoma implant surgery.

SD: Standard Deviation.

No surgery-related complications were observed, including tube and plate exposure and endophthalmitis. In all cases, Hoffmann elbows were successfully covered with the lamellar scleral flap.

## Discussion

These GDDs inserted via the pars plana route are used to manage IOP in eyes with refractory glaucoma, particularly when conjunctival scarring from prior intraocular surgery is present. A GDD implanted via the pars plana route reduces IOP as effectively as a GDD inserted into the AC and is not associated with a shallow AC or endothelial disorders [9]. The IOP remained sufficiently reduced in 84.6% of patients 1 year following GDD placement in the superotemporal quadrant [10]. In contrast, a surgical success rate of 69% was observed in the current study. This lower success rate may have been because 8 of the 13 eyes (61.5%) included in the current study had neovascular glaucoma. Previous studies examining GDD implants in eyes with neovascular glaucoma reported a 56% - 67% success rate [11,12].

The BGI placement location, in order of preference, is as follows: superotemporal quadrant, inferotemporal quadrant, inferonasal quadrant, and superonasal quadrant. Most BGI procedures are performed in the superotemporal quadrant because rectus muscles are easily exposed in this location, making BGI plate placement easier. However, the superonasal quadrant should be avoided for larger GDDs, because the implant or an overlying bleb may interfere with superior oblique muscle function, resulting in acquired Brown's syndrome [13,14]. In these cases, inferonasal placement is thought to be better, because eye movement is not affected (the inferior oblique muscle lies between the outer and inferior rectus muscles). Hess charting was not performed in the group of patients examined here, but obvious eye movement disorders did not occur following BGI surgery.

The risk of infection has been shown to increase following tube shunt surgery when the Hoffmann elbow or tube is exposed [15]. Therefore, a lamellar scleral flap or preserved sclera (in eyes with a scarred or thinned sclera) is used to cover Hoffmann elbows. Unfortunately, preserved sclera is not easily acquired by all facilities, and many surgeons are forced to rely on a lamellar scleral flap. In all cases ex-

amined here, BGI insertion via the inferonasal quadrant allowed for easy creation and use of a lamellar scleral flap because the conjunctiva and sclera were, in general, surgically-naïve. However, it should be noted that it was especially important to trim the vitreous base prior to BGI placement, because remnant vitreous can plug the implant tube during insertion. Therefore, this surgery should only be performed after the vitreous has been removed. A combined vitrectomy/BGI placement procedure may be needed, and endophotocoagulation during vitrectomy is needed in eyes with neovascular glaucoma or proliferative diabetic retinopathy. Conventional pars plana vitrectomy is performed with 3 ports, and sclerotomies are usually placed in the superonasal, superotemporal, and inferotemporal quadrants. Unfortunately, the resulting scleral holes may damage tissue, and creating a lamellar scleral flap in these locations should be avoided. Filtration surgery is generally not performed in the inferonasal quadrant. Therefore, conjunctival and scleral tissue in this quadrant is generally well-preserved and not scarred from prior surgeries or associated infections. As a result, covering the plate using inferonasal scleral and conjunctival tissue was not problematic in the examined group of patients.

Our study had several limitations. First, the retrospective nature of this study limited subject numbers and data uniformity. Second, the space in which the BGI is inserted is narrower in the inferonasal quadrant than in the superotemporal or inferotemporal quadrants. When aqueous liquid flows out around the BGI plate, a narrow space severely limits plate function. Therefore, further studies that compare plate function in the four quadrants are needed to better understand how space influences plate function. Third, this study only examined patients for 1 year. Studies with a longer follow-up period are needed to assess long-term risks for plate exposure and elevated IOP following inferonasal BGI placement.

### Conclusion

IOP significantly decreased from preoperative levels following inferonasal BGI insertion. However, some eyes with neovascular glaucoma had poor postoperative IOP control because plate function was compromised by this site's narrow space. Therefore, inferonasal BGI insertion seems to have comparable outcomes to superotemporal BGI insertion, except in eyes with neovascular glaucoma. However, further investigation regarding long-term outcomes is needed.

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### Author Contributions

M.S. and R.H. conceived the study design and conduct; M.S., I.Y., H.M., and T.M. collected the data; M.S., R.H., I.Y., H.M., and T.M. participated in data management, analysis, and interpretation; M.S., R.H., I.Y., H.M., and T.M. prepared, reviewed, and approved the manuscript.

### Conflicts of Interest

There are no conflicts of interest to declare.

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