Jpn J Ophthalmol
DOI 10.1007/s10384-011-0035-1

CLINICAL INVESTIGATION

Suprachoroidal implant surgery in intractable glaucoma

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Received: 8 June 2010 / Accepted: 22 February 2011

Abstract
Purpose To report the early results of suprachoroidal silicone implant surgery in intractable glaucoma.
Materials and methods A modified silicone implant with no valve was implanted into the suprachoroidal space of 15 eyes with intractable glaucoma.
Results The mean age of the patients was 53.0 ± 24.5 (range 7–85) years, the mean follow-up time was 17.1 ± 4.8 (range 10–28) months, and the mean preoperative intraocular pressure (IOP) of patients receiving two or more medications was 33.1 ± 9.8 mmHg. At the last follow-up visit, mean IOP was 16.5 ± 7.9 (range 10–35) mmHg (Wilcoxon signed rank test, $p = 0.001$). The functional success, i.e., IOP ≤21 mmHg both with and without antiglaucomatous drugs, was 93.3%. The total success rate, i.e., IOP ≤21 mmHg without medication, was 13.3%. The average number of antiglaucomatous drugs used was 3.8 (range 2–5) preoperatively, and 2.2 postoperatively (range 0–4) (Wilcoxon signed rank test, $p = 0.011$). There was a ≥30% decrease in the IOP of 66.6% of the eyes. Shallow choroidal detachment as proof of drainage was evident in all cases.
Conclusion Drainage of the aqueous humor from the anterior chamber to the suprachoroidal space via implantation of a modified silicone implant is effective in lowering the IOP in intractable glaucoma.

Keywords Complications · Glaucoma · Glaucoma drainage device · Intraocular pressure · Suprachoroidal implant

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Introduction

Despite the high incidence of surgical failure due to cicatrization, filtering surgery with adjunctive antimetabolite therapy might increase the outcome of intractable glaucoma in some cases [1–3]. However, antimetabolite therapy is associated with a large number of postoperative complications, and filtering surgery with adjunctive antimetabolite therapy is not always successful. An alternative method which facilitates aqueous drainage is a glaucoma shunt implantation to provide a passage from the anterior chamber to the subconjunctival space. Although the implantation of such a shunt is a complex procedure with numerous pre- and postoperative complications, the success rate for glaucoma shunts in intractable glaucoma has been reported to be >50% in most series [1], with subconjunctival fibrosis reported as the most common cause of failure [4]. The results that have been reported after incisional needling and excisional revision of the subconjunctival adhesion at the filtration site are disappointing. The virtual space between the external surface of the choroid and the internal surface of the sclera does not clinically manifest under physiological conditions. However, this suprachoroidal space is reported to be used to achieve glaucoma shunting in eyes with cicatrized conjunctiva [1, 5].

In this retrospective study, we report the short-term results of suprachoroid silicone implants in 15 eyes with intractable glaucoma.

Materials and methods

Fifteen eyes of 14 patients (9 women, 5 men) who had undergone suprachoroidal shunt implantation for

Published online: 27 May 2011

intractable glaucoma after previous glaucoma surgical procedures between July 2007 and June 2009 were enrolled in the study. Preoperative diagnosis was open angle glaucoma in seven eyes, secondary glaucoma due to trauma in four eyes and juvenile glaucoma in four eyes. The inclusion criteria were the presence of at least one prior unsuccessful glaucoma surgery and advanced glaucoma. A suprachoroidal drainage shunt was implanted in all eyes to control intraocular pressure (IOP).

The anterior chamber angles were evaluated at the first visit using a Goldmann three-mirror lens. At baseline and on each subsequent examination, an anterior and posterior segment evaluation by slit-lamp and specular microscopy

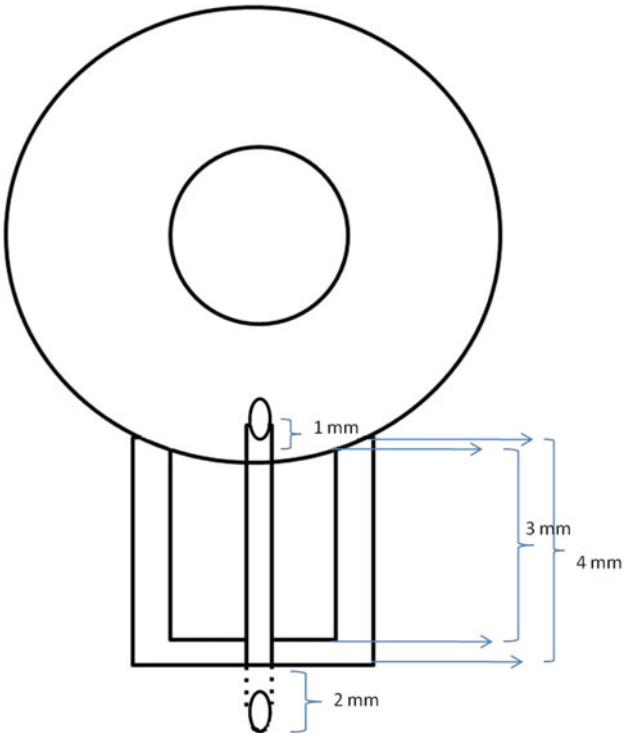

Fig. 1 The position of the implanted beveled edged silicon tube. Note that the suprachoroid part is approximately 2 mm

was performed. A Goldmann applanation tonometer was used to measure the IOP at each visit. The mean follow-up time was 17.1 ± 4.8 (range 10–28) months. Functional success was defined as an IOP of ≤21 mmHg both with and without antiglaucomatous medication at postoperative month 6. Total success was defined as an IOP of ≤21 mmHg without antiglaucomatous medication at postoperative month 6. Any IOP result >21 mmHg was considered to be a failure, and an IOP <5 mmHg was classified as hypotony.

All surgery, except on children (general anesthesia), was performed under topical anesthesia by the same surgeon (HA). A silicone tube (internal diameter 0.3 mm, external diameter 0.6 mm) with beveled edges was implanted in all eyes.

As described by Jordan et al. [5], we first made a fornix-based conjunctival flap, then prepared 4 × 4-mm superficial and 3 × 3-mm deep posterior limbus-based scleral flaps (Fig. 1). Unlike the surgical approach employed by Jordan et al. [5], which was always in the inferior quadrant, we chose the healthiest conjunctival area, rather than any one specific area, for the surgical approach, and our scleral flap was not triangular but rectangular. A small incision was made on the sclera to access the suprachoroidal space. A deep scleral flap was created to visualize the suprachoroidal space access without causing choroidal injuries. Viscoelastics were used both to protect the anterior chamber from mechanical trauma and to dissect the suprachoroidal space. A 23-gauge needle was inserted through the limbus to the anterior chamber, and the silicone tube was pushed to the anterior chamber from one side through the suprachoroidal space. The length of all the tubes placed in the suprachoroidal space was 2 mm. The silicone tube was stabilized with a single 10.0 nylon suture (Fig. 2a, b); the scleral flaps were sutured with 10.0 nylon, and the conjunctiva was sutured with 8.0 vicryl sutures. No antimetabolite agent was used.

Topical corticosteroids and antibiotics were prescribed four times daily for the first postoperative month. The patients were examined at postoperative weeks 1 and 4 and at 1-month intervals thereafter. This study was approved by

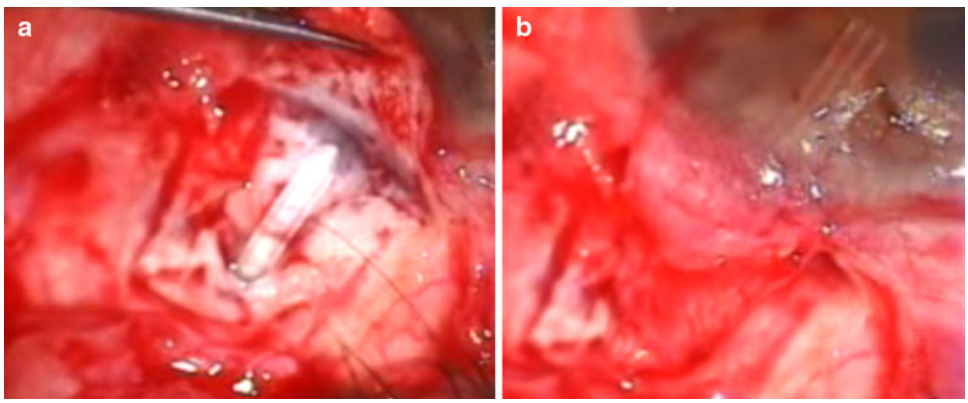

Fig. 2 **a** Silicone tube introduced to both the anterior chamber and suprachoroidal space, **b** silicone tube in the anterior chamber

our Institutional Review Board (IRB) and complies with the Declaration of Helsinki. The results are reported as the mean ± standard error (SE). The Wilcoxon signed rank test was used for statistical evaluation, and a p value <0.05 was considered to be significant.

Results

The demographic data and preoperative clinical characteristics of 15 eyes of 14 patients who were enrolled are presented in Table 1. The mean age of the patients was 53.0 ± 24.5 (range 7–85) years. All enrolled eyes had undergone numerous glaucoma surgical procedures (1.9 ± 1.0, range 1–4). Placement of the modified silicone implant to the suprachoroidal space was achieved in all cases.

Mean preoperative IOP of the patients receiving two or more medications was 33.1 ± 9.8 mmHg. At the last follow-up visit, the mean IOP was 16.5 ± 7.9 (range 10–35) mmHg (Fig. 3). The difference between pre- and postoperative IOP was statistically significant (Wilcoxon signed rank test, $p = 0.001$). The functional success rate was 93.3%, whereas the total success rate was 13.3%. A ≥30% decrease in IOP was detected in 66.6% of the eyes.

The average number of antiglaucomatous drug used pre- and postoperatively was 3.8 (range 2–5) and 2.4 (range 0–4), respectively (Wilcoxon signed rank test, $p = 0.011$).

Shallow choroidal detachment as proof of drainage was evident on B-mode ultrasonography images in all cases throughout the follow-up period. No resistant postoperative hypotony or IOP spikes were encountered. None of the eyes developed any complications, such as shallow anterior chamber, corneal edema, tube migration to anterior chamber, hyphema, suprachoroidal hemorrhage, retinal detachment, phthisis bulbi or endophthalmitis, which can occur with this kind of surgery. No bleb or conjunctival leaks were detected during the follow-up period.

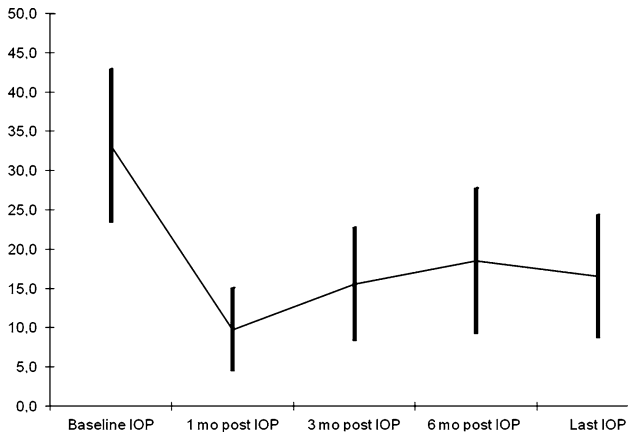

Fig. 3 Baseline intraocular pressure (*IOP*) and change in IOP of the patients over time (mean ± standard error)

The pre- and postoperative corneal endothelial cell count was 590.45 ± 26.34 and 587 ± 19.23, respectively, and the difference was not statistically significant (Wilcoxon signed rank test, $p = 0.21$).

The suprachoroidal drainage implant surgery is efficient as a means of IOP reduction, antiglaucomatous drug number reduction, and functional success rate (Table 1). Overall, the technique was safe with only minor complications, but no visual acuity loss or corneal endothelial damage.

Discussion

The aqueous humor can leave the eye via one of two routes: (1) through the trabecular meshwork into the Schlemm channel and then into the intrascleral and episcleral venous plexus; (2) through a second pathway that originates with the passage of the aqueous humor through the uveoscleral route. The aqueous humor flows along the interstitial tissue of the ciliary muscle into the suprachoroidal space and out through the sclera or through the vascular channels of the sclera into the connective tissue of the orbit [6]. Bill et al. [7] demonstrated that the uveoscleral outflow accounts for <20% of the total drainage of aqueous humor in human eyes. However, recent studies show a much higher role for the contribution of uveoscleral outflow in the total drainage of aqueous humor. Toris et al. [8] report that the uveoscleral outflow accounts for 54% of the total outflow in young healthy humans.

The suprachoroidal space is the virtual space between the external surface of the choroid and the internal surface of the sclera. Under physiological conditions, this space does not manifest clinically. The uveoscleral outflow can be influenced directly both surgically and pharmacologically (e.g. with latanoprost) [9]. The classic transscleral form of cyclodialysis was first described by Leopold Heine in 1905 as a novel surgical treatment for glaucoma and was the first surgical approach to exploit the resorptive IOP-lowering capacity of the choroid [1].

In 1973, Portney [10] reported five eyes with intractable glaucoma that had undergone cyclodialysis in combination with implantation of a T-shaped silicone elastomer to keep the ciliary body detached from the sclera and for permanent connection of the anterior chamber to the suprachoroidal space. However, the surgery failed in all the eyes. The results of histological testing on the ultimately enucleated eyes revealed that the presence of inflammatory cells and fibrous scar formation only a few weeks after the initial surgery had caused failing of the internal fistula. Scarring

Table 1 Patients characteristics

Patient no.	Age (years)	Sex	Diagnosis	Pre-BCVA	Post-BCVA	Pre-IOP (mmHg)	Post-IOP (mmHg)	Pre-Drugs (*n*)	Post-Drugs (*n*)	Previous glaucoma surgeries
1	28	M	SG	20/40	20/40	38	10	5	4	TE (×1), GDD (×1)
2	34	F	SG	20/500	20/500	53	10	5	2	TE (×2)
3	73	M	POAG	20/500	20/800	40	12	5	3	TE (×3)
4	25	F	JG	20/1250	20/320	42	14	3	4	GDD (×1)
5	80	F	POAG	20/1250	20/1250	25	23	3	4	NPGS (×1)
6	57	M	JG	20/40	20/28.5	30	10	3	1	GDD (×1)
6	57	M	JG	20/25	20/20	30	10	4	1	GDD (×1)
7	59	M	SG	20/100	20/66.6	30	10	4	3	TE (×2)
8	63	F	POAG	20/25	20/20	20	16	3	4	TE (×1)
9	56	F	POAG	20/1250	20/1250	40	12	2	4	TE (×4)
10	7	F	SG	20/200	20/200	38	10	4	3	TE (×2), GDD (×1)
11	78	F	POAG	20/400	20/50	22	10	3	1	TE (×1)
12	19	F	JG	20/200	20/400	44	10	4	3	TE (×2), GDD (×1)
13	85	F	POAG	20/100	20/400	25	10	4	0	TE (×3)
14	74	M	POAG	20/100	20/200	21	10	5	0	NPGS (×1)

F, Female, *M* male, *BCVA* best corrected visual acuity,*SG* secondary glaucoma, *POAG* primary open angle glaucoma, *JG* juvenile glaucoma, *TE* trabeculectomy, *GDD* glaucoma drainage device, *NPGS* non-penetrating glaucoma surgery

in the suprachoroidal space was probably the main factor hindering long-term success.

Ozdamar and colleagues [11] implanted a modified Krupin valve, which is usually designed for episcleral fixation, into the suprachoroidal space in four blind human eyes. They reported a clinical IOP-lowering success rate of 75% (IOP <21 mmHg, no medications). There were no severe postoperative complications, and they found no histopathological findings related to fibrous encapsulation of the valve.

Another antiglaucomatous implant procedure for suprachoroidal drainage has been described by Yablonski [12]. This author enrolled 23 eyes in a clinical trial, of which only three had undergone previous incisional glaucoma surgery. After a mean of 324 ± 136 days, 18 eyes required laser suture-lysis of the scleral nylon sutures or postoperative 5-fluorouracil to control the IOP. A significant drop in IOP from a preoperative value of 25.4 to a postoperative value of 13.8 mmHg and a significant decrease in the need for topical antiglaucoma medication (preoperative 3.0, postoperative 1.1) were noted.

An approach using a tube implant for suprachoroidal drainage has been described by Jordan and coworkers [5]. Thirty-one eyes with intractable glaucoma that had undergone multiple previous filtration and/or cyclodestructive procedures (mean 3.5 ± 1.9) were included in this prospective case series. They performed the surgery at the inferior conjunctival area, which has appeared to be less traumatized in previous surgeries. The authors reported a success rate of 70% after 30 weeks, 60% after 1 year and 40% after 76 weeks. The mean functional survival time of the implanted silicone tube was 56 weeks. No serious cases of postoperative bleeding, hypotony or infection were noted. The first failure peak was observed after only 4 weeks, and the second after 1 year. Ultrasound biomicroscopy revealed that fibrous obstruction of the posterior lumen of the silicone tube in all failed eyes was the cause of the failure.

A new device for suprachoroidal drainage is the Gold Micro Shunt (GMS; SOLX, Waltham, MA), which is made of biocompatible, 99.95% 24-carat gold [1]. The GMS can be implanted by making either a special corneal incision or a scleral incision at a distance of 2.5 mm from the limbus, inserting the GMS first anteriorly into the anterior chamber and then posteriorly into the suprachoroidal space. Melamed and colleagues reported a case series of 38 eyes with an 11.7-month follow-up [13]. They observed a mean IOP decrease of 9 mmHg (from 27.6 to 18.2 mmHg; $p < 0.001$). Surgical success was achieved in 30 patients (79%) (IOP >5 and <22 mmHg, both with and without antiglaucoma medication). Eight patients had mild to moderate transient hyphema.

In our series, the suprachoroid implant surgery was successful in controlling glaucoma in 66.6% of eyes over a mean follow-up period of 17.1 ± 4.8 (range 10–28) months, which is similar to success rates reported in other studies [5, 11]. Unlike filtrating surgeries, the goal in this type of surgery is not to achieve subconjunctival filtration; therefore, conjunctival scarring does not affect the operation success rate as much as it affects that of filtrating

surgeries. As all of our eyes had undergone at least one (range 1–4) glaucoma surgery, this success rate is comparable with that of the previously reported studies [5, 11, 12]. Although Melamed et al. report a higher success rate (79%) using GMS, this device is expensive, especially for less developed countries [13]. As reported by Jordan et al. [5], we noticed a tendency in the IOP to increase in the postoperative week 4, probably due to scar formation [5]. To overcome this IOP rise, we added antiglaucomatous medication to the therapeutic regimen, achieving a success rate of 93.3% of eyes. We did not come across any mild or severe complications in any of our cases with this cheap and practical equipment [5, 11, 13]. We also did not detect any significant decreases in the best corrected visual acuity due to tube implantation. Although our follow-up time was relatively short, the success rate of this technique for suprachoroid implant surgery in intractable glaucoma seems to be promising.

In conclusion, we have shown that suprachoroid implant surgery can effectively control IOP in eyes with intractable glaucoma. However, the long-term benefit of the newer and partially promising antiglaucomatous suprachoroid implants that improve uveoscleral outflow still has to be proven in prospective randomized multicenter trials.

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