

Long-term Outcomes of Domestic Hunan Aqueous-Drainage Implantation in Refractory Glaucoma

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Abstract

Purpose: To evaluate the long-term outcomes of a non-valved, Chinese-made Hunan aqueous drainage device (HAD) in patients with refractory glaucoma, compared to trabeculectomy.

Methods: This was a retrospective observational case series, including 27 patients with refractory glaucoma who either underwent HAD implantation ($n=11$) or trabeculectomy ($n=16$). The mean follow-up was 27.9 ± 13.5 (mean \pm SD) months. Intraocular pressure (IOP), visual acuity and postoperative complications were measured.

Results: IOP was significantly lower at the last follow-up in both two groups compared with the baseline IOP (HAD: 58.4 to 19.0 mmHg, $P<0.001$; trabeculectomy: 58.4 to 23.7 mmHg, $P<0.001$). One week, 1 month and 1 year after the operation, the average IOP of the HAD group was significantly lower than that of trabeculectomy group ($P<0.05$ at all time points). However, the IOP did not differ significantly between the two groups at the time of last follow-up.

Conclusion: HAD implantation serves as a good option to control IOP in refractory glaucoma. (*Eye Science* 2011; 26: 225–229)

Keywords: China; glaucoma drainage devices; refractory glaucoma; trabeculectomy

Refractory glaucoma is characterized as eye diseases in which intraocular pressure (IOP) cannot be controlled below 21 mmHg, even after drug and surgical therapies. Refractory glaucoma mainly includes neovascular glaucoma; aphakic or intraocular lens glaucoma; glaucoma induced by filtration-surgery

failure; glaucoma accompanied by uveitis; traumatic glaucoma; and glaucoma induced by vitreous surgery. Drug administration yields undesirable efficacy on glaucoma treatment, and, combined with systemic administration of anti-glaucoma medicine, produces serious adverse reactions. In addition, the filtration duct is likely to suffer scarring, which causes filtration-duct obstruction and prevents the construction of an effective filtration-duct during conventional filtration surgery. Hence, the surgical success rate is low (11–52%) and the prognosis is relatively poor¹.

The emergence of aqueous-drainage devices provides a novel option for glaucoma treatment. In 2000, our hospital initially introduced the Hunan aqueous-drainage implant (HAD) to cure refractory glaucoma, along with the application of antimetabolites into glaucoma treatment. In 2003, we began to adopt HAD implantation in combination with adjunctive mitomycin C, and compared the surgical efficacy with trabeculectomy. Long-term follow up was conducted to evaluate the efficacy and safety of HAD implantation upon refractory glaucoma.

Materials and methods

Clinical information

Twenty-seven patients (27 eyes) with refractory glaucoma were admitted to Zhongshan Hospital, affiliated to Xiamen University, between June 2003 and May 2008; these were 15 males and 12 females, aged from 34 to 76 years, with mean age 42.4 ± 10.0 years. Among the enrolled patients, 14 patients had neovascular glaucoma; 4 patients suffered from uveitis secondary glaucoma; 3 patients had traumatic glaucoma; 2 patients had IOL glaucoma; and 4 patients had glaucoma owing to filtration-surgery fail-

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ure. All cases had no surgical history of ciliary-body injuries. Among the 27 participants, 11 cases received HAD implantation (7 cases of neovascular glaucoma; 1 case of uveitis secondary glaucoma; and 3 cases of glaucoma induced by failure of filtration surgery); and 16 patients were subjected to trabeculectomy (7 cases of neovascular glaucoma; 3 cases of uveitis secondary glaucoma; 3 cases of traumatic glaucoma; 2 cases of IOL glaucoma; and

1 case of glaucoma caused by filtration-surgery failure). No statistical difference was noted between the two groups regarding age, gender division or glaucoma type ($P > 0.05$), as indicated in Table 1. Prior to surgery, mean IOP in the HAD implantation group was (58.4 ± 11.8) mmHg, and (58.4 ± 9.4) mmHg in the trabeculectomy group. No significant difference was found between the two groups ($P > 0.05$), as shown in Table 2.

Table 1 Gender, age and type data of two groups of patients with refractory glaucoma

	Age	Sex		Glaucoma type				
		Male	Female	Neovascular glaucoma	Uveitis secondary glaucoma	Traumatic glaucoma	IOL glaucoma	Filtration surgery failure-induced glaucoma
HAD implant group	43.5±12.6	6	5	7	1	0	0	3
Trabeculectomy group	41.6±8.1	9	7	7	3	3	2	1
<i>P</i> *	0.649	0.930		0.310				

*Pre-operative data(age, gender, type of glaucoma)saw no statistically significant difference($P > 0.05$).

Table 2 Pre- and post-operation intraocular pressure of the two groups (mmHg)

	Pre-operation	1 week post-operation	1 month post-operation	1 year post-operation	After follow-up	<i>P</i> *
HAD implant group	58.4±11.8	9.47±1.87	10.1±2.51	15.5±4.16	19.0±10.2	0.000
Trabeculectomy group	58.4±9.4	17.4±8.84	15.6±6.89	19.6±5.04	23.7±7.12	0.000
<i>P</i> **	0.997	0.007	0.020	0.034	0.179	

* The post-operative IOP of both groups were significantly lower than pre-operative levels ($P < 0.001$).

** There was no significant difference between the pre-operative IOP of the two groups ($P > 0.05$). The IOP of the HAD group was significantly lower than that of the trabeculectomy group, one week, one month and one year post-operatively ($P < 0.05$). By the end of follow-up, the IOP of the HAD group was lower than that of the trabeculectomy group, but the difference was not statistically significant ($P > 0.05$).

HAD implant; the HAD implant was made from high-elastic medical silicone rubber, (Beijing Rubber Product Design & Research Institute), and consisted of a non-valve drainage tube (inner diameter = 0.3 mm; outer diameter = 0.63 mm) and a fan-shaped drainage disc with an area of 180 mm². The frontal section of the drainage disc was fitted with a triangle pressure ridge to prevent low IOP occurring during early post-operative stages².

Surgical procedure

Anesthesia treatment; retrobulbar anesthesia was performed using a 2 ml 2% lidocaine solution. Proparacaine hydrochloride, at a concentration of 0.5%, was administered in droplet form three times before the formal operation.

HAD implantation; quadrants were selected depending on surgical situation; the eyeball was properly fixed by pulling the corresponding rectus with

sutures; and the visual field was exposed. A conjunctival flap, regarding the fornix as the base, was made. Subconjunctival tissues were separated, and the sclera was fully exposed. Complete cauterization was employed for hemostasis. Cotton containing 0.35 mg/ml mitomycin C was placed beneath the conjunctival flap for five minutes, and then washed using 100 ml BBS. A rectangle sclera flap, regarding the corneoscleral limbus as the base, was incised, 3 mm × 2 mm in size, to half of the thickness of the sclera. Hemostasis treatment was then administered. BBS was used for rinsing to ensure the drainage was unobstructed, then a drainage disc fitted on the sclera (the sclera surface between the two rectuses) using 6-0 nylon suture, with its frontal edge 8 to 10 mm from the corneoscleral limbus.

A No.2 syringe was used to puncture the anterior chamber under the scleral flap, around 2 mm from

the corneoscleral limbus. The drainage tube was cut to a proper length and the frontal end incised to a sloping shape, and then inserted into the anterior chamber to a depth of 2 mm, making the tube slope upward. Viscoelastics (1% sodium hyaluronate) formed the anterior chamber. The drainage tube was parallel to the iris surface, but had no contact with the iris and corneal endothelium. The catheter was fixed by sutures and the drainage tube was bundled up beneath the conjunctiva using 8-0 absorbable suture, and the scleral flap and conjunctival flap were sutured.

Trabeculectomy procedure: proper quadrants were chosen. The eyeball was properly fixed by pulling the corresponding rectus with sutures, and the visual field was exposed. A conjunctival flap was made, regarding the corneoscleral limbus as the base. The subconjunctival tissues were separated, and complete cauterization was employed for hemostasis. A rectangular scleral flap, 3 mm×2 mm in size, with a depth of half the scleral thickness, was incised. Cotton containing 0.35 mg/ml mitomycin C was placed beneath the conjunctival flap and scleral flap for five minutes, and then washed using 100 ml BBS. Puncturing was performed via the anterior chamber; the excised corneal trabecular tissue measuring 2 mm×1 mm, and removed the surrounding iris. The scleral flap was sutured using 10-0 nylon suture for two to three stitches, and formed an anterior chamber. The fascia bulbi and bulbar conjunctiva flap received watertight sutures on site.

Post-operative treatment: tobramycin dexamethasone sodium phosphate eye drops were administered every two hours, and the dose was gradually decreased 1 month later. In the two immediately post-operative weeks, compound tropicamide eye drops were administered two to three times daily. For those patients who presented a shallow anterior chamber, a 1% atropine ointment was administered one to two times daily and/or 1% atropine eye drops were administered three times daily. The conjunctival sutures were removed two weeks after surgery.

Follow up: post-operative follow-up endured from 13 to 57 months, 27.89 ± 13.47 months on average. The main parameters included vision acuity; IOP; anterior-chamber depth; drainage-tube position; and

bulbar conjunctiva. Filtration-bleb morphology and post-operative complications were detected and measured, respectively.

Statistical analysis: SPSS 14.0 software was used for data analysis in this study. The chi-square test and paired t-test were employed. $P < 0.05$ was considered as statistically significant.

Results

Vision acuity: The vision acuity measured at the last follow-up was deemed as final vision. In the HAD implant group, the vision acuity of seven patients was maintained at the pre-operative level (63.6%); two patients showed improved vision acuity (18.2%); and two patients had declined vision acuity (18.2%). Of the patients in the trabeculectomy group, nine had unchanged vision acuity (56.3%); two underwent improved vision acuity (12.5%); and five had decreased vision acuity (31.3%).

Intraocular Pressure (IOP): in the HAD implant group, mean IOP was (9.47 ± 1.87) mmHg one week post-operatively; (10.1 ± 2.51) mmHg one month post-operatively; (15.5 ± 4.16) mmHg one year post-operatively; and (19.0 ± 10.2) mmHg at the end of follow-up. In the trabeculectomy group, mean IOP was (17.4 ± 8.84) mmHg one week post-operatively; (15.6 ± 6.89) mmHg one month post-operatively; (19.6 ± 5.04) mmHg one year post-operatively; and (23.7 ± 7.12) mmHg after follow-up. In both groups, post-operative IOP was significantly decreased compared with the pre-operative level ($P < 0.05$). The mean IOP in the HAD implant group was significantly lower than that in the trabeculectomy group at one week, one month and one year post-operative ($P < 0.05$). However, no statistical significance was found in mean IOP between the two groups ($P > 0.05$), as shown in Table 2. One year post-operatively, the IOP in the HAD implant and trabeculectomy groups had declined by 73.5% and 66.4%, respectively. After follow-up, the IOP in the HAD implant and trabeculectomy groups had decreased by 67.5% and 59.4%, respectively.

Surgical success rate: after the follow-up, seven cases (63.6%) had IOP < 21 mmHg without usage of IOP-lowering agents in the HAD implant group and five cases (31.3%) in the trabeculectomy group.

Drug doses: in the HAD implant group, three pa-

tients required topical administration of IOP-lowering agents, one of whom received one single drug, and the other two patients took two drugs together. In the trabeculectomy group, 11 patients (68.8%) required the administration of a supplementary topical agent, three among whom underwent one single drug, six receiving two agents together, and two receiving three agents together.

Surgical complications; in the HAD implant group, those complications occurring early after the operation included three cases of transient hyphema (27.3%) and five cases of shallow anterior chamber (45.5%). In the trabeculectomy group, three patients had transient hyphema (18.8%) and four patients

presented a shallow anterior chamber (25.0%) during the early post-operative stage. These complications were relatively improved after proper treatment. In the HAD implant group, long-term complications included one case of complicated cataract (9.09%) and one case of corneal endothelial decompensation (9.09%). In the trabeculectomy group, one patient had cataract complications (6.25%), and one patient presented corneal endothelial decompensation (6.25%), as indicated in Table 3, below. For one patient, the HAD implant was removed and anti-infection treatment was administered owing to complicated bacterial keratohectosis occurring three month post-operatively.

Table 3 Vision acuity and short-term complications in the two groups

	Vision acuity				Complications	
	Unchanged	Increase	Decline	Hyphema	Shallow anterior chamber	Corneal endothelial decompensation
HAD implant group	7	2	2	2	5	1
Trabeculectomy group	9	2	5	3	5	1

Discussion

Refractory glaucoma has been a great challenge facing clinicians. There are different types of refractory glaucoma that present various pathogenesis and clinical characteristics. However, multiple factors, including intraocular inflammation, neovascular in anterior eye segment, repeated operations, and subconjunctival scars, negatively affect the diffusion of topical-drug administration, which leads to the insensitivity of glaucoma agents, requires the constant administration of a combination of many glaucoma drugs, fails to control IOP within the proper range, and presents poor compliance.

Various complications occur following filtration surgery, such as aggravated intraocular inflammation and hyphema, which are regarded as relevant factors in blocking of the filtration duct and causing surgical failure post-filtration-surgery. Hence, filtration surgery yields a low success rate and poor prognosis. Trabeculectomy produces varying success rates for patients with different types of glaucoma: 11–33% for neovascular glaucoma; 33–39% for IOL secondary glaucoma; and 36–51% for those receiving trabeculectomy after failed filtration surgery³. In recent years,

more and more drainage implantations have been introduced into the treatment of refractory glaucoma, owing to the simultaneous development of drainage implants. Novel types of drainage implants, such as the Ex-PRESS miniature drainage pin and the ultra-micro gold-made shunt⁴, have been applied by overseas scholars. However, the traditional tube-equipped drainage disc still serves as the predominantly used device in refractory glaucoma treatment, including non-restrictive aqueous-drainage devices (Molteno, Sckocket, Baerveldt, HAD) and restrictive aqueous devices (Krupin, Joseph, Ahmed, Optimed)².

Aqueous-drainage implantation is capable of effectively controlling IOP of patients with refractory glaucoma post-operatively and alleviating excessively high IOP-induced damage to visual function. Post-operative complications occurring during the early post-operative stage include low IOP; shallow anterior chamber; choroidal detachment; and choroidal hemorrhage. Major complications one-month post-operatively include drainage-tube displacement; drainage-tube or drainage-disc exposure; rear tenon capsule wrap-induced surgical failure; aqueous-mis-orientation drainage and infections⁵.

HAD, a non-valve aqueous device made in China

in 1993, belongs to a non-restrictive aqueous-drainage device. HAD is equipped with a triangle pressure ridge at the frontal part of the drainage disc to prevent low IOP occurring during the early post-operative stage. We implanted the drainage tube behind the anterior chamber intra-operatively and adopted absorbable sutures binding a drainage tube via the subconjunctival site, in an attempt to avoid the risk of low IOP during the early post-filtration-surgery stage. An 8-0 absorbable suture (Vicryl) retained 55% tension strength two weeks post-operatively; 20% three weeks postoperatively; and had fully absorbed 60-90 days post-operatively, which exerted no effect upon aqueous drainage one month post-operatively.

However, the HAD is designed as a non-valve device. In this study, the IOPs in the HAD group were significantly lower than those in the trabeculectomy group one week and one month post-operatively. The incidence of shallow anterior chamber in the HAD group also exceeded that in the trabeculectomy group, which is associated with excessive aqueous filtration during the early post-operative stage. In addition to binding the drainage tube, we also utilized viscoelastic to construct an anterior chamber intra-operatively. This reduced the risk of low IOP and shallow anterior chamber during the early post-operative stage; it also prevented the incidence of hyphema. In the HAD group, 11 patients had neither severe hyphema nor grade II/III shallow anterior chamber during the early post-operative stage. One year post-operatively, the IOPs in the HAD implant group were controlled better than those in the trabeculectomy group, and had decreased by 73.9% and 66.4%, respectively. Subsequently, the IOPs in the two groups were elevated, and declined by 67.5% and 59.4%, respectively, after the follow-up. No statistical difference was noted between the two groups.

The main aim in treating refractory glaucoma is to lower IOP and alleviate patients' suffering. Pre-operation, most patients with refractory glaucoma have undergone severe impairment of the visual function. In this investigation, the visual acuity of the majority of enrolled patients was lower than pre-operative-ly. In the two groups, over half of the participants main-

tained post-operative IOP at the pre-operative level, and no significant difference was noted between the two groups regarding vision acuity, which correlates with the fact that most patients' IOPs in the two groups were controlled within the safe range. Of those patients with deteriorated vision acuity, one case was complicated by bacterial keratohectosis, and four of the remaining six cases presented decreased vision acuity following the progression of fundus oculi diseases. Hence, vision acuity is not a suitable parameter for evaluating the efficacy and safety of IOP-lowering treatments.

In consideration of the financial burden on the patients, we did not compare the IOP-lowering effects between the HAD implantation and alternative drainage-device implantations. Currently, the success rate of the Ahmed drainage-valve implant, serving as the most commonly used in glaucoma treatment, achieved 70-80% success one year post-operatively; 60-63.3% two years post-operatively; and declined to 49% five years post-operatively⁶⁻⁹. In this study, we found that the HAD implantation yielded a success rate similar to aqueous-drainage operations, such as that with the Ahmed drainage-valve implantation. Similar complications were mainly characterized as hyphema and shallow anterior chamber, with a similar incidence. Compared with other drainage devices, the HAD implant yields a similar IOP-lowering effect and safety level. The HAD implant has a lower price and higher cost performance. In addition, the disadvantages of non-restrictive aqueous drainage can be countered by using absorbable sutures binding the drainage tube, which has excellent histocompatibility and induces no rejections in affected eyes.

To sum up, the HAD serves as an aqueous implant with higher cost performance. Additionally, the HAD implant produces similar IOP reduction and surgical safety to other drainage devices in the treatment of refractory glaucoma, while yielding higher IOP reduction than trabeculectomy. Most patients' visual functions can be maintained after at least one year of follow-up. Use of the HAD implantation as a surgical technique, therefore serves as an effective treatment of refractory glaucoma.

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