Membrane-tube-type glaucoma shunt device for refractory glaucoma surgery

난치성 녹내장 수술을 위한 막-튜브형 녹내장 션트 장치

문헌 핵심요약

1. **연구 목적:**
   - Finetube MT라는 새로운 녹내장 션트 장치의 안전성과 효능 평가.
2. **튜브 구조:**
   - e-PTFE(확장 폴리테트라플루오로에틸렌) 막으로 구성된 저수지와 내강 스텐트를 포함한 실리콘 튜브로 구성
3. **방법:**
   - 기존 치료에 반응하지 않은 44개의 눈에 대해 장치를 이식하고 수술 전후의 안압(IOP), 약물 사용량 및 합병증을 조사.
4. **결과:**
   - **안압 감소**: 평균 안압이 32.8 mmHg 에서 16.9 mmHg 로 감소(48.5% 감소, $p < 0.01$).
   - **약물 감소**: 사용 약물이 평균 2.5개에서 1.1개로 감소.
   - **성공률**: 1년 후 92.4%, 3년 후 85.0%의 성공률 유지.
   - **합병증 최소화**: 수술 후 저안압, 튜브 노출 등의 주요 합병증 없음.
5. **의의:**
   - 기존 장치보다 더 안전하고 예측 가능한 IOP 조절 가능, 공간 및 합병증 관련 제한 사항 극복.

Finetube MT

1. **핵심 특장점**
   - 효과적인 안압 조절: 평균 안압 48.5% 감소, 성공률 3년 동안 85% 유지
   - 안전성 우수: 수술 후 주요 합병증 (저안압, 튜브 노출 등) 미발생
   - 환자 편의성: 약물 사용량 절반 이상 감소
2. **혁신적인 구조**
   - e-PTFE 막 저수지: 높은 생체 적합성과 낮은 염증 반응
   - 소형 실리콘 튜브 및 스텐트: 공간 절약 및 합병증 최소화
3. **사용 편의성**
   - 튜브 스텐트 조정 가능: 단계적 안압 감소 기능
   - 최소 침습적 이식 기술

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GLAUCOMA

Membrane-tube-type glaucoma shunt device for refractory glaucoma surgery

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Abstract
Purpose To evaluate the safety and efficacy of a novel membrane-tube (MT)-type glaucoma shunt device for refractory glaucoma surgery. The device consists of an expanded polytetrafluoroethylene membranous reservoir, as well as a silicone tube (300-μm external and 200-μm internal diameter) with an intraluminal stent. We named the device "Finetube MT".
Methods The Finetube MT was implanted into 44 glaucomatous eyes that had insufficient intraocular pressure (IOP) control despite medical treatment or previous trabeculectomy. The membranous reservoir was placed underneath the Tenon's capsule, with each end located below the recti muscles; the tube was placed in the anterior chamber through a partial-thickness scleral track. We investigated the baseline and post-operative IOP values, the number of IOP-lowering medications used, and complications.
Results The mean age of the subjects was 51.6 ± 17.2 years, and the mean follow-up duration was 22.5 ± 12.0 months. One year after the surgery, the mean IOP had decreased from 32.8 ± 12.2 mmHg to 16.9 ± 6.4 mmHg (48.5 % reduction; $p < 0.01$), and the mean number of IOP-lowering medications used had decreased from 2.5 ± 0.8 to 1.1 ± 0.9 ($p < 0.01$). We considered the surgery as a success when the IOP was between 6 and 21 mmHg, *and* had been reduced by ≥ 20 % from baseline; by this standard, the success rate was 92.4 % after 1 year, and 85.0 % after 3 years. Neither postoperative ocular hypotony-related complications nor tube exposure occurred in any case.
Conclusions The Finetube MT showed promising surgical outcomes as a treatment for refractory glaucoma, with minimal risk of postoperative ocular hypotony or tube-related complications.

Keywords Glaucoma · Glaucoma drainage device · Surgery · Trabeculectomy · Intraocular pressure

Introduction

Glaucoma drainage devices (GDDs) are often used to control intraocular pressure (IOP) in patients with glaucoma. However, GDD implantation can lead to various complications, such as postoperative ocular hypotony, as well as mass effect-related problems (e.g., device exposure, eyelid protrusion, ptosis, and ocular motility disturbance) [1, 2]. Various techniques have been used to prevent ocular hypotony, including tube ligation, unidirectional valves, and staged operations [1]. Nonetheless, ocular hypotony remains a possibility [3–6]. Meanwhile, in eyes with refractory glaucoma, conjunctival conditions are usually poor. For example, excessive conjunctival vascularity, thinning, decreased movability, or scarring often occurs in eyes with neovascular glaucoma, uveitic glaucoma, traumatic glaucoma, a history of previous operations, or long-term use of IOP-lowering medications. Therefore, these eyes may have insufficient subconjunctival space, and the conjunctiva may bleed or form buttonholes during GDD implantation. In such cases, the implanted GDD can exert pressure on the overlying conjunctiva; this can lead to wound leakage, conjunctival erosion, or exposure of the device after surgery.

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To develop a glaucoma shunt device that achieves more predictable and safer IOP control, with fewer complications than conventional glaucoma surgeries, we designed two membrane-tube (MT)-type glaucoma shunt devices (MT devices). These consisted of an expanded polytetrafluoroethylene (e-PTFE) membrane, as well as a silicone tube with an intraluminal stent. We named the devices the "MicroMT" and the "Finetube MT" [7]. The MicroMT, similar to conventional trabeculectomy, drains aqueous humor from the anterior chamber, to the anterior subconjunctival space below a partial-thickness lamellar scleral flap. The Finetube MT drains the aqueous humor from the anterior chamber to the post-equatorial sub-Tenon's space, similar to conventional GDDs, such as the Ahmed Glaucoma Valve (AGV; New World Medical, Rancho Cucamonga, CA, USA) and the Baerveldt Glaucoma Implant (BGI; Abbott Laboratories Inc., Abbott Park, IL, USA) [7]. In this study, we investigated the safety and efficacy of the Finetube MT in treating refractory glaucoma.

Materials and methods

Subjects

This was a retrospective, non-comparative, interventional case-series study. The institutional review board of Kim's Eye Hospital, Seoul, South Korea approved the present study protocol. We analyzed the clinical data of 44 eyes of 44 patients who had undergone Finetube MT implantation between March 2011 and June 2013. All procedures conformed to the guidelines of the Declaration of Helsinki, and all patients gave informed consent before surgery. All eligible subjects were older than 18 years of age, had been diagnosed with glaucoma, and had insufficient IOP control despite medical treatment. The Finetube MT was implanted when the patient had (1) poor conjunctival condition (e.g., excessive vascularity, thinning, decreased movability, or scarring as a result of previous ocular surgery), or (2) neovascular, uveitic, or traumatic glaucoma, in which poor surgical outcome is expected using trabeculectomy. Cases were consecutively enrolled during the study period; if the condition of the eye was judged to have a relatively high risk of surgical failure from trabeculectomy, patients were consulted regarding whether they would undergo Finetube MT implantation or other procedures. The selection of surgical method was mainly determined by the patient's preference, and Finetube MT implantation was performed when the patient specifically chose the procedure.

All subjects had undergone a comprehensive ophthalmic assessment that included slit-lamp biomicroscopy; IOP measurement using the Goldmann applanation tonometer; a visual acuity test, the results of which were presented as logarithm of the minimum angle of resolution (logMAR); optic disc and fundus photography; and standard automated perimetry using the Swedish Interactive Threshold Algorithm-standard strategy program of the Humphrey Field Analyzer (HFA model 640; Humphrey Instruments Inc., San Leandro, CA, USA). Glaucoma was diagnosed when the eye showed the characteristic optic disc/retinal nerve fiber layer changes, with corresponding visual field abnormalities.

We reviewed the medical records of the subjects and collected pre-operative data: namely, age at surgery, sex, diagnosis, visual acuity, IOP, number of previous operations, and number of IOP-lowering medications used. Parameters such as IOP, number of IOP-lowering medications used, visual acuity, and complications were investigated 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year after surgery, as well as each year thereafter.

Profile of the Finetube MT

The Finetube MT was designed to drain aqueous humor from the anterior chamber to the post-equatorial sub-Tenon's space. We used a silicone tube as a conduit, which had a 300-μm external diameter and 200-μm internal diameter (Silicone No. 2, ARAM Micro Tubing, Japan). The tube was threaded with a 5-0 nylon suture (ETHILON, polyamide 6, Ethicon, Inc., Somerville, NJ, USA) using forceps under magnification. This was to prevent early postoperative hypotony as well as to further reduce IOP in a stepwise manner after surgery, since retracting the stent would increase aqueous outflow (Fig. 1). We named this tube plus the intraluminal stent as "Finetube". To create a reservoir, we cut a 0.1-mm-thick e-PTFE membrane (GORE® PRECLUDE® Pericardial Membrane, W.L. Gore & Associates, Inc., Flagstaff, AZ, USA) into an 18 × 13 mm oval shape, with an area of approximately 180 mm^2. Two of these oval membranes were glued together along the margin of the anterior half of the entire circumference with a width of 1–2 mm with a medical grade silicone adhesive (Silastic Medical Adhesive Silicone, Type A, Dow Corning Corporation, Midland, MI, USA). Sealing of the membrane margin was primarily intended to prevent growth of surrounding tissue into the internal space between the membranes, which contained the distal opening of the silicone tube. A 30-mm-long silicone tube threaded with a 60-mm-long 5-0 nylon suture as an intraluminal stent was fixed between the two membranes during sealing. Next, the postluminal area of the 5-0 nylon stent was pulled out from one side of the glued margin and inserted back into the other side in a loop-like fashion between the two e-PTFE membranes (Fig. 1).

Surgical technique

In all cases, the Finetube MT was produced in the same way, and surgery was performed, by the same experienced surgeon (B.H.A.). The operation was performed under local anesthesia, which was induced by subconjunctival injection of 2 % lidocaine.

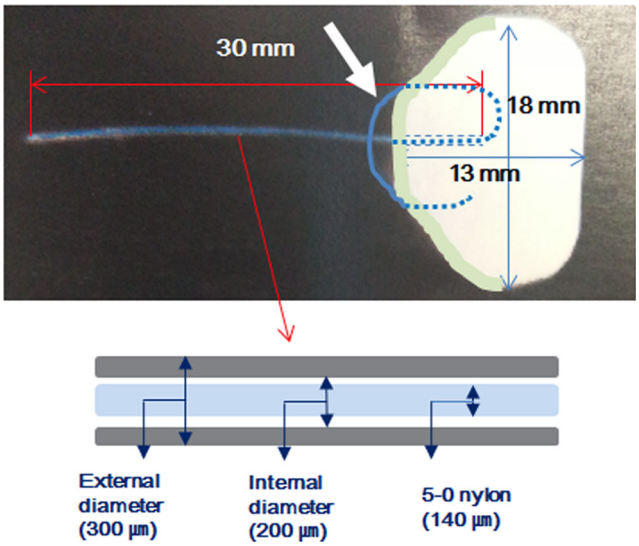

Fig. 1 Profiles of a membrane-tube (MT)-type glaucoma shunt device with a Finetube (Finetube MT). The Finetube MT consists of a fine silicone tube (with a 300-μm external diameter and a 200-μm internal diameter), as well as an intraluminal 5-0 nylon stent and expanded polytetrafluoroethylene (e-PTFE) membrane (180 mm^2 surface area). One end of the Finetube is fixed between two layers of e-PTFE membranes. Two of these oval membranes were glued together along the margin of the anterior half of the entire circumference with a width of 1–2 mm (*green area*). The 5-0 nylon intraluminal stent (approximately 140 μm in diameter) passes through the Finetube and between the two e-PTFE membranes. The post-luminal part of 5-0 nylon was placed in a loop-like fashion between the two layers of e-PTFE membranes (*blue dashed curve*). During retraction or removal of the 5-0 nylon stent, an exposed part of the 5-0 nylon stent on the opposite side of its end (*white arrow*; this side was placed on the temporal side of the eye during surgery) was pulled anteriorly

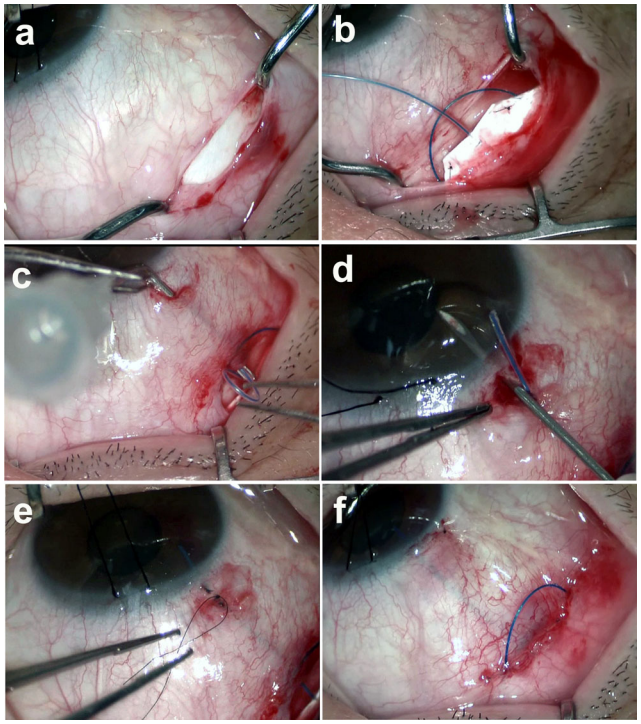

Fig. 2 The surgical technique for implantation of the membrane-tube (MT)-type glaucoma shunt device with a Finetube (Finetube MT). **a** A conjunctival incision is made 8–10 mm posterior to the limbus. **b** The membranous reservoir is inserted underneath the Tenon's capsule, with each end located under the two recti muscles. **c** The silicone tube is passed through a partial thickness scleral tunnel, which is created using a 23-gauge needle. **d** A corneoscleral track is made using a 26-gauge needle at the limbus, and the silicone tube is inserted into the anterior chamber. **e** The corneoscleral track and conjunctival wound are closed using 10-0 nylon sutures. **f** The post-luminal part of 5-0 nylon stent is left partially exposed through the conjunctiva to be pulled out when intraocular pressure must be further reduced

An 8-mm conjunctival incision was made 8–10 mm posterior to the limbus (Fig. 2a; Video). The membranous reservoir was then inserted in a folded fashion underneath the Tenon's capsule, with each end located under the two recti muscles (Fig. 2b). The anterior margin of the membrane was fixed onto the sclera 10 mm posterior to the limbus using 10-0 nylon sutures on both sides. A second conjunctival incision was made at the limbus. Using a 23-gauge needle, a partial thickness scleral track was made from the limbal wound to the forniceal wound (Fig. 2c). The tube tip was inserted into the lumen of 23-gauge needle; the needle was then retracted, and the tube remained in the scleral tunnel (Fig. 2c). The appropriate length of silicone tube was estimated (approximately 1.5 mm of tube was to be placed in the anterior chamber), and the tube was cut. Paracentesis was then performed through the corneoscleral incision using a 26-gauge needle, and the silicone tube was inserted into the anterior chamber (Fig. 2d). Next, the corneoscleral track and conjunctival wound were closed using 10-0 nylon sutures (Fig. 2e). The forniceal incisions of the conjunctiva and Tenon's capsule were closed using separate 10-0 nylon sutures, and the post-luminal 5-0 nylon stent was left partially exposed through the conjunctiva to be pulled out when necessary (Fig. 2f).

After surgery, patients were instructed to use prednisolone acetate 1 % ophthalmic suspension (PRED FORTE, Allergan, Irvine, CA, USA) and moxifloxacin hydrochloride 0.5 % solution (VIGAMOX, Alcon Laboratories, Fort Worth, TX, USA) four times a day for 1 month. Thereafter, topical steroid use was tapered. When post-operative IOP did not reach the reference level (IOP < 21 mmHg and ≥ 20 % reduction from baseline), the intraluminal stent was partially retracted using forceps under a slit-lamp biomicroscope in an outpatient clinic. If the IOP did not decrease sufficiently after partial stent retraction, the stent was completely removed. During retraction or removal of the 5-0 nylon stent, an exposed part of the 5-0 nylon stent on the opposite side of its end (this side was placed on the temporal side of the eye during surgery) was pulled anteriorly. Even though the pressure was not high, we removed the intraluminal stents completely in all cases 4 weeks after surgery when flow restriction by the stent was

no longer needed. When the intraluminal stent was partially retracted or completely removed, IOP was measured 1 h later.

Statistical analysis

We considered the surgery a success when the IOP was between 6 and 21 mmHg, *and* had been reduced by ≥ 20 % from baseline, with or without IOP-lowering medications. When IOP had been reduced by < 20 %, was < 6 mmHg or > 21 mmHg on at least two consecutive follow-up visits, or when additional glaucoma surgery was required to control IOP, we defined the surgery as a failure. To assess the success rate, we performed a Kaplan–Meier survival analysis. The follow-up duration was defined as the length of time from surgery until the last documented follow-up visit, or, in the case of failure, from surgery until the date when failure was first noted. To evaluate changes in IOP, the number of IOP-lowering medications used, and visual acuity, we used the Wilcoxon signed-rank test. A p-value < 0.05 was considered statistically significant. Statistics were analyzed using SPSS version 18.0 (SPSS, Chicago, IL, USA).

Results

Table 1 details the clinical characteristics of the subjects. Forty-four eyes of 44 subjects (14 women and 30 men) were included in the present study. The mean age of the subjects was 51.6 ± 17.2 years, and the mean follow-up duration was 22.5 ± 12.0 months. The 44 eyes comprised 18 (41.0 %) with primary open-angle glaucoma, nine (20.5 %) with secondary open-angle glaucoma, seven (15.9 %) with neovascular glaucoma, six (13.6 %) with chronic angle-closure glaucoma, three (6.8 %) with uveitic glaucoma, and one (2.3 %) with traumatic glaucoma. The mean number of previous glaucoma operations was 1.5 ± 1.4.

Table 1 Baseline characteristics of the eyes

Variables	
Number of eyes (patients)	44 (44)
Age at the operation (years)	51.6 ± 17.2 (28–82)
Women (*n*, %)	14 (31.8)
Follow-up duration (months)	22.5 ± 12.0 (4–42)
Intraocular pressure (mmHg)	32.8 ± 12.2 (21–56)
Glaucoma medications (*n*)	2.5 ± 0.8 (1–4)
Visual acuity (logMAR) (range)	0.7 ± 0.7 (0–2)
Previous glaucoma surgery (*n*)	1.5 ± 1.4 (0–4)
Glaucoma diagnosis, (*n*, %)	
Primary open-angle	18 (41.0)
Secondary open-angle	9 (20.5)
Neovascular	7 (15.9)
Chronic angle-closure	6 (13.6)
Uveitic	3 (6.8)
Traumatic	1 (2.3)

Data are presented either as numbers or as mean ± standard deviation with range

IOP change, number of IOP-lowering medications, and visual acuity

One day after the surgery, the mean IOP had decreased from a pre-operative value of 32.8 ± 12.2 mmHg to 10.0 ± 5.6 mmHg (p < 0.01). IOP was less than 6 mmHg in nine eyes (20.5 %); 4 mmHg in eight eyes, and 5 mmHg in one eye. None of the eyes showed a shallow anterior chamber or hypotony maculopathy, and their IOP increased to ≥ 6 mmHg in the first postoperative week without additional management. Tube blockage due to blood clots or inflammatory cells was not found in any of the cases. One week after the operation, the mean IOP was 11.5 ± 3.9 mmHg (p < 0.01). One month after the operation, the mean IOP was 21.6 ± 8.6 mmHg, and after the intraluminal stent had been completely removed, the mean IOP had decreased to 12.6 ± 5.7 mmHg (p < 0.01). None of the patients complained of irritation or sensation of a foreign body due to the exposed part of the 5-0 nylon loop. The mean IOP values 1, 2, and 3 years after the surgery were 16.9 ± 6.4 mmHg, 14.4 ± 3.8 mmHg, and 14.8 ± 4.2 mmHg, respectively (p < 0.01; Fig. 3; Table 2). The mean number of IOP-lowering medications had decreased from 2.5 ± 0.8 before surgery to 1.1 ± 0.9, 1.0 ± 0.7, and 1.4 ± 0.7 1, 2, and 3 years after surgery, respectively (p < 0.01; Table 2). The mean baseline logMAR visual acuity was 0.7 ± 0.7. The mean visual acuity values 1, 2, and 3 years after the operation were 0.7 ± 0.8, 0.7 ± 0.7, and 0.8 ± 0.8, respectively. During the follow-up period, no significant changes in visual acuity occurred (p > 0.05).

Success rate and post-operative complications

The cumulative survival rate (standard error) 1 year after surgery was 92.4 % (4.3), while that 3 years after surgery was 85.0 % (6.4; Fig. 4). In all cases, increased IOP was the reason for the surgical failure; no eye was defined as surgical failure owing to ocular hypotony. Hyphema was the most common complication, occurring in four eyes (10 %, Table 3). In two eyes (5 %) there was plugging material at the end of the tube, without IOP elevation; the material was successfully removed using neodymium-doped, yttrium aluminum garnet (Nd:YAG) laser treatment. Corneal decompensation was found in one eye (2.3 %) with a low corneal endothelial cell count and corneal opacity (867/mm^2) before surgery. In this case, keratoplasty was scheduled after the IOP control; thus, the Finetube MT implantation was performed prior to the keratoplasty. None of the patients experienced ocular hypotony-

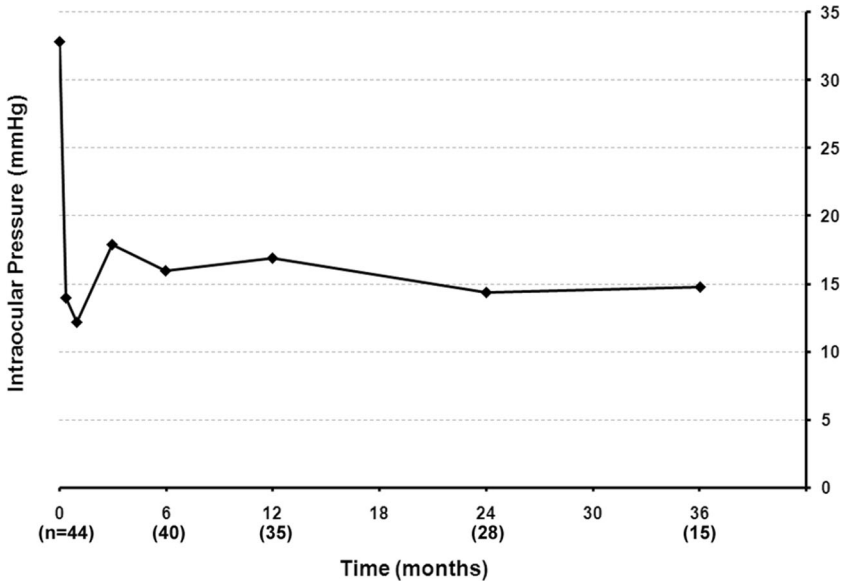

Fig. 3 Changes in intraocular pressure after implantation of the membrane-tube (MT)-type glaucoma shunt device with a Finetube (Finetube MT)

related complications, such as shallow anterior chamber, choroidal effusion, or hypotonic maculopathy. Similarly, no tube-related complications were found, such as conjunctival erosion or tube exposure. No other complications were observed, such as suprachoroidal hemorrhage, endophthalmitis, diplopia, eyelid problems, or ocular motility disturbance.

Table 2 Intraocular pressure (IOP) and number of IOP-lowering medications at baseline and follow-up visits

	n	IOP (mmHg)	Number of medications
Baseline	44	32.8 ± 12.2	2.5 ± 0.8
range		21–56	1–4
1 day*	44	10.0 ± 5.6	0
range		4–27	
1 week*	44	11.5 ± 3.9	0
range		6–22	
1 month*	44	21.6 ± 8.6	0
range		8–48	
After stent removal		12.6 ± 5.7 6–26	
3 months*	44	17.9 ± 5.6	0.5 ± 0.7
range		6–34	0–3
6 months*	40	16.0 ± 4.5	1.0 ± 0.8
range		7–30	0–3
1 year*	35	16.9 ± 6.4	1.1 ± 0.9
range		10–35	0–3
2 years*	28	14.4 ± 3.8	1.0 ± 0.7
range		9–24	0–2
3 years*	15	14.8 ± 4.2	1.4 ± 0.7
range		10–21	0–3

Data are presented either as numbers or as mean ± standard deviation with range

* Both post-operative IOP and the number of IOP-lowering medications had significantly decreased over the pre-operative values (Wilcoxon signed-rank test, $p < 0.05$)

Discussion

In the present study, we described the surgical technique and outcomes of a novel MT-device (the Finetube MT) for refractory glaucoma surgery. According to our clinical experience, the Finetube MT showed safe and effective IOP control in refractory glaucoma, with minimal risk of post-operative ocular hypotony or tube-related complications.

Although GDD implantation is often used successfully in refractory glaucoma surgery, complications still occur [1–6]. To develop a GDD with a lower risk of complications, we modified the conventional GDD in three ways: we replaced (1) the plates of the AGV and BGI with a thinner e-PTFE

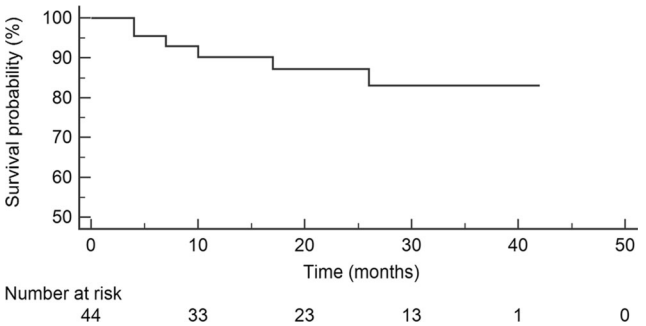

Fig. 4 The Kaplan–Meier survival curve after implantation of the membrane-tube (MT)-type glaucoma shunt device with a Finetube (Finetube MT)

Table 3 Post-operative complications

	Number (%)
Hyphema	4 (9.1)
Tube plugging	2 (4.5)
Corneal decompensation	1 (2.3 %)
Device (membrane or tube) exposure	0
Ocular hypotony (<6 mmHg)	0
Shallow anterior chamber	0
Choroidal effusion	0
Suprachoroidal hemorrhage	0
Diplopia	0
Ocular motility disturbance	0
Eyelid problems	0
Endophthalmitis	0

membrane reservoir, (2) the tubes of the AGV and BGI with a smaller tube and intraluminal stent (Finetube), and (3) both plates and tubes with an e-PTFE membrane and Finetube (Finetube MT).

As a candidate material for a safe and effective aqueous reservoir, we focused on the e-PTFE membrane. In an initial study, the e-PTFE membrane was implanted into 40 rabbit eyes; it was biocompatible, showing (1) low inflammation and adhesion to adjacent structures, and (2) no adverse effects on the corneal endothelium [8]. On the basis of these promising results, we modified the conventional GDD using the e-PTFE membrane. Specifically, we created an MT-device with an e-PTFE membrane and conventional silicone tube. The tube had an approximately 600-μm external diameter and a 300-μm internal diameter, which is used in the AGV and BGI. This device reduced IOP effectively, with minimal risk of complications, such as diplopia, eyelid problems, or shunt device exposure [9, 10]. However, even though a temporary tube-occlusion suture was applied using 8-0 vicryl with an intraluminal 5-0 nylon stent, postoperative ocular hypotony occurred [9, 10].

Thus, we reasoned that if a smaller tube could control IOP just as effectively, it may reduce the risk of ocular hypotony and tube-related complications. To determine the proper tube dimensions, we performed *in vitro* experiments (data not yet published), finding that a tube with an external diameter of 300 μm, an internal diameter of 200 μm, and an intraluminal stent of 5-0 nylon (Finetube), reduced pressure and allowed adjustment, with minimal risk of hypotony. To test the utility of the Finetube, we replaced the conventional silicone tubes of the AGV and BGI with Finetubes. According to our experience, an AGV or BGI that had been modified with a Finetube reduced IOP to a degree similar to that of the AGV or BGI, but without ocular hypotony (this result will be presented in detail in follow-up reports).

Finally, to minimize the complications of the plates and tubes of conventional GDDs, we modified our previous MT-device [9, 10] using the Finetube (Finetube MT). Although studies differ regarding the definition of success, as well as the characteristics of subjects, our clinical data show that the Finetube MT reduced IOP in a manner comparable to that of the AGV or BGI. Similarly, the success rate of the Finetube MT was similar to that of the AGV or BGI [2–6]. To compare the safety and efficacy of the Finetube MT with those of other GDDs, further randomized controlled trials would be necessary.

Various methods have been introduced to prevent postoperative ocular hypotony after GDD implantation; for example, valved devices or tube ligation are often used [1]. Nonetheless, post-operative ocular hypotony-related complications may still occur [3–6]. In contrast, when the Finetube MT was implanted in the present study, no ocular hypotony-related complications occurred during the follow-up period. Furthermore, the IOP can be further reduced—easily and safely—by retracting or removing the intraluminal stent; indeed, complete removal of the stent 4 weeks after the operation reduced the IOP in this study by an additional 43.5 %. This predictable and safe post-operative IOP control is a notable advantage of the Finetube MT.

One month after Finetube MT implantation, the mean IOP was approximately 10 mmHg higher than the mean IOP 1 week after surgery. As the elevation in IOP was immediately resolved by removal of the intraluminal stent without additional need for medication or other procedures, we think that this increase in IOP may have been caused mainly (with passage of time) by the increased resistance to fluid flow through the tube. This may represent a distinct mechanism from the hypertensive phase observed after AGV implantation due to fibrosis around the device.

In eyes with refractory glaucoma, the conjunctivae tend be in poor condition as a result of previous ocular surgery, injections, tissue thinning or scarring, ocular pathology, or prolonged use of IOP-lowering eye drops. For this reason, there is insufficient subconjunctival space in such eyes, making GDD implantation technically difficult, and increasing the risk of various complications. The Finetube MT has a thin (0.2 mm), foldable, and malleable membranous reservoir that occupies less space than the plates of conventional GDDs; it also has a tube with a smaller diameter than the conventional silicone tube. This may lessen the risk of complications related to space restrictions, such as device (membrane or tube) exposure, diplopia, ocular motility disturbance, or eyelid problems; indeed, in the present study, these complications were not found.

Corneal decompensation is another important complication of GDD implantation [1–6]. After implantation of the Finetube MT, corneal decompensation was found in one eye (2.3 %) with a low preoperative corneal endothelial cell count.

Currently, little is known about the effect of tube profile on the corneal endothelium. We think that a smaller tube may confer a lower risk of corneal decompensation. However, preoperative and postoperative specular microscopic findings were not compared in the present study. Further studies investigating the effect of tube diameter on corneal endothelium are warranted.

One shortcoming of a smaller tube is the possibility of tube occlusion by inflammatory materials, blood clots, or silicone oil. In the present study, there were two cases of tube plugging which were found 1 week after the surgery. We believe that the blockage materials included a fibrin clot in one eye and tissue debris in the other eye. However, this did not cause IOP elevation in either case. Moreover, in both cases, no further plugging occurred after Nd:YAG laser treatment. Nevertheless, there remains a chance of tube occlusion when large blood clots or silicone oil droplets form in the anterior chamber. Further studies regarding this issue are indicated.

In conclusion, we have presented the surgical technique and clinical outcomes of Finetube MT implantation to treat refractory glaucoma. The Finetube MT effectively controlled IOP, with minimal risk of postoperative ocular hypotony or tube-related complications. We think that Finetube MT implantation may be a good surgical option in refractory glaucoma treatment.

Compliance with ethical standards

Funding No funding was received for this research.

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.

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 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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