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ORIGINAL RESEARCH

Surgical outcomes of membrane-tube-type glaucoma shunt device in indigenous West Africans

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Purpose: The aim of this study was to report the safety and efficacy of the membrane-tube (MT)-type glaucoma shunt device (Finetube MT) in the management of refractory glaucoma in indigenous West Africans.

Methods: The Finetube MT was implanted into 25 eyes of 25 West African patients with refractory glaucoma. These patients had inadequate intraocular pressure (IOP) control despite maximum tolerable IOP-lowering medications with or without previous ocular surgeries. IOP, postoperative complications, interventions, visual acuities, and the number of IOP-lowering medications were analyzed preoperatively and postoperatively.

Results: The mean (standard deviation [SD]) age of the patients was 49.7 (20.9) years. The mean (SD) follow-up duration was 21.0 (10.6) months. Postoperatively, the mean (SD) IOP reduced from a preoperative value of 38.1 (10.3) mmHg to 14.5 (4.6), 16.1 (7.8), and 14.7 (3.0) mmHg at 1, 2, and 3 years postoperatively, respectively, representing 61.9%, 57.7%, and 61.4% reduction from baseline ($P<0.01$). The mean (SD) number of IOP-lowering medications reduced from 4.1 (1.0) to 0.6 (0.9) at 1 year and 0.9 (1.1) at 2 years after the operation ($P<0.01$). Using an IOP level between 6 and 21 mmHg and reduced by ≥20% from baseline, the cumulative survival rate (standard error) was 96.0% (3.9%) at 6 months, 89.0% (6.0%) at 18 months, and 81.3% (10.6%) at 3 years after the operation. There was no postoperative ocular hypotony, tube occlusion, or device exposure.

Conclusion: The Finetube MT may effectively control IOP with minimal risk of postoperative complications in indigenous West Africans.

Keywords: glaucoma, intraocular pressure, glaucoma shunt device, West Africa

Introduction

Glaucoma has a huge health burden in sub-Saharan Africa (SSA).[1] The African region has the highest incidence and prevalence of glaucoma, and it is disproportionately affected by blindness.[2] Glaucoma accounts for 15% of blindness in SSA compared to 8% in the world.[1] A recent study done in Nigeria reported that approximately one in every five patients with primary glaucoma was blind.[3] Reported prevalence of glaucoma in population-based studies within SSA ranges from 5.3% among South African blacks[4] to as high as 6.9% in South West Nigeria.[5] Budenz et al[6] reported a prevalence of glaucoma as high as 17.8% among males aged between 70 and 79 years and 20.1% among those older than 80 years in Ghana, West Africa.

Currently, lowering intraocular pressure (IOP) is the most effective way to prevent development and progression of glaucoma. Glaucoma can either be treated medically, surgically, or with the use of lasers. The cost of medical treatment in much of SSA is high and oftentimes unaffordable. This is further complicated with the problem of poor compliance and unavailability of medications in these resource-constrained

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regions. In a study done in South West Nigeria, only 27.2% of glaucoma patients self-reported 100% adherence with their medication within the study period.[7]

Although trabeculectomy has been advocated as the first line of the surgical management for primary open-angle glaucoma in SSA, studies show that the failure rate is higher in Africans compared to Caucasians.[8–10] Moreover, Africans are more likely to require surgical interventions after trabeculectomy compared with Caucasians because Africans have a greater concentration of conjunctival fibroblasts and macrophages, suggesting a more aggressive wound healing process.[11] In addition, the acceptability of the procedure is reported to be as low as 8%.[12] Many surgeons in SSA are reluctant to perform trabeculectomy because of the uncertain outcomes,[13] especially in the early postoperative period when sudden high or low IOP can lead to visual impairment.

Implantation of a glaucoma drainage device (GDD) is a useful surgical option in refractory glaucoma. Surveys have demonstrated an increase in the popularity of GDDs as an alternative to trabeculectomy, especially in eyes that have undergone previous ocular surgery.[14,15] Previous studies done in SSA have demonstrated the efficacy of GDDs in indigenous Africans.[16–18] However, these devices are relatively expensive to the much of patients in SAA and therefore not readily available. Thus, we have tried to develop a novel GDD with a lower price and similar or better surgical outcomes compared to conventional GDDs.[19,20] A newly developed membrane-tube (MT)-type glaucoma shunt device (Finetube MT) designed by the authors drains aqueous humor from the anterior chamber to the post-equatorial sub-Tenon's space, similar to conventional GDDs, such as Ahmed glaucoma valve (AGV; New World Medical, Rancho Cucamonga, CA, USA) and the Baerveldt glaucoma implant (BGI; Abbott Laboratories, Abbott Park, IL, USA). According to our previous study, the Finetube MT showed safe and effective IOP control in Korean patients.[20] We thought that Finetube MT may also be useful for the IOP control in indigenous West Africans.

The aim of this study was to evaluate the safety and efficacy of the Finetube MT in treating refractory glaucoma in indigenous West Africans. These preliminary data provides information on the surgical outcomes of this device in this population and forms the basis for future prospective studies on the use of GDDs in the surgical management of glaucoma in SSA.

Methods

This study is a retrospective, non-comparative, non-randomized, interventional case series. The study conformed to the tenets of the Declaration of Helsinki, and all patients gave informed written consent. Ethical approval was obtained from the institutional review board of the University of Ibadan/University College Hospital, Ibadan. Patients enrolled were those who underwent Finetube MT implantation between March 2013 and April 2016 and those with a minimum follow-up period of 6 months. All eligible patients had glaucoma with inadequate IOP control despite maximum tolerable medical therapy with or without previous trabeculectomy. Patients with secondary glaucoma, such as neovascular glaucoma, uveitic glaucoma, or traumatic glaucoma, in whom poor outcome was expected with trabeculectomy were indicated for the Finetube MT implantation as the first-line surgical treatment.

All patients underwent comprehensive eye examination that consisted of best-corrected visual acuity test, slit-lamp examination, IOP measurement by Goldmann applanation tonometry, and gonioscopy using a 4-mirror Posner lens. Automated full-threshold visual fields test was performed for patients with best-corrected visual acuity better than 6/60 using the 24-2 Swedish Interactive Threshold Algorithm standard program on the Humphrey 740 Visual Field Analyzer (Carl Zeiss Meditec AG, Jena, Germany). Pupils were dilated, and stereoscopic examination of the vitreous, retina, and optic nerve head was done with the 78-diopter lens.

Profile of the Finetube MT has been described in detail in an earlier study.[20] In brief, it consists of an aqueous reservoir membrane with a surface area of ~180 mm^2 and a silicone tube with a 300 μm external diameter and a 200 μm internal diameter with an intraluminal stent of 5-0 nylon thread (Figure 1A). The tube induces aqueous drainage from the anterior chamber to the membrane, and the intraluminal stent prevents excessive aqueous drainage through the tube and enables additional aqueous drainage after the surgery by retracting it.[19,20]

Surgical technique

All surgeries were done by one surgeon (OO). The procedure for the Finetube MT implantation has been presented in detail in an earlier study.[20] Briefly, this involved creating a parallel conjunctival incision 8–10 mm away from the limbus superotemporally. The superior and lateral recti muscles were identified with a squint hook. The membrane reservoir was then inserted underneath the Tenon's capsule, and the wings of the membrane were inserted under the two recti muscles. The anterior aspect of the membrane was sutured to sclera with 9-0 nylon (Figure 1B). A second perpendicular conjunctival incision was made ~2–3 mm away

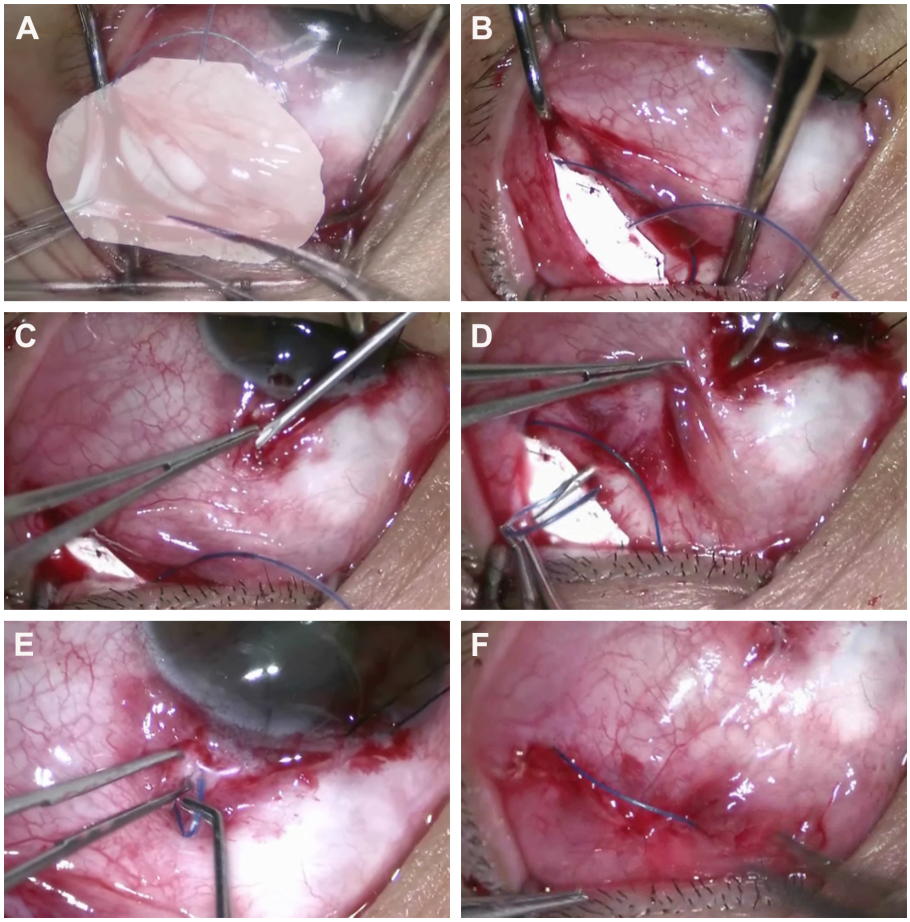

Figure 1 Surgical technique of MT-type glaucoma shunt device (Finetube MT) implantation.
Notes: The Finetube MT consists of a aqueous reservoir membrane with a surface area of ~180 mm^2 and a silicone tube with a 300 μm external diameter and a 200 μm internal diameter with an intraluminal stent of 5-0 nylon thread (**A**). Conjunctival incision was made 8–10 mm away from the limbus superotemporally. The membrane reservoir was then inserted underneath the Tenon's capsule and the anterior aspect of the membrane was sutured to sclera (**B**). A second conjunctival incision was made ~2–3 mm away from the superotemporal aspect of the limbus. By using a 23-gage needle, a track was made within the sclera to the forniceal wound (**C**). The tube tip was then inserted into the lumen of 23-gage needle; the needle was retracted such that the tube was passed into the partially thick scleral tunnel (**D**). A track was then made into the anterior chamber from the perilimbal scleral track using a 26-gage needle, and the silicone tube was inserted into the anterior chamber (**E**). The scleral track, conjunctiva, and Tenon's capsule were closed with 10-0 nylon sutures. The 5-0 nylon stent was left partially exposed through conjunctiva such that it can be pulled out after the operation when further IOP reduction is necessary (**F**).
Abbreviations: MT, membrane tube; IOP, intraocular pressure.

from the superotemporal aspect of the limbus. By using a 23-gage needle, a partially thick scleral tunnel of ~1 mm length was made and a track was made within sclera to the forniceal wound (Figure 1C). The tube tip was then inserted into the lumen of 23-gage needle; the needle was retracted such that the tube was passed into the partially thick scleral tunnel (Figure 1D). The tube was cut beveled up such that ~2 mm of the tube was placed into the anterior chamber. A track was then made into the anterior chamber from the perilimbal scleral track using a 26-gage needle, and the silicone tube was inserted into the anterior chamber (Figure 1E). The scleral track, conjunctiva, and Tenon's capsule were closed with 10-0 nylon sutures. The 5-0 nylon stent was left partially exposed through conjunctiva such that it can be pulled out after the operation when further IOP reduction is necessary (Figure 1F). At the end of operation, subconjunctival injections of dexamethasone and gentamicin were given. After surgery, patients were placed on topical antibiotics of moxifloxacin hydrochloride 0.5% solution (Vigamox; Alcon Laboratories, Inc., Fort Worth, TX, USA) and dexamethasone ophthalmic suspension (Maxidex 0.1%; Alcon Laboratories, Inc.) 2 hours for 2 weeks and then four times for another 4 weeks.

When postoperative IOP did not reach the desired level (IOP $<$21 mmHg and $\geq$20% reduction from baseline), we gently retracted the intraluminal stent partially using forceps under the slit lamp biomicroscope in the outpatient clinic. After removing the stent, IOP was measured again 1 hour later. If the IOP was still unsatisfactory despite partial removal of the stent, the whole stent was removed.

Independent of the IOP, the stent was removed in all cases at 4 weeks after the operation when the flow restriction by the stent was no longer needed; by this time, there will be wound healing around the plate and it may reduce the risk of ocular hypotony.[19,20]

Data collection and statistical analysis

Preoperative data collected were patient's age, sex, diagnosis, IOP, best-corrected visual acuity, optic disk findings, mean deviation value of visual field test, and number of IOP-lowering medications. Postoperative IOP within 48 hours; at 1 month, 3 months, 6 months, 1 year, and 2 years; and at the last visit were collected. Other data, such as the postoperative best-corrected visual acuity and number of IOP-lowering medications, were also collected. We analyzed changes in postoperative IOP, visual acuity, and number of IOP-lowering medications compared with baseline status by using Wilcoxon signed-rank test.

We defined surgical success based on the consensus on surgical outcome by the World Glaucoma Association.[21] Complete success was defined as an IOP of ≤21, ≤18, and ≤15 mmHg without the use of IOP-lowering medications following the operation, and qualified success was defined as an IOP of ≤21, ≤18, and ≤15 mmHg with or without the use of IOP-lowering medications after the surgery. In order to compare our study results with previously done similar study results,[20] we also considered success as an IOP between 6 and 21 mmHg and reduced by ≥20% from baseline, with or without the use of IOP-lowering medications. Patients with IOP <6 mmHg or IOP >21 mmHg on two consecutive follow-up visits or requiring additional glaucoma surgery to control IOP were considered failures. These criteria were used for the calculation of cumulative survival rate by using Kaplan–Meier survival analysis. We defined postoperative ocular hypotony as an IOP <6 mmHg. Data were collated and analyzed using the IBM Statistical Package for the Social Sciences (SPSS) software version 21 (IBM Corporation, Armonk, NY, USA). The significance level was set at $P<0.05$.

Results

A total of 25 eyes of 25 patients were enrolled. The clinical characteristics of the patients are presented in Table 1. The mean (standard deviation [SD]) age was 49.7 (20.9) years and males accounted for 16 (64%) patients. The mean follow-up period was 21.0 (10.6) months with a range of 6–36 months. Failed trabeculectomy was the most common indication for Finetube MT surgery accounting for 10 (40%) patients. The mean (SD) preoperative IOP was 38.1 (10.3) mmHg (range, 22–62 mmHg). The mean number of preoperative IOP-lowering medication was 4.1 (1.0; range, 2–5). All the eyes showed nearly total cupping of optic disk and mean deviation of visual field test worse than −30 dB.

Table 1 Clinical characteristics of patients before the MT-type glaucoma shunt device implantation

Characteristics	Values
Age (years)	49.7 (20.9)
Sex, n (%)	
Male	16 (64)
Female	9 (36)
Previous ocular surgery, n (%)	
Trabeculectomy	10 (40)
Cataract surgery	9 (36)
Intravitreal injections	3 (12)
None	3 (12)
Diagnosis, n (%)	
POAG with failed trabeculectomy	10 (40)
POAG with pseudophakia	5 (20)
POAG without previous surgery	1 (4)
Uveitic glaucoma	4 (16)
Neovascular glaucoma	3 (12)
Chronic angle closure glaucoma	1 (4)
Steroid induced glaucoma	1 (4)
IOP (mmHg)	38.1 (10.3)
Range	22–62
Number of IOP-lowering medications	4.1 (1.0)
Range	2–5
Visual acuity (logMAR)	0.36 (0.31)
Range	0.05–1.0

Note: Data are presented as mean (SD) for continuous variables and number (%) for categorical variables.
Abbreviations: MT, membrane tube; POAG, primary open-angle glaucoma; IOP, intraocular pressure; logMAR, logarithm of the minimum angle of resolution; SD, standard deviation.

After the Finetube MT implantation, the mean IOP reduced to 10.9 (6.7), 14.2 (5.3), 14.7 (5.1), 14.5 (4.6), 16.1 (7.8), and 14.7 (3.0) mmHg at postoperative first day, 1 month, 6 months, 1 year, 2 years, and 3 years, respectively, representing 71.4%, 62.7%, 61.4%, 61.9%, 57.7%, and 61.4% reduction from baseline ($P<0.01$; Figure 2).

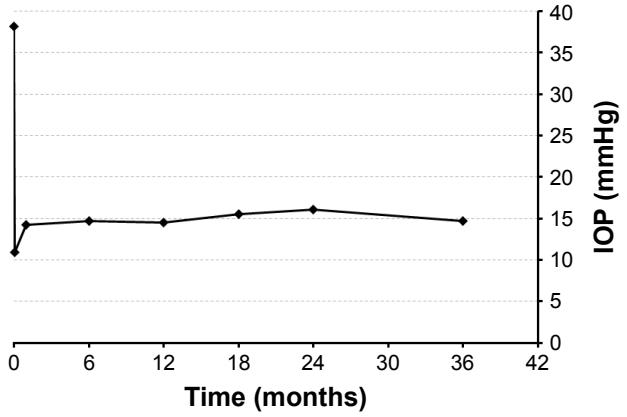

Figure 2 Changes in IOP after the MT-type glaucoma shunt device implantation.
Abbreviations: IOP, intraocular pressure; MT, membrane tube.

Table 2 Success rate (%) after MT-type glaucoma shunt device implantation

Post-operative time	Complete success			Qualified success		
	≤21 mmHg	≤18 mmHg	≤15 mmHg	≤21 mmHg	≤18 mmHg	≤15 mmHg
6 months (n=25)	96.0	80.0	52.0	96.0	96.0	64.0
12 months (n=22)	50.0	45.5	40.9	90.9	86.4	59.1
18 months (n=18)	55.6	55.6	44.4	89.0	83.3	50.0
24 months (n=12)	58.3	58.3	41.7	83.3	83.3	58.3

Abbreviation: MT, membrane tube.

Based on a cutoff value of ≤21 mmHg, complete success rate was 96.0%, 50.0%, and 58.3% at postoperative 6, 12, and 24 months, respectively. Qualified success rate was 96.0%, 90.9%, and 83.3% at postoperative 6, 12, and 24 months, respectively (Table 2). By using the survival analysis, the cumulative survival rate (standard error) was 96.0% (3.9%), 89.0% (6.0%), and 81.3% (10.6%) at postoperative 6, 18, and 36 months, respectively (Figure 3). Three eyes were classified as surgical failure at postoperative 6, 18, and 24 months. All of these eyes were defined as failure because of high IOP.

The mean (SD) number of IOP-lowering medications decreased from a preoperative value of 4.1 (1.0) to a postoperative value of 0.6 (0.9) and 0.9 (1.1) at postoperative 1 and 2 years, respectively ($P<0.01$). There was no significant change in visual acuity after the operation ($P>0.05$). Postoperative complications included tube retraction at postoperative 6 months in one case and a case of microbial keratitis in a poorly controlled diabetic patient 3 months after the operation. There were no other observed complications, such as postoperative ocular hypotony, shallow anterior chamber, choroidal effusion, hyphema, infection, occlusion of tube, exposure of the device, eyelid problems, or ocular motility disturbance. Two patients had encapsulated blebs and underwent needling revision of the fibrous tissues around the device at postoperative 4 and 6 months, respectively, while another patient had progression of a preexisting corneal decompensation. This patient had neovascular glaucoma and had undergone three surgeries previously, including 360° transscleral cyclophotocoagulation for intractable glaucoma before presentation at our clinic. This patient subsequently underwent Descemet's stripping automated endothelial keratoplasty and at postoperative 3 years, still had well-controlled IOP. When postoperative IOP, number of IOP-lowering medication, and success rates were compared between the eyes with previous trabeculectomy and eyes without previous trabeculectomy, there was no significant difference ($P>0.05$).

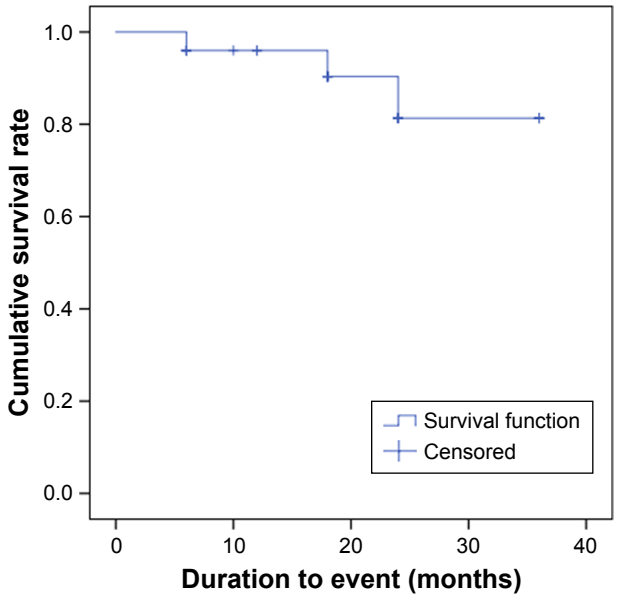

Figure 3 Kaplan–Meier survival curve after the MT-type glaucoma shunt device implantation.
Note: Success was defined as an IOP between 6 and 21 mmHg and reduced by ≥20% from baseline, with or without the use of IOP-lowering medications.
Abbreviations: MT, membrane tube; IOP, intraocular pressure.

Discussion

The most common glaucoma surgery in SSA remains trabeculectomy even though the African race is associated with a higher failure rate of this surgery compared to Caucasians.[8,9] Other glaucoma surgeries, such as GDD implantation, are not commonly performed in much of SSA; there have been only a few reports regarding the outcomes of GDD implantation in East Africans.[16–18] This is mainly because of the high cost of the devices and the need for patch graft materials, such as scleral graft and pericardial tissue, which are often not readily available in many parts of SSA. Therefore, it is always a huge challenge for ophthalmologists in SSA to deal with cases of failed trabeculectomies or refractory glaucoma, which is expected to have a risk of surgical failure after trabeculectomy.

According to our clinical experience, the Finetube MT implantation showed a possibility of safe and effective IOP control in West Africans with refractory glaucoma. Furthermore, although it is not commercially available yet, the Finetube MT can be made easily with simple materials

and the tubes do not need additional cover materials as they are tunneled into the sclera. Therefore, we think that the Finetube MT may be appropriate for resource-constrained settings, such as in SAA.

The main indications for Finetube MT implantation in our study were failed trabeculectomy with high IOP despite maximum tolerable medical therapy and eyes with refractory glaucoma, such as neovascular and uveitic glaucoma. Studies have demonstrated an increase in the use of GDDs as an alternative to trabeculectomy, especially in eyes that have undergone previous ocular surgery.[14,15] More recently, the indications for the GDDs have broadened and GDDs are being considered as the first-line surgical treatment option.[22–24] In much of SSA, however, the low socioeconomic status of many patients and the relatively high cost of these devices make this difficult. The decision to use GDDs in the current study was based on the results of the Trabeculectomy versus Tube (TVT) study.[22] The TVT study initially showed similar outcomes between tube shunt surgery and trabeculectomy with mitomycin-C (MMC) in the postoperative 1 year; however, 5 years after the operation, patients who underwent tube shunt surgery had a higher success rate compared with those who underwent trabeculectomy with MMC.[22] Although the Finetube MT used in our study is different from that used in the TVT study, we think that the results may be similar because both devices have a similar mechanism of aqueous drainage from the anterior chamber to post-equatorial sub-Tenon's space.

The results of the present study showed that the Finetube MT implantation induced a 61.9%, 57.7%, and 61.4% reduction in IOP at postoperative 1, 2, and 3 years, respectively. This is similar to the results of the previous study performed with the Finetube MT in Korean patients.[20] In terms of IOP reduction, results of our study are also in line with results of previous studies with conventional GDDs, such as AGV and BGI.[25–28] Regarding the surgical outcomes of GDD implantation in indigenous Africans, Kiage et al[16] in Kenya showed that after AGV implantation, a mean preoperative IOP of 36.4 mmHg reduced to 16.7 mmHg 2 months after the operation. Giorgis[18] in Ethiopia reported that a mean preoperative IOP of 31.38 mmHg reduced to 17.15 mmHg 6 months after the operation. Although the follow-up duration in these studies was short, the results suggest that GDDs may be promising in the surgical management of glaucoma in SSA.

Given that the flow through the tube is most largely affected by the tube diameter, postoperative ocular hypotony is prevented in Finetube MT by using a smaller diameter tube with an intraluminal stent. Compared to tubes of conventional GDDs (AGV and BGI) that have an internal diameter of 300 μm and an external diameter of ~600 μm, the Finetube MT has an internal diameter of 200 μm and an external diameter of 300 μm. Therefore, Finetube MT may have less possibility of excessive aqueous drainage compared to the tubes used in AGV or BGI.

Furthermore, the Finetube MT uses a tube with an intraluminal stent. This was purposed to prevent early postoperative ocular hypotony and induce additional IOP reduction after the operation by retracting the stent. In this study, no eye showed postoperative ocular hypotony or hypotony-related complications, such as shallow anterior chamber, choroidal detachments, and effusions. In cases with early IOP rise, stents were retracted or removed, and this induced effective additional IOP reduction. This can provide a controlled stepwise reduction of IOP postoperatively by gradual retraction of the intraluminal stent; intraluminal stent retraction of approximately half the length of the tube reduces IOP by an additional 3–5 mmHg.[19,20] Regardless of the IOP level, all stents were completely removed by 1 month after the operation. We hypothesized that at this time, subconjunctival and episcleral tissue fibrosis would have developed, which induces resistance to aqueous flow.[20] Therefore, no ocular hypotony may develop after the complete removal of the intraluminal stent.

Other major complications of GDDs are mass effect of device and corneal decompensation. In our study, no eye showed mass effect-related complications, including tube erosion or exposure, membrane exposure, eyelid problems, and ocular motility disturbance. This may be attributable to a smaller diameter of tube and a thinner and flexible aqueous reservoir of Finetube MT compared to other GDDs, such as BGI and AGV. Therefore, Finetube MT can be implanted in eyes without sufficient subconjunctival space owing to thinning or fibrosis of conjunctiva. When implanting Finetube MT, no patch graft material is required. This would be an important advantage in SSA where patch graft materials are usually not available. In the present study, corneal decompensation was found in only one eye that had previous multiple ocular surgeries and had a low preoperative corneal endothelial cell count prior to the surgery. We think that a smaller tube may induce a lower risk of corneal decompensation.[19,20] Further studies investigating the effect of tube diameter on corneal endothelium are warranted.

GDD implantation is usually associated with less need for postoperative follow-up compared to trabeculectomy, and the TVT study revealed a decreased requirement for reoperation

among eyes treated with GDDs compared to eyes treated with trabeculectomy.[22] By using Finetube MT, the most common necessary postoperative intervention was stent retraction or removal. We think that a relatively simple postoperative management would be another advantage of Finetube MT, especially in regions where patients have poor compliance or regular postoperative follow-up is limited.

Based on our clinical experience, a tube with a smaller diameter than conventional tubes showed similar IOP reduction with a lower prevalence of tube-related complications.[19,20] However, we think that there still remains a possibility of tube occlusion by inflammation materials, blood clots, or silicone oil.

Conclusion

We have presented the clinical outcomes of Finetube MT implantation to treat refractory glaucoma in the indigenous West Africans. Although the sample size was not large and follow-up period was not long, Finetube MT implantation showed effective IOP control, with minimal risk of postoperative ocular hypotony or tube-related complications. We suggest that Finetube MT implantation may be a good surgical option in the surgical management of refractory glaucoma, especially in resource-constrained communities. Further studies with a greater number of eyes and longer period of follow-up are needed to further elucidate the efficacy and safety of the Finetube MT in SSA.

Disclosure

The authors report no conflicts of interest in this work.

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