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Research Article

Tube Placement into the Long Scleral Tunnel with a Catheter Needle without a Scleral Valve and/or Graft Patch: 1-Year Outcome

Rinko Akamine, Naomi Miyamoto, Mami Kusaka and Masayuki Akimoto*

Ophthalmology, Osaka Red Cross Hospital, Japan

***Corresponding Author:** Masayuki Akimoto, Ophthalmology, Osaka Red Cross Hospital, Japan.

Received: February 10, 2022; **Published:** March 18, 2022

Abstract

Objectives: To develop a technique for introducing a tube shunt into the anterior chamber of the eye through a long scleral tunnel, without a scleral valve or graft patch.

Methods: We selected 20 eyes of 17 patients with refractory glaucoma. A 6-mm long scleral tunnel was made using a 24-gauge catheter needle. A catheter guided the introduction of the tube. We performed Baerveldt glaucoma implant (BI) and Ahmed glaucoma valve implant (AV) on 10 eyes each. The primary outcome measures included intraocular pressure, supplemental medical therapy score, and intraoperative and post-operative complications.

Results: The mean preoperative intraocular pressure and (medical therapy score) was 29.1 ± 3.8 mmHg (5 (4-7)) and 26.7 ± 2.5 mmHg (5 (4-7)) in the BI and AV group, respectively. The mean postoperative intraocular pressures were 13.3 ± 1.2 mmHg (0 (0-0)) and 18.8 ± 1.3 mmHg (0 (0-1)) and 14.1 ± 1.0 mmHg (0 (0-0)) and 14.0 ± 1.1 mmHg (0 (0-1)) at 1 month and 1 year, respectively. We observed anterior chamber hemorrhage in five cases in each group. Two patients in the AV group had vitreous hemorrhage and underwent surgery. We recorded hypotony of < 5 mmHg in case 2 in the BI group. However, it was absent in the AV group. Malignant glaucoma occurred in one case in the BI group. Tube exposure and corneal erosion were absent.

Conclusion: The catheter needle successfully guided the drainage tube into the anterior chamber. The outcomes were comparable to previous reports on glaucoma implant surgery. A long scleral tunnel can be an alternative for scleral valves and graft patches.

***Keywords:** Baerveldt Glaucoma Implant; Ahmed Glaucoma Valve Implant; Long Scleral Tunnel; Scleral Valve; Graft Patch*

Abbreviations

BI: Baerveldt Glaucoma Implant; AV: Ahmed Glaucoma Valve Implant; IOP: Intraocular Pressure; ASOCT: Anterior Segment Optical Coherence Tomography

Introduction

Glaucoma is a chronic optic neuropathy and a leading cause of vision loss. The number of people with glaucoma is expected to increase to approximately 111.8 million by 2040 [1]. Lowering the intraocular pressure (IOP) is the only treatment modality [2]. Tube-shunt surgery is one of the treatments with an efficacy no less than that of trabeculectomy. The latter is the gold standard for glaucoma surgery [2,3]. However, there are some complications of tube-shunt surgery, with tube erosion being a major concern [3,4]. Scleral valve and patch grafts are commonly used to prevent such complications. Nonetheless, their application takes time and effort. We contrived the technique of inserting the tube inside the scleral tunnel using a 24-G catheter needle of which the size of the outer sheath is the same as that of the tube. Eventually, a scleral valve or graft patch would not be required. We previously reported on the effectiveness of introducing the tube into the vitreous cavity in patients with neovascular glaucoma [5]. Therefore, this technique could be applied to anterior chamber tube shunt surgery.

Aim of the Study

In addition, we aimed to differentiate between Baerveldt glaucoma implant (BI) and Ahmed glaucoma valve implant (AV). The purpose of this study was to evaluate the 1-year outcomes of anterior chamber tube shunt surgery using the aforementioned scleral tunnel method.

Materials and Methods

This study was a hospital-based, single-center case series. We obtained written informed consent from each patient for the original surgery. The procedures used were approved by the Ethics Committee of the Osaka Red Cross Hospital. The study adhered to the tenets of the Declaration of Helsinki and registered in UMIN Clinical Trials Registry (UMIN000042976).

Patients

We recruited patients with primary or secondary refractory glaucoma. Twenty eyes of 17 patients underwent BI or AV implantation at the Osaka Red Cross Hospital between October 2018 and April 2019. Baerveldt implantation and Ahmed valve implantation were conducted on 10 eyes each. All patients underwent comprehensive ophthalmologic examinations prior to surgery. Furthermore, they underwent medical check-ups for 1 year post-surgery.

Primary outcome measures

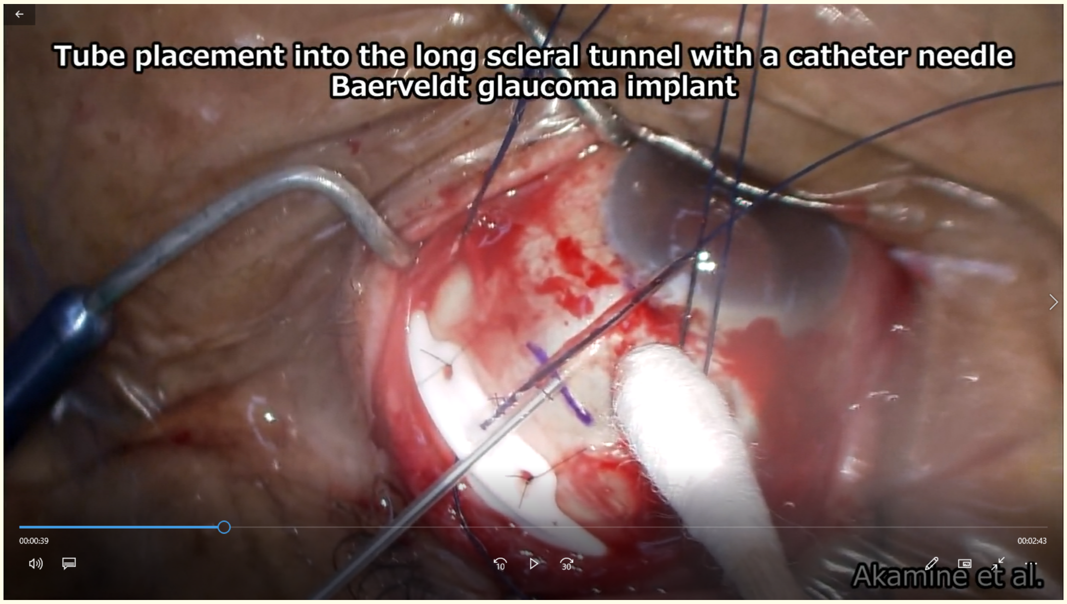
We measured IOP before surgery and at 1, 2, 3, 6, 9 and 12 months post-surgery. The medical therapy was scored as follows: 1 point for one type of glaucoma eye drop, 2 points for combination eye drops, and 2 points for oral acetazolamide. Following the surgery, we used a gonioscope to check the site of the tube. We measured the distance between the tube and the cornea using anterior segment optical coherence tomography (ASOCT). Moreover, we recorded the pre- and postsurgical complications.

Statistical analysis

On the basis of previous report [3], we assumed that 13.0mmHg reduction of IOP and 1.9 reduction of medical therapy score would be expected after either BI or AV implantation. 4 and 6 patients each would be needed to establish the superiority of the test with 80% power at a 5% two-sided significance level. To verify that the data are consistent with a normal distribution, Kolmogorov-Smirnov test was performed. For those which have normal distribution, we conducted a paired t-test for the comparison between before and after surgery and an unpaired t-test for the comparison between two groups. For those which doesn't have normal distribution, we conducted Wilcoxon signed-rank test for the comparison between before and after surgery and Mann-Whitney U test for the comparison between two groups. EZR (Easy R) was used for the statistical analysis [6]. The statistical significance was set up at $P < 0.05$.

Surgical technique

The supplementary material (Video 1) summarizes the procedures used.



Video 1

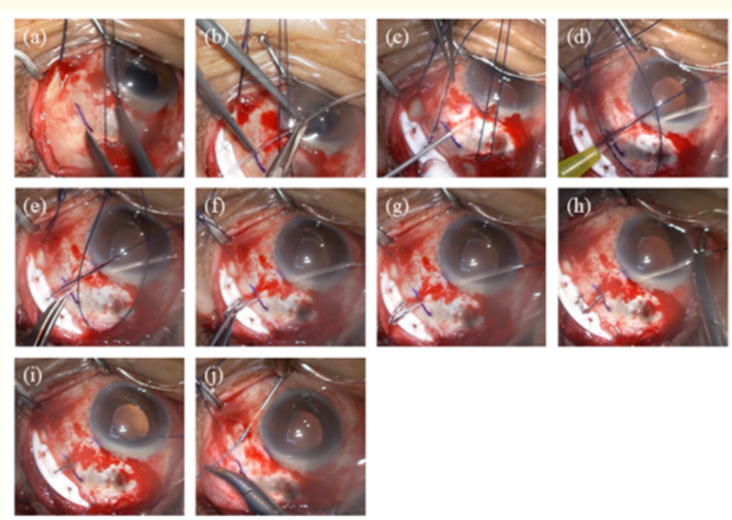


Figure 1: *Surgical procedure of tube placement inside the anterior chamber; (a) Scleral surface was marked at 6 mm from the limbus; (b) The tube of proper length has been cut; (c) A scleral tunnel has been made using the 24-G catheter; (d) The catheter reaches the anterior chamber and outside the eye next; (e) The rear end of the catheter has been removed, and the catheter has been slit; (f) The tip of the tube has been inserted inside the catheter; (g) Insertion of the stent thread and tube inside the catheter; (h) The stent thread and catheter are tightly held together and pulled out; (i) Introduction of the tube inside the anterior chamber; and (j) The end of the stent thread is buried inside the sclera.*

Following a conjunctival incision at the limbus, we secured a wide and bare scleral field, and scleral surface was marked at 6 mm from the limbus (Figure 1a). The BI or AV implantation was set between the external muscles. We fixed them to the sclera using an 8-0 nylon thread and cut the tube at a proper length (Figure 1b). A 6-mm long scleral tunnel was made using a 24-G catheter needle (Figure 1c). We inserted the catheter into the anterior chamber. It was extruded from the anterior chamber using a 25-G needle (Figure 1d). We left the external tube of the catheter and cut off the catheter base. A small slit incision was made using a pair of spring-handled scissors (Figure 1e). The stent thread was inserted into the tube of the BI and then into the left catheter. We used the stent to insert the tip of the tube into the catheter as a guide. After introducing the tip of the tube (Figure 1f and 1g), the catheter was pulled from the other side (Figure 1h). This was followed by the insertion of the tube inside the anterior chamber (Figure 1i). The root of the tube was tied with 6-0 vicryl. We buried the rear end of the stent thread inside the sclera using a 26-G needle in cases that underwent BI (Figure 1j). It was then cut after Tenon's capsule, and the conjunctiva was sutured using absorbable threads. We removed the stent thread on observing a > 20 mmHg increase in the IOP ≥ 2 weeks post-surgery. Nonetheless, the stent thread was not used in cases that underwent AV. All surgeries were performed by one surgeon (MA).

Results

The mean preoperative IOP (medical therapy score) was 29.1 ± 3.8 mmHg (5 (4-7)) and 26.7 ± 2.5 mmHg (5 (4-7)) in the BI and AV group, respectively. The mean postoperative IOPs were 13.3 ± 1.2 mmHg (0 (0-0)) and 18.8 ± 1.3 mmHg (0 (0-1)), 15.2 ± 1.4 mmHg (0 (0-0.75)), and 13.9 ± 1.2 mmHg (0.5 (0-1.75)), 14.0 ± 0.6 mmHg (0 (0-0)) and 13.8 ± 0.9 mmHg (0.5 (0-1)), 13.1 ± 1.0 mmHg (0 (0-0)) and 12.2 ± 1.1 mmHg (0.5 (0-1)), 1, 3, 6, and 9 months, respectively (Figure 2a and 2b). At 12 months, the mean IOP were 14.1 ± 1.0 mmHg (52% reduction, $P < 0.009$) and 14.0 ± 1.1 mmHg (49% reduction, $P < 0.002$). The score showed 98% ($P = 0.008$) and 89% ($P = 0.02$) reduction. There was no significant difference of IOP and score between BI and AV groups one year after surgery ($P = 0.70$ and $P = 0.34$).

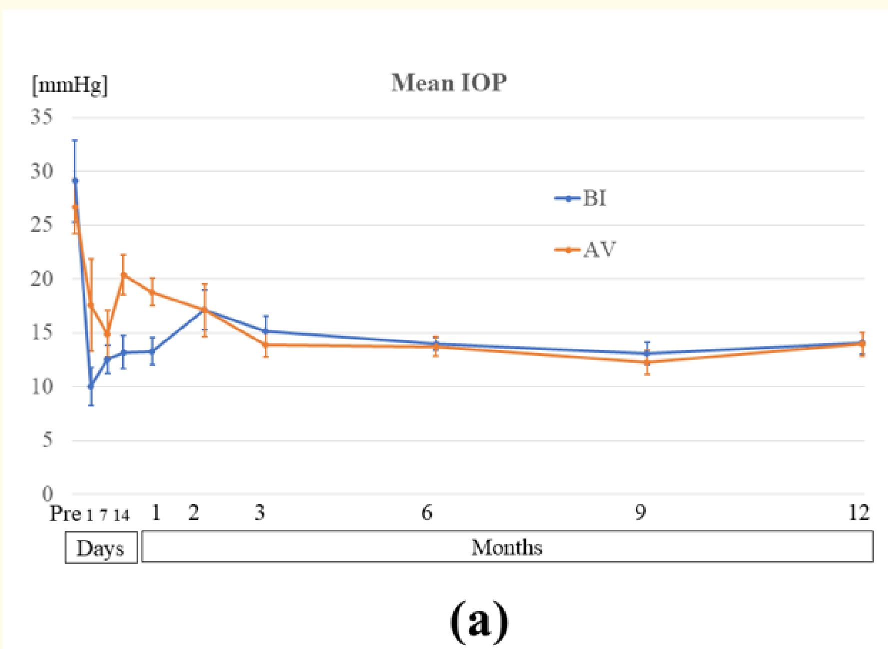


Figure 2a

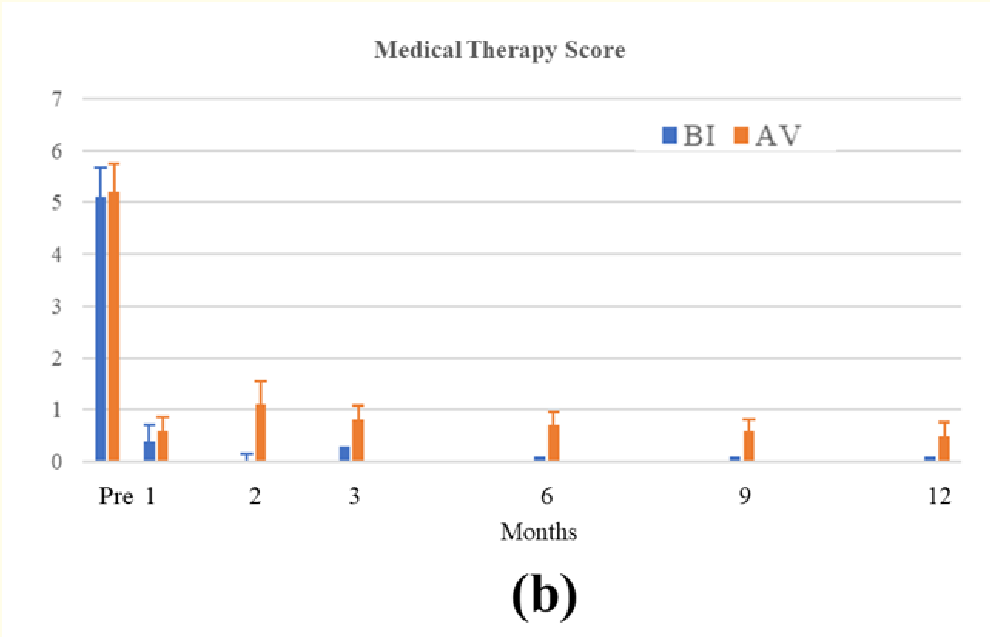


Figure 2b

Figure 2: (a) The mean intraocular pressure of the Baerveldt glaucoma implant (BI) and Ahmed glaucoma valve implant (AV) groups; (b) The medical therapy score of the BI and AV groups.

The current pandemic prevented one patient from meeting us at 12 months. Thus, we excluded his data from the mean IOPs at a particular point.

There were certain postsurgical complications. We observed anterior chamber hemorrhage in five cases in each group. Furthermore, two patients in the AV group had vitreous hemorrhage and underwent surgery. The hemorrhage was self-limiting in the remaining eight cases. Hypotony < 5 mmHg was recorded in case 2 and in one patient in the BI and AV groups, respectively. Malignant glaucoma occurred in one case in the BI group, thus additional vitrectomy was saved. None of the cases had tube exposure and corneal erosion.

We observed diffuse large conjunctival blebs in all cases. Figure 3 comprises the representative images. The number of corneal endothelial cells decreased from 2083 ± 220/mm^2 to 1322 ± 192/mm^2 in average in BI group, and from 1902 ± 73/mm^2 to 1608 ± 174/mm^2 in average in AV group, 12 months postoperatively. The tube exactly went through the trabecular meshwork in four and three cases in the BI and AV groups, respectively. One case in each group passed the anterior border of the meshwork. Four and six cases in the BI and AV groups, respectively, passed behind the meshwork. Furthermore, only one case in the BI group passed ahead of the meshwork, thus increasing the proximity of the tube to the cornea. The ASOCT image and gonioscope findings were similar. The average distance between the tube and the cornea was 0.769 ± 0.22 mm and 0.606 ± 0.16 mm in the BI and AV groups, respectively.

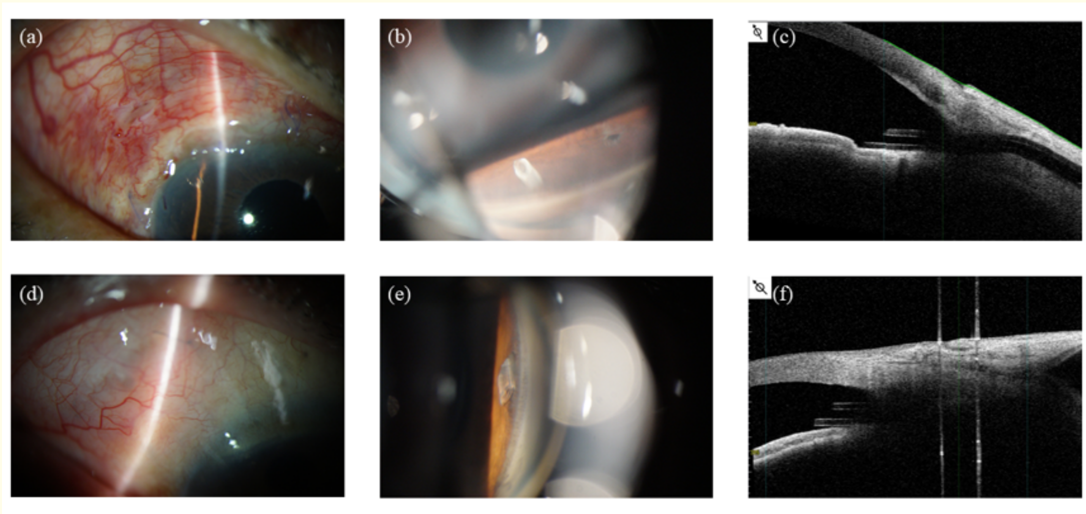


***Figure 3:** (a), (b), and (c) The upper column comprises pictures of patient 3 in the Baerveldt glaucoma implant group; (d), (e) and (f) The lower column comprises pictures of patient 4 in the Ahmed glaucoma valve implant group; (a), (d) No tube exposure on the conjunctival surface; (b), (e) Observation with a gonioscope showing exit of the tube from the iris meshwork; and (c), (f) Anterior segment optical coherence tomography showing exit of the tube went through the iris meshwork.*

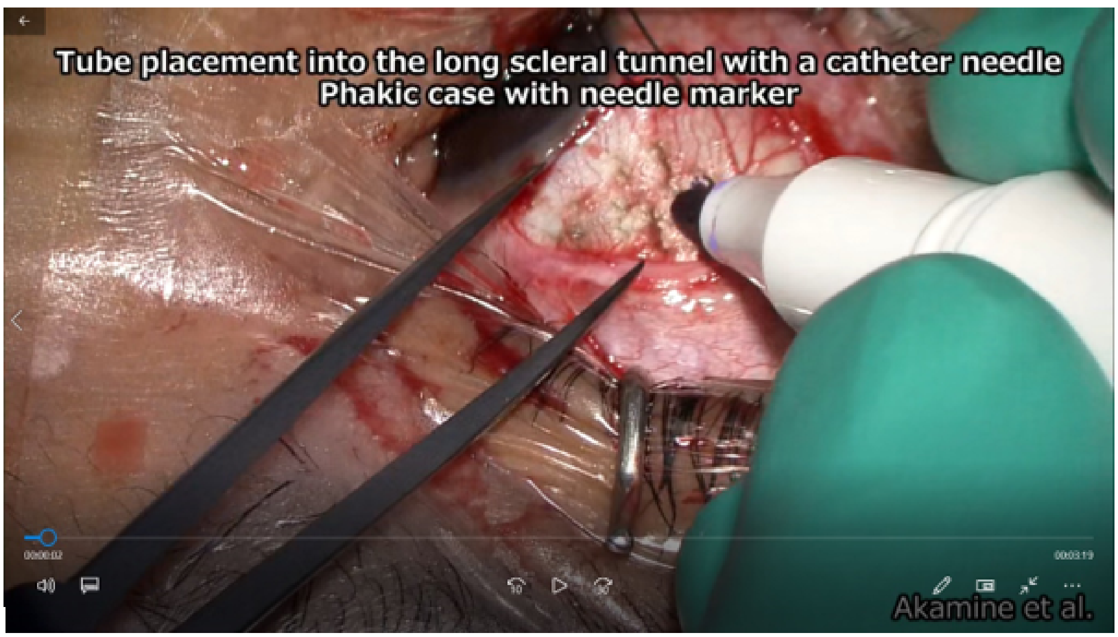
Discussion

We successfully inserted the tube into the anterior chamber through the 6-mm long scleral tunnel, using the catheter needle. The mean IOP change was almost similar to previous reports. In TVT study, for example, the mean preoperative IOP and the score of tube group was 25.1 ± 5.3 mmHg and 3.2 ± 1.1, and the mean postoperative IOP and the score of the group was 12.5 ± 3.9 mmHg and 1.3 ± 1.3 [3]. In other words, the IOP immediately decreased post-surgery in both groups.

Previous studies reported on the method of creating a tunnel without a scleral valve or graft patch. Nonetheless, a slit knife, wider than the tube diameter, was used. Furthermore, there was no report on the use of a catheter tube for making a tunnel [7-11]. Making a long tunnel with a catheter, which has same diameter with the tube, results in less leakage through and around the tube as compared with a tunnel using a crescent knife. This could contribute to shorten the hypotensive period after surgery.

We recorded 5 cases in each group of anterior chamber hemorrhage. The rate of hemorrhage was more frequent than that in previous reports [5]. The procedure used might result in hemorrhage inside the tunnel, compared with other techniques. Unlike creating a scleral flap, we could not cauterize the bleeding vessels inside the tunnel. We also did not cauterize the bleeding vessels in the operation field. This in turn led to hemorrhage reflux inside the tube. Apart from the aforementioned 20 cases, we cauterized the sclera before closure that likely reduced the hemorrhage. However, further research is needed to validate our findings. All three cases with hypotony experienced an anterior chamber hemorrhage. This can be attributed to the impact of hypotony on backflow bleeding. Moreover, the case of malignant glaucoma can be attributed to misleading of aqueous humor. Thus, we performed anterior vitrectomy and posterior capsule incision to prevent this misleading. This was followed by an immediate reduction in the IOP. We did not use a graft patch. However, there was no tube exposure 1-year postoperatively, thus suggesting the patches were no longer needed for the new technique.

Endothelial cell loss is an issue in cases of tube placement into the anterior chamber. Despite the proven mechanism of endothelial damage, this unobvious decrease can be an outcome of the proximity of the tube to the cornea [12,13]. Some surgeons prefer tube insertion into the ciliary sulcus [13-15]. However, we recently modified the insertion technique of the catheter needle to avoid this complication. We marked 2 points; 2 mm and 6 mm away from the limbus. The 8-0 nylon needle was pierced from the 2 mm mark into the anterior chamber. A surgical gonioscope confirmed the passage of the needle head through the posterior trabecular meshwork. We replaced the needle if its position was inappropriate until it was placed at the right position. The catheter needle was inserted into the sclera from the 6 mm mark towards the pierced needle until it started swinging. We subsequently changed the direction of the catheter towards the anterior chamber. The use of the needle as an outer guide of the trabecular meshwork improved the tube placement (Video 2).



Video 2

There are several limitations in our study. First, this research was a single-institution study with a small number of cases, therefore there could be selection bias. Second, we evaluate the 1-year results after operation, thus continuous observation and evaluation are needed. Third, some cases required additional surgical intervention, this may affect the IOP change. Fourth, we couldn't directly compare the outcome with those of the conventional non-tunnel technique. Further studies are required to evaluate the long-term effects of this technique.

Both BI and AV effectively lowered the IOP and decreased the number of medications for patients with glaucoma, without the use of a scleral patch graft or valve. The aforementioned techniques successfully prevented tube exposure 1-year postoperatively. Early postoperative complications are a concern, thus necessitating better prevention techniques.

Conclusion

Both BI and AV effectively lowered the IOP and decreased the number of medications for patients with glaucoma, without the use of a scleral patch graft or valve. The aforementioned techniques successfully prevented tube exposure 1-year postoperatively. Early post-operative complications are a concern, thus necessitating better prevention techniques. Further studies are needed to evaluate the long-term effects of the technique.

Acknowledgements

We would like to thank Editage [http://www.editage.com] for editing and reviewing this manuscript in English language. The 72nd Annual Congress of Japan Clinical Ophthalmology, Kyoto, Japan, October 2019; 2020 ASCRS Virtual Annual Meeting, May 2020; 38th Congress of the ESCRS, October 2020.

Conflict of Interest

M. Akimoto is a consultant at Kowa Co. Ltd. No conflicting relationship exists for any other author.

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Volume 13 Issue 4 April 2022