

Partial thickness cornea tissue from small incision lenticule extraction

A novel patch graft in glaucoma drainage implant surgery

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Abstract

Objective: The aim of the present study was to observe the feasibility and effect of cornea slice acquired from femtosecond laser surgery, small incision lenticule extraction (SMILE) as patch graft for the prevention of drainage tube exposure and to compare with the sclera.

Methods: The research is a prospective comparative randomized study. Patients who received Ahmed glaucoma valve implantation surgery from August 2015 to January 2017 at the Xiamen Eye Center were randomly divided into 2 groups. Group A (corneal group) included 131 cases (135 eyes), receiving the 3 layers of allogeneic cornea slices as graft. Group B (scleral group) included 124 cases (127 eyes), using the sclera as allograft. The appearance, graft, conjunctiva melting, and tube exposure were the primary observation points.

Results: After followed up for 6 to 20 months, a thinner appearance was seen in 3 eyes (2.2%) in the corneal graft group and 7 eyes (5.5%) in the scleral group. Conjunctiva melted and drainage tube exposed in 0 eyes (0%) in the corneal graft group and 2 eyes (1.6%) in the scleral group. One eye needed repair surgery. There was no statistical difference between the 2 groups ($P > .05$). After surgery, the intraocular pressure was reduced significantly in both groups ($P < .05$). The white sclera slice could be seen under the conjunctiva, thereby affecting the cosmetic appearance.

Conclusion: The cornea slice acquired from SMILE surgery can effectively prevent drainage tube exposure. Moreover, it is easy to acquire, safe, and cheaper, giving the patient a better cosmetic appearance.

Abbreviations: AS-OCT = anterior segment optical coherence tomography, BCVA = best-corrected visual acuity, IOP = intraocular pressure, NVG = neovascular glaucoma, SMILE = small incision lenticule extraction.

Keywords: Ahmed glaucoma valve implantation surgery, cornea slice, tube exposure

1. Introduction

With the gradual increase in the number of patients with refractory glaucoma, drainage implant surgery has become a more frequently performed clinical procedure. In some hospitals, this surgery has become a primary select for the treatment of glaucoma.^[1] Drainage tube exposure is a major complication of drainage implant surgery. The exposure site is generally located within 6 mm of the limbus.^[2] To prevent drainage tube exposure, a layer of patch graft is usually used to cover the drainage tube. Some surgeons use an autologous lamellar scleral flap, and others

use allogeneic materials. However, when and if the autologous sclera flap melts, especially when the inner sclera is eroded, the eyes will be at a higher risk of development of endophthalmitis.^[3,4] Therefore, the use of allogeneic graft during surgery is still the preferred approach.^[5] Freedman successfully used glycerol-preserved allograft sclera to cover the anterior drainage tube in 1987.^[6] Brandt used the dura as a drainage tube graft material in 1993.^[7] Subsequently, a variety of materials have been used, such as the sclera, pericardium, dura, amniotic membrane, and femoral fascia.^[8–12] Each material has its own advantages and disadvantages (Table 1).^[13,14] Thus far, there is no consensus on which material is the best choice for the prevention of drainage tube exposure.

Donor cornea tissue has been used in tube shunt coverage in recent years.^[5,15–21] Its tight structure makes the cornea unlikely to melt. Moreover, the cornea tissue has the advantage of aesthetics (especially when it is placed at the bottom).^[5,16,20,22] However, because of the lack of cornea sources, especially in China, allograft corneal materials for corneal transplantation are scarce and expensive, thereby making it difficult to use cornea as a graft material in glaucoma drainage implant surgery.

Small incision lenticule extraction (SMILE) is a new type of femtosecond laser for the treatment of myopia. In this surgery, a lens-like partial thickness corneal slice is excised by laser. The slice is then removed through a small incision. This corneal slice has a diameter of approximately 7 mm and a thickness of 100 to 150 μm . We used 3 layers of this cornea slice as the patch graft and observed its effect for the prevention of drainage tube

Editor: Jui-Yang Lai.

This study was supported by Xiamen Science and Technology Project (no: 3502Z20154029).

The authors have no conflicts of interest to disclose.

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Medicine (2019) 98:9(e14500)

Received: 8 June 2018 / Received in final form: 6 January 2019 / Accepted: 20 January 2019

<http://dx.doi.org/10.1097/MD.0000000000014500>

Table 1**Advantages and disadvantages of sclera, dura, pericardium and allogeneic cornea.**

| Advantages | Disadvantages |
|---|--|
| <i>Sclera</i> | |
| 1. Most affordable | 1. Can be of variable quality |
| | 2. May need thinning (to prevent Dellen) |
| | 3. No guarantee of sterility |
| | 4. Variably available on an urgent basis secondary to limited shelf life |
| | 5. Could be seen through the conjunctiva after surgery |
| <i>Dura</i> | |
| 1. Longest track record of Use among nonscleral Patch materials | 1. Most expensive material |
| 2. Sterile | |
| 3. Shelf life \pm 5 yr | |
| 4. Easily handled | |
| <i>Pericardium</i> | |
| 1. Not as costly as Dura | 1. Shorter track record of use vs Dura |
| 2. Sterile | 2. Somewhat variable thickness |
| 3. Shelf life \pm 5 years | |
| 4. Easily handled | |
| <i>Allogeneic cornea</i> | |
| 1. A better cosmetic appearance vs sclera | 1. Difficult to obtain |
| | 2. Somewhat variable thickness |

exposure and the impact on cosmetic appearance. We also compared the cornea slice with the sclera to determine whether the former is a better choice as a patch graft.

2. Patients and methods

2.1. Patients

This study was a prospective randomized study. It followed the tenets of the Declaration of Helsinki and was approved by the ethics committee of the Xiamen Eye Center. Patients who received Ahmed glaucoma valve (New World Medical, Inc, Rancho Cucamonga, CA) implantation surgery from August 2015 to January 2017 at the Xiamen Eye Center were observed.

The patients were randomly divided into 2 groups. Group A (corneal group) included 131 cases (135 eyes), receiving 3 layers of allogeneic cornea slice acquired from the SMILE surgery as a graft. While group B (scleral group) included 124 cases (127 eyes), using the sclera as allograft. There were no statistically significant differences in age, gender, visual acuity, intraocular pressure (IOP) before surgery, type of glaucoma, and site of implantation (Table 2).

2.2. Preparation of sclera allograft from donor eye

Written consents to freely offer their eyeballs were obtained from the donors. Blood examination was conducted for all donors to exclude infectious diseases. The sclera was separated from other tissues after the cornea was cut from fresh eye for keratoplasty, and it was rinsed several times with saline solution and tobramycin. The sclera was then trimmed to many small pieces of about $6 \times 8 \text{ mm}^2$ size with a thickness of 350 to 600 μm and placed in sterile anhydrous glycerol for storage at 4°C. At the time of surgery, the sclera piece was rinsed with balanced salt solution under sterile conditions and soaked in tobramycin diluent for rehydration. After rinsing again with balanced salt solution, the sclera was covered on the drainage tube.

Table 2**Demographic and clinical data.**

| | Corneal group | Scleral group |
|---|--------------------|--------------------|
| Cases | 131 (135 eyes) | 124 (127 eyes) |
| Gender (male:female) | 69:62 | 65:59 |
| Age, yr | 58.3 | 59.1 |
| Range | 5–77 | 7–76 |
| BCVA | LP-0.5 | HM-0.4 |
| IOP, mm Hg | 36.1 ± 9.7 | 35.9 ± 10.4 |
| Glaucoma medications | 3.7 ± 1.54 | 3.7 ± 1.47 |
| Glaucoma type (eyes) | | |
| NVG | 26 cases (29 eyes) | 22 cases (24 eyes) |
| Intravitreal injection (Lusentis) | 23 cases (25 eyes) | 21 cases (23 eyes) |
| Hyphema | 6 | 6 |
| After trauma surgery | 25 cases (25 eyes) | 22 cases (22 eyes) |
| After vitrectomy | 31 cases (32 eyes) | 33 cases (33 eyes) |
| After glaucoma surgery | 36 cases (36 eyes) | 35 cases (36 eyes) |
| Others | 13 cases (13 eyes) | 12 cases (12 eyes) |
| Operation site (superotemporal:infratemporal) | 111:24 | 106:21 |

All $P > .05$.

BCVA=best-correct visual acuity, IOP=intraocular pressure, NVG=neovascular glaucoma.

2.3. Preparation of corneal allograft from SMILE surgery

Written consent to freely offer their corneal slices was obtained from the patients. Blood examination was conducted to exclude infectious diseases. The corneal slices obtained from SMILE surgery were immediately placed in sterile anhydrous glycerol and stored at 4°C. The slices were removed from the glycerol and washed with balanced salt solution during surgery. After rehydration with the tobramycin diluent, the corneal slices were rinsed again with balanced salt solution and applied to cover the drainage tube.

2.4. Surgical technique

All FP7 Ahmed glaucoma valve tubes were implanted through a fornix-based conjunctiva incision with the plate secured 10mm from the limbus. The tube was inserted into the anterior chamber through a scleral track posterior to the limbus by using a 23-gauge needle. Then, the 3 layers of corneal slice taken from SMILE surgery or sclera graft was used to cover the anterior tube and fixed with 10-0 nylon suture. The surgeries were conducted by the same doctor.

2.5. Statistical analysis

All the data were recorded on Microsoft Excel spreadsheets. Student t test was used to compare mean age, gender, best-corrected visual acuity (BCVA), IOP, and other patient characteristics. Chi-squared test was used to compare type of glaucoma, implantation site, and rate of exposure. Significance was set at the 5% level. Statistical analysis was performed with SPSS software V.22 (SPSS, Inc, Chicago, IL).

3. Results

3.1. Patient information

There were no statistically significant differences in age, gender, visual acuity, IOP before operation, type of glaucoma, and site of implantation (Table 2). Eyes that had traumatic injury and had undergone vitrectomy were classified as vitrectomy, and eyes

Table 3
Postoperative data.

| | Corneal group | Scleral group |
|------------------------|---------------|---------------|
| Follow-up (months) | 15.2±5.6 | 14.9±4.8 |
| IOP (mmHg) | 15.6±7.3 | 16.4±5.5 |
| BCVA | NLP-0.6 | NLP-0.5 |
| Glaucoma medications | 0.8±0.5 | 0.9±0.7 |
| Graft thinner (eyes) | 3 (2.2%) | 7 (5.5%) |
| Tube exposure (eyes) | 0 (0%) | 2 (1.6%) |
| Plate exposure (eyes) | 0 (0%) | 0 (0%) |
| Repair surgery (eyes) | 0 (0%) | 1 (0.8%) |
| Endophthalmitis (eyes) | 0 (0%) | 0 (0%) |

All $P > .05$.

IOP=intraocular pressure, BCVA=best-correct visual acuity.

with neovascular glaucoma after vitrectomy were classified as neovascular glaucoma. Other categories included iridocorneal endothelial syndrome, Axenfeld–Rieger syndrome, and congenital aniridia. Most of the patients with neovascular glaucoma received anterior chamber and/or intravitreal injection of ranibizumab (lucentis) 0.05 mL 3 days before the drainage valve implantation. Some patients with neovascular glaucoma had hyphema before surgery.

3.2. Clinical efficacy

The patients were followed up for 6 to 20 months (Table 3). The visual acuity, IOP, the anterior chamber, the cornea or sclera graft, the conjunctiva, the drainage tube, and the drainage plate were observed. After surgery, the IOP was significantly reduced in both groups compared with presurgery (cornea group: 36.1 ± 9.7 mm Hg vs 15.6 ± 7.3 mm Hg; sclera group: 35.9 ± 10.4 mm Hg vs 16.4 ± 5.5 mm Hg) (Fig. 1). However, there was no significant difference between the 2 groups. The visual acuity showed no difference before and after surgery.

The white sclera slice was observed in the surgical area under the conjunctiva (Fig. 2A). Moreover, the scleral graft was often

exposed to the palpebral fissure area with eye rotation, thereby affecting the cosmetic appearance, but the corneal graft did not affect the appearance of the eye as can be seen in Figure 2B. Under the conjunctiva in slit lamp examination, the Ahmed valve coverage by sclera, transparent corneal film was observed (Fig. 2B).

3.3. Image examination

The cornea and sclera graft on the tube were detected by anterior segment optical coherence tomography (AS-OCT) (Fig. 3). With the progression in time, the corneal graft was not very transparent like that before showed in the AS-OCT image (Fig. 3C). But it was still lucid under slit lamp. A thinner appearance of $<150 \mu\text{m}$ as measured by AS-OC was seen in 3 eyes (2.2%) in the corneal graft group and 7 eyes (5.5%) in the scleral group, which the sutures fixing shunt tube to the eye could be seen through sclera graft. No significant difference was found between the 2 groups ($P > .05$). No eye encountered conjunctiva melting or drainage tube exposing in the corneal graft group. Conjunctiva melted and the drainage tube was exposed in 2 eyes (1.6%). One eye was secondary glaucoma after congenital cataract surgery, and had a larger eyeball. The other had traumatic cataract and vitreous surgery, and the plate was placed infratemporally. The exposure time was 4 and 7 months after glaucoma surgery. Exposure range was 0.5 to 3 mm (Fig. 4). A small hole conjunctiva melt in 1 eye was cured after treatment to rejuvenate the epithelium. The other eye required surgical repair. Allogenic sclera graft and autologous conjunctiva transplant were performed. Sclera graft rapidly melted and became thinner again after repair surgery. But the drainage tube was not re-exposed.

3.4. Recurrence and other complications

During surgery, hyphema was observed in 4 eyes (3.0%) in the cornea group and 4 eyes (3.2%) in the scleral graft group (Table 4). Postsurgery complications include shallow anterior chamber and choroid detachment. Shallow anterior chamber

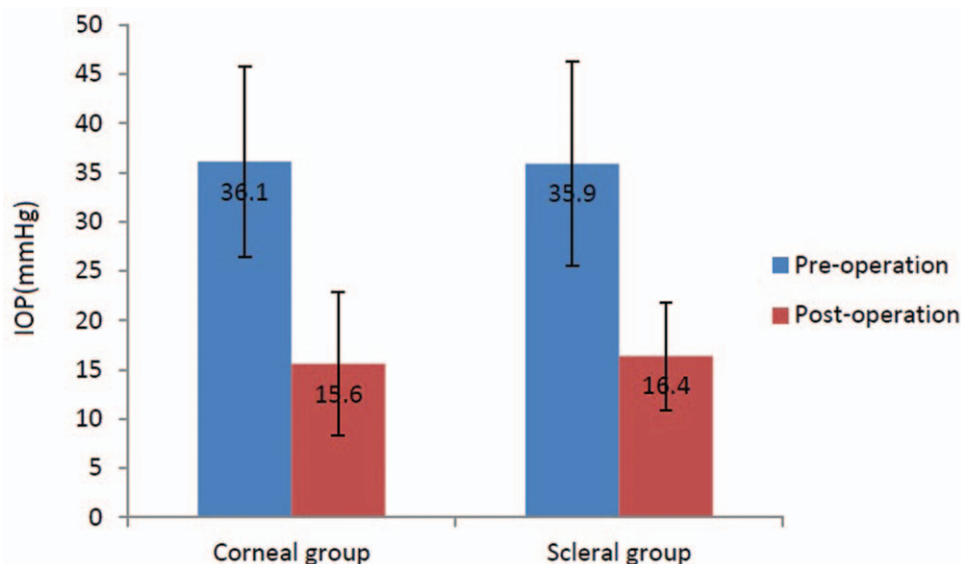


Figure 1. Preoperation and postoperation intraocular pressure (IOP).

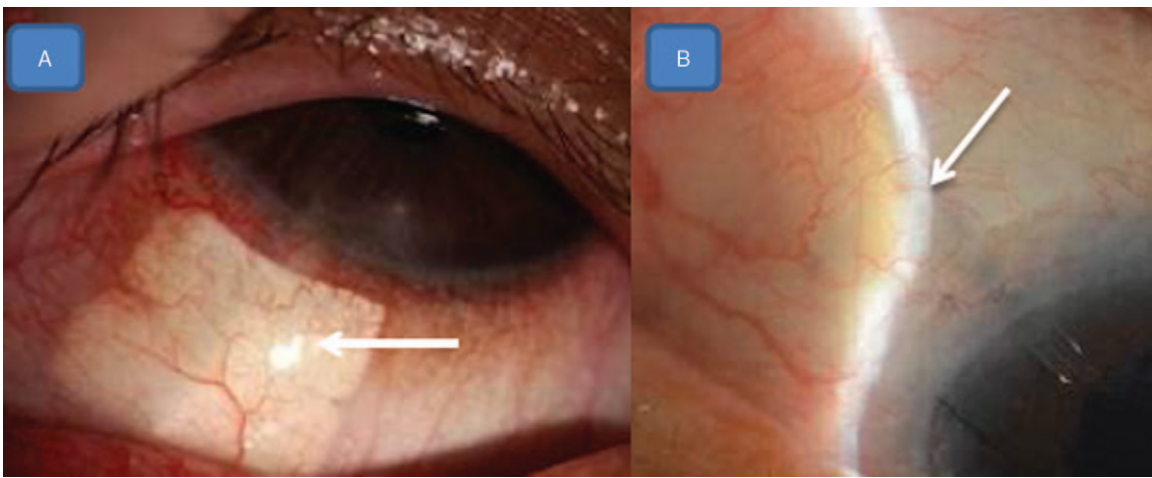


Figure 2. (A) White scleral patch under the conjunctiva. (B) The tube could be seen clearly through the transparent cornea patch.

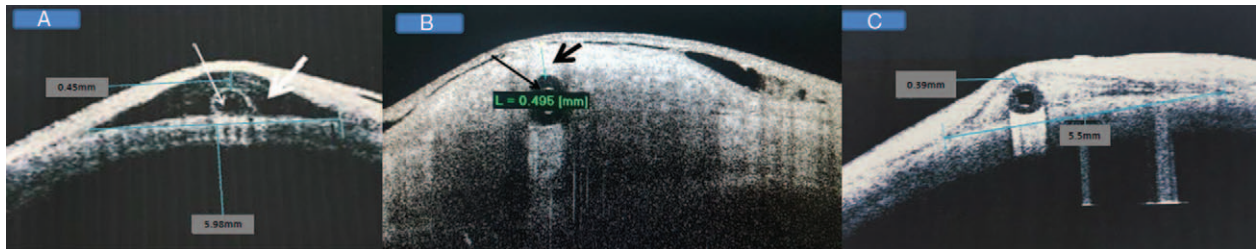


Figure 3. (A) Anterior segment optical coherence tomography (AS-OCT) shows the corneal graft on the tube 1 month after the surgery. Thick arrow shows the corneal slice. The thickness of the corneal slice is 0.45 mm. The thin arrow shows the tube. (B) AS-OCT shows the scleral graft on the tube. Thick arrow shows the sclera and the thickness of the sclera is 0.495 mm. The thin arrow shows the tube. (C) AS-OCT showed the cornea patch on the tube 1 year after surgery. The corneal graft was not very transparent like before. The 3-layer structure was obvious. But slit examination showed the corneal graft was still transparent.

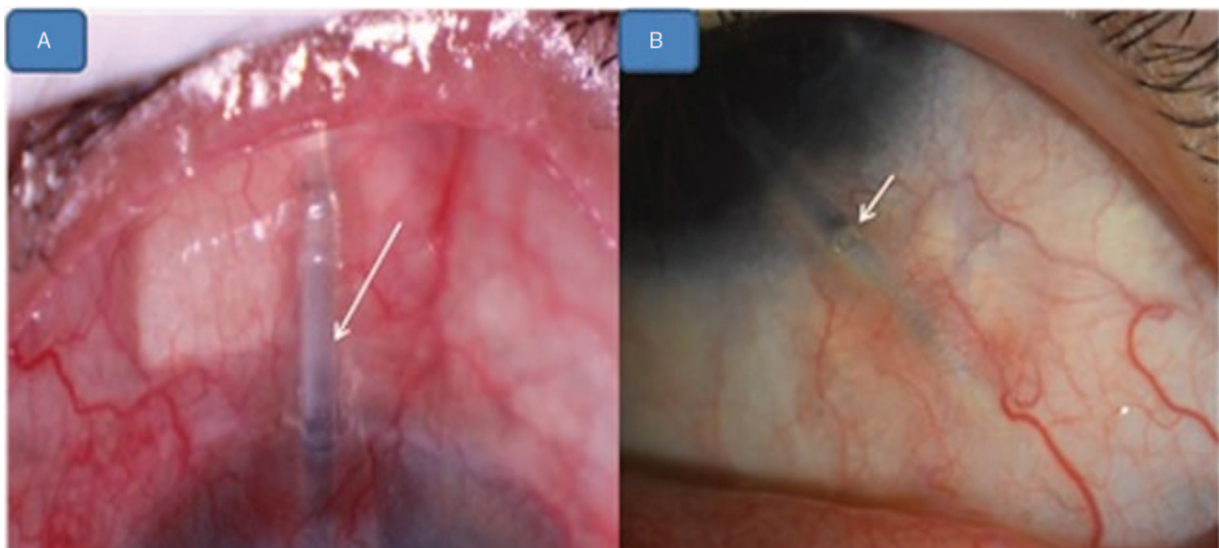


Figure 4. The patch graft and conjunctiva melt in two cases in scleral group. (A) shows the exposure range was 0.5 to 3 mm near the limbus, (B) shows the other exposure case in the scleral group, a small hole conjunctiva melt as the arrow point out in B.

| | Corneal group | Scleral group |
|--------------------------|---------------|---------------|
| During surgery | | |
| Hyphema | 4 (3.0%) | 4 (3.2%) |
| Postsurgery | | |
| Shallow anterior chamber | 7 (5.2%) | 6 (4.7%) |
| Choroid detachment | 9 (6.7%) | 10 (7.9%) |
| Further surgery | | |
| Cataract | 4 (3.0%) | 3 (2.4%) |
| Vitrectomy | 2 (1.5%) | 3 (2.4%) |
| Glaucoma surgery | 0 (0%) | 0 (0%) |

All $P > .05$.

occurred in 7 eyes (5.2%) in the cornea group and 6 eyes in the scleral group. Choroid detachment occurred in 9 eyes (6.7%) in the cornea group and 10 eyes (7.9%) in the scleral group. There was no statistical difference between the 2 groups ($P > .05$).

4. Discussion

In this study, we observed the feasibility and effect of corneal slice acquired from SMILE surgery to prevent tube exposure in glaucoma drainage valve surgery and compared the method with the use of allogeneic sclera graft. The ideal graft should be long enough to cover the tube from the limbus to the drainage plate. However, in clinic practice the drainage valve tube exposure site is usually located within 1 to 6 mm from the limbus. A possible reason is that this area has thin Tenon fascia tissue and may be more easily affected by eyelid or pressure friction. Thus the graft is usually 6 to 8 mm in length and needs to cover the anterior tube, especially the site where the tube penetrates into the tunnel to the anterior chamber (Fig. 2). The diameter of the corneal slice used in this study is approximately 7 mm and can completely cover the anterior part of the tube that is more easily exposed. The thickness of the cornea graft is 100 to 150 μm . To achieve an adequate thickness, 3 layers of corneal slices were overlaid during the operation. AS-OCT showed that the entire thickness of the 3 corneal slices is about 300 to 450 μm (Fig. 3A), which is not thinner than lamellar corneal grafts used by other investigators.^[5,17]

In this study, we observed that the corneal slice taken from SMILE surgery could be used as an effective patch graft in drainage valve implant surgery. No drainage valve tube exposure occurred. In the sclera group, the tube was exposed in 2 eyes (Table 3). It has been reported that the rate of drainage tube exposure or drainage plate prolapse is 2% to 30.5%.^[23-27] Spierer used a partially thick cornea as the graft in drainage valve surgery in 45 eyes. Follow-up was done for an average of 27 months and showed good long-term results, corneal graft melting occurred in 3 eyes (6.7%), and tube exposure and additional surgery to repatch or suture the conjunctiva over the tube was required in 1 eye (2.2%).^[5] However, when 3 layers of corneal slices were used as the patch graft, there was no tube exposure in our study. Because the corneal graft is transparent, it is difficult to determine whether the corneal graft is melting or is thinner by using the slit lamp examination. The AC-OCT was used to measure the thickness of the graft. The corneal graft was considered to be thinner if the thickness of the corneal graft is $<150 \mu\text{m}$. In the sclera group, the criterion of thinner graft is that the suture fixing tube to the sclera can be seen through the slit lamp examination.^[14] In our study, 3 eyes became thinner in the

cornea group and 7 eyes (5.5%) in the scleral graft group (Table 2). Immune-mediated processes and eyelid mechanical pressure or friction are considered to be potential factors for graft and conjunctiva melting and drainage valve duct exposure.^[14] In our study, exposure in the scleral group occurred in 1 case with secondary glaucoma after congenital cataract surgery, and with a larger eye ball. The other patient had traumatic cataract and vitreous surgery, and the plate was placed infratemporally. This patient also had diabetes mellitus. The allogeneic scleral graft also rapidly melted after repair surgery, but no tube exposure occurred. In Ekici study, 169 eyes undergoing drainage valve surgery were observed. The graft was partial thickness cornea and the mean follow-up time was 4.8 months. Tube exposure was found in 3 eyes (1.8%), and 2 of them had allergic conjunctivitis.^[17] Spierer's study reported 4 cases of tube exposure, with 1 of them having uveitis.^[5] In addition, patients who have had multiple operations, those with an inferior implantation, those with trauma, those who have diabetes, and children are also considered to be more prone to tube exposure.^[24,28-32]

Biocompatibility, availability, immunologic safety, storage conditions, ease of use, cost, comfort, and aesthetics need to be considered in the selection of the graft material.^[20] There are various kinds of graft materials that are currently being used. However, the sclera will affect the overall aesthetic, the pericardium melts easily, while the dura is too expensive.^[14] Corneal allograft has many advantages over other materials.^[12,16,20,22,33] The cornea is structurally tight and hard, and thus does not easily melt. Moreover, the translucency of the cornea gives the patient's eye a better cosmetic appearance, especially when the surgical site is at the inferior conjunctiva. We can clearly observe the drainage tube running through the transparent cornea and find displacement, distortion, and other abnormalities of the drainage tube. Some surgeons temporarily ligate the drainage tube to prevent too much drainage in the early postoperative period. Through the transparent cornea, the laser lysis of suture can easily be performed when needed. However, allogeneic cornea is very expensive (about \$3000 in China) and unfortunately, it is difficult to obtain enough corneal grafts to meet the clinical needs. Even in many developed countries, the number still falls far short of the required number to satisfy the demands. In our study, we obtained the corneal graft from SMILE myopia laser surgery and the total thickness of the graft was similar to that used by other scholars. Our hospital has an eye bank to handle and store corneal grafts. Obtaining, storing, and implantation of the graft are done under sterile conditions. There are approximately 3000 SMILE surgeries performed per year in our hospital. Therefore, the corneal graft is easy to obtain and the cost was cheap. The 3 layers of corneal slices used in our surgery cost only about \$70. Therefore, the corneal slice obtained from SMILE surgery is the most affordable material in our area (vs \$150 for allogeneic sclera, and \$700 for pericardium and dura, respectively). Moreover, we can also support other hospitals. The prices of grafts in the United States are \$150 for sclera and \$250 for pericardium and dura, respectively.^[14] Cornea is a little more expensive. In this study, there was no infection, no rejection in the corneal graft, suggesting that it is safe, easy to obtain and effective. Since the SMILE surgery has now more and more been carried out, this surgery can be performed on a large scale. This cornea slice has also been used to repair small defect of cornea and sclera.^[34]

In conclusion, the corneal graft acquired from SMILE surgery can effectively prevent drainage tube exposure. Moreover, it is easy to obtain and is cheaper, and it gives a better cosmetic

appearance to the patient's eye. This study is a prospective controlled study. All surgeries were performed by 1 doctor, and the procedure is the same for all patients, thereby making the results referable. However, the follow-up time of our study was relatively short, with an average of 12 months. The ultrastructural and biomechanical changes of the partial-thickness corneal tissue and sclera during the process are unclear. These properties will determine the long-term effectiveness of the allogeneic graft during surgery. We need future studies to assess long-term effectiveness of the corneal slice acquired from SMILE surgery.

Author contributions

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