· Clinical Research ·

Treatment of superficial corneal opacities with corneal stromal lenticule obtained through SMILE surgery

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Abstract
● **AIM:** To evaluate the clinical efficacy and feasibility of superficial corneal opacities treated by excimer laser phototherapeutic keratectomy (PTK) combined with small incision lenticule extraction (SMILE)-derived corneal stromal lenticule transplantation.
● **METHODS:** A retrospective interventional case series of nine patients aged 12–59y with superficial corneal opacity caused by different pathologies who underwent standardized PTK combined with SMILE-derived corneal stromal lenticule transplantation was examined. Lenticule patches were fixed with fibrin glue. All patients underwent pre- and post-operative clinical assessments at different times for up to 12mo. Slit lamp microscopy, corneal density, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and anterior segment optical coherence tomography (AS-OCT) were examined.
● **RESULTS:** The patients' mean age was 36.00±5.80 (12–59)y. Seven eyes (77.8%) gained UDVA and CDVA at the last measurement compared to their preoperative levels. The densities of the total cornea, the total anterior corneal layer, and the anterior corneal layers of 0–2 and 2–6 mm decreased significantly by 12.4%, 27.5%, 46.7%, and 32.8%, respectively. After human allogeneic transplantation, the implanted lenticules of all eyes were clearly visible by AS-OCT and remained transparent without displacement or graft rejection. The thickness of the central cornea and corneal lenticule transplants were stable throughout the entire postoperative period. One case experienced the postoperative complication of delayed corneal epithelial healing.
● **CONCLUSION:** PTK combined with SMILE-derived corneal lenticule transplantation improves long-term visual acuity. Therefore, it is a new, safe, and effective method for treating superficial corneal opacity.
● **KEYWORDS:** corneal opacity; corneal lenticule; transplant; phototherapeutic keratectomy
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INTRODUCTION
Corneal opacity is a common clinical condition arising from various etiologies, including trauma, corneal edema, corneal dystrophies, corneal degenerations, trachoma, and other corneal infections[1-2]. The traditional treatment for corneal opacities is penetrating or lamellar keratoplasty. However, these procedures may lead to various complications, including severe astigmatism, postoperative infection, keratitis, and host-corneal rejection, years after the procedure[3-5]. Moreover, over half of patients globally cannot receive transplants due to the severe shortage of corneal donors[6-7].
Excimer laser phototherapeutic keratectomy (PTK) has been widely used to treat corneal diseases such as scarring, dystrophies, degenerations, and recurrent corneal erosions for over 30y due to its excellent controllability, smoothness, and safety[8-9]. However, the recurrence of the original corneal disease and hyperopic shift have been reported after PTK[8,10-11]. Therefore, there is an urgent need to explore new, safer methods to effectively improve corneal transparency without causing hyperopic shift in patients.
Small incision lenticule extraction (SMILE) using a femtosecond laser is a relatively new technique for correcting myopia and

Table 1 Patients' clinical features

No.	Age (y)	Sex	Corneal diseases	Eye	Complications
1	57	Male	Band-shaped keratopathy	Right	No
2	12	Female	Band-shaped keratopathy	Left	No
3	44	Male	Corneal dystrophy	Right	No
4	22	Male	Corneal dystrophy	Right	No
5	34	Female	Corneal opacity	Right	No
6	40	Male	Corneal dystrophy	Left	No
7	38	Female	Corneal opacity	Left	No
8	59	Male	Corneal dystrophy	Right	Delayed corneal epithelization
9	18	Female	Corneal opacity	Left	No

myopic astigmatism that was first used in 2008. Since its introduction, its safety, effectiveness, minimal invasiveness, and predictability have been widely reported[12-13]. Since the corneal stromal lenticules created by SMILE surgery have good transparency and retain the original corneal stromal collagen fiber arrangement order, they can be reused as a viable alternative to human donor corneal tissue for transplantation[14-16]. Previous studies have transplanted corneal stromal lenticules from SMILE surgeries into patients with progressive keratoconus without implant rejection after surgery[17-18].

Corneal stromal lenticules have been used to correct hyperopia, to treat presbyopia[19-21], and as corneal grafts to treat corneal diseases such as corneal dermoid[22]. However, these lenticules likely have more applications in corneal diseases. Therefore, in this study, we report using porcine fibrin adhesive to transplant corneal lenticules created by SMILE surgery into nine patients with corneal opacities after excimer laser PTK and discuss the safety and clinical efficacy of this procedure.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved by the Ethics Committee of Hainan Eye Hospital of Zhongshan Ophthalmic Center (Sun Yat-sen University, China; ethics acceptance number: 2023-038-01, trial registration number: ChiCTR2400083499), and followed the ethical guidelines of the Declaration of Helsinki. Corneal lenticule donor patients underwent routine SMILE surgeries. Donor and recipient patients were fully informed, and written informed consents were obtained from all patients or their guardians after the nature of the study and its potential risks were explained to them.

Participants and Study Design The inclusion criteria for this study were patients 1) with corneal opacity, 2) with postoperative corneal thickness ≥400 μm, 3) who met the indications for corneal lenticule transplantation, 4) volunteered to participate in this study and sign a written informed consent. The exclusion criteria were patients 1) with other ocular diseases that may interfere with the study results, such as keratitis, uveitis, severe dry eye, retinal detachment, or severe cataract; 2) with uncontrolled systemic diseases, such as serious heart disease, renal insufficiency, or serious infection; 3) who were unable to comply with study protocols or requirements; 4) who were pregnant or lactating.

Nine eyes from nine patients (five men and four women; age range: 12–59y) with corneal opacities underwent excimer laser PTK combined with surgical corneal lenticule transplant between August 2021 and August 2023 by the same surgeon (Zhong XW).

All patients were diagnosed based on the results from slit-lamp microscopy, corneal topography, and anterior segment optical coherence tomography (AS-OCT). Patient 1 was diagnosed with band-shaped keratopathy of both eyes that had never been treated. Patient 2 was a 12-year-old girl with band-shaped keratopathy, occlusion of the pupil, and a congenital cataract of the left eye. Patients 3, 4, 6, and 8 were diagnosed with corneal dystrophy, of which patients 3, 6, and 8 underwent penetrating keratoplasty in both eyes. Since recurrence has been shown after penetrating keratoplasty, PTK was performed in both eyes. Patient 4 (the son of patient 3) underwent binocular PTK in 2014. Patients 3, 4, 6, and 8 experienced recurrence after surgery. Patients 5, 7, and 9 experienced eye injuries during childhood. Table 1 summarizes the patients' clinical characteristics.

Human Corneal Lenticule Acquisition The corneal lenticule donors in this study were healthy individuals aged 20–30y, all of whom were scheduled to undergo SMILE surgery and signed the consent for lenticule donation. The corneal lenticules for this study were extracted during SMILE surgeries at Hainan Eye Hospital of Zhongshan Ophthalmic Center (Figure 1A). The VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) was used to make a small incision for lenticule extraction at a power setting of 500 kHz using the SMILE system software. The laser cut energy was 140 nJ, and a small side cut at 90° with a width of 2.0 mm was used to acquire the lenticule. The thickness of the corneal cap was set at 120 mm (all patients had the same cap thickness), and the optical zone of the lenticule was 6.5 mm. The lenticule capsule was immersed in phosphate-buffered saline, and each

Table 2 Treatment parameters

No.	Ablation parameters			Corneal lenticule parameters	
	Size (mm)	Location	Depth (μm)	Central thickness (μm)	Refraction (D)
1	7.0	Centered	140	144	−7.50/−0.50×180°
2	8.0	Centered	100	141	−7.00/−0.75×180°
3	6.6	Centered	100	155	−8.75
4	6.6	Centered	100	140	−7.25/−0.50×155°
5	6.6	Centered	120	133	−7.25
6	6.6	Centered	170	166	−8.50/−1.00×170°
7	6.6	Centered	140	164	−9.00/−0.25×25°
8	6.6	Centered	170	164	−9.25
9	6.6	Centered	150	130	−7.00

lenticule graft was used within half an hour of removal. The corneal lenticule parameters are listed in Table 2.

PTK and Corneal Lenticule Transplant Procedure Corneal ablations were conducted *via* therapeutic PTK laser cutting. The PTK procedure was performed using the Wavelight EX500 excimer laser platform (Alcon, Fort Worth, TX, USA) with a repetition frequency of 250 kHz (pulse frequency =30 Hz, transition zone =1 mm), pulse energy of 1.1 mJ, an optical zone of 6.6–8.0 mm, and a laser cutting depth of 100–170 μm depending on the degree of corneal opacity. The ablation parameters are listed in Table 2. Then, the corneal lenticule was attached to the central position of the recipient's corneal surface using porcine fibrin adhesive (Harbin Hanbang Medical Science and Technology Co., Ltd., China), which was evenly coated (Figure 1). Using a microscope, the surgeon ensured that the lens was in the center of the ablation area.

All patients tolerated the procedure well and wore bandage contact lenses after surgery. These were removed 2–3wk later when the corneal epithelium was remodeled. After surgery, patients received 0.5% levofloxacin eye drops four times per day for one week; 0.3% tobramycin combined with 0.1% dexamethasone eye drops (Tobradex; Alcon Laboratories, Fort Worth, TX, USA) four times per day for two weeks; and 0.1% sodium hyaluronate eye drops four times per day for 1mo.

Clinical Examinations The ophthalmic examinations included slit lamp microscopy, corneal density, intraocular pressure, uncorrected distance visual acuity (UDVA), subjective refraction, corrected distance visual acuity (CDVA), and AS-OCT. Corneal densitometry was measured using a Pentacam HR (Oculus, Wetzlar, Germany), clinical assessment postoperatively was achieved by using slit lamp microscopy (Nikon, Tokyo, Japan), and the thickness of the central cornea and corneal lenticule transplant were measured *via* AS-OCT (Zeiss, Oberkochen, Germany). All examinations were performed preoperatively and at 1wk, 1, 2, 6, and 12mo postoperatively.

Statistical Analysis The data were analyzed using the SPSS software (version 27.0; IBM, Inc., USA). Numerical data are expressed as the mean±standard deviation. Pre- and post-operative corneal densitometry was compared using a paired-sample *t*-test. $P<0.05$ was considered statistically significant.

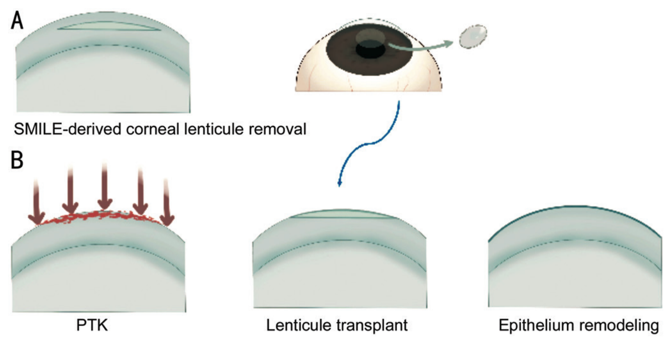

Figure 1 Graphical representation of PTK combined with SMILE-derived corneal stromal lenticule transplantation procedure A: The corneal lenticule acquisition procedure during SMILE surgery; B: The PTK combined with epikeratophakia procedure. PTK: Phototherapeutic keratectomy; SMILE: Small incision lenticule extraction.

RESULTS

All patients completed at least one month of postoperative follow-up. The surgery and postoperative follow-up were uneventful. None of the nine patients experienced postoperative corneal graft rejection, ulceration, or neovascularization. However, there was pronounced stromal edema around the implant after surgery, although the graft edema subsided substantially after two weeks. All patients except patient 8 achieved corneal epithelialization at two weeks postoperative.

Visual Acuity and Intraocular Pressure The pre- and post-operative visual acuity and refractive outcomes of all patients are presented in Table 3. Seven eyes (77.8%) achieved UDVA and CDVA at the final follow-up compared to their preoperative levels. Regarding refractive outcomes, none of the nine patients exhibited a hyperopic shift postoperatively. In addition, their intraocular pressure remained stable postoperatively.

Slit-lamp Microscopy The nine patients' pre- and post-lenticule transplantation slit-lamp results were compared

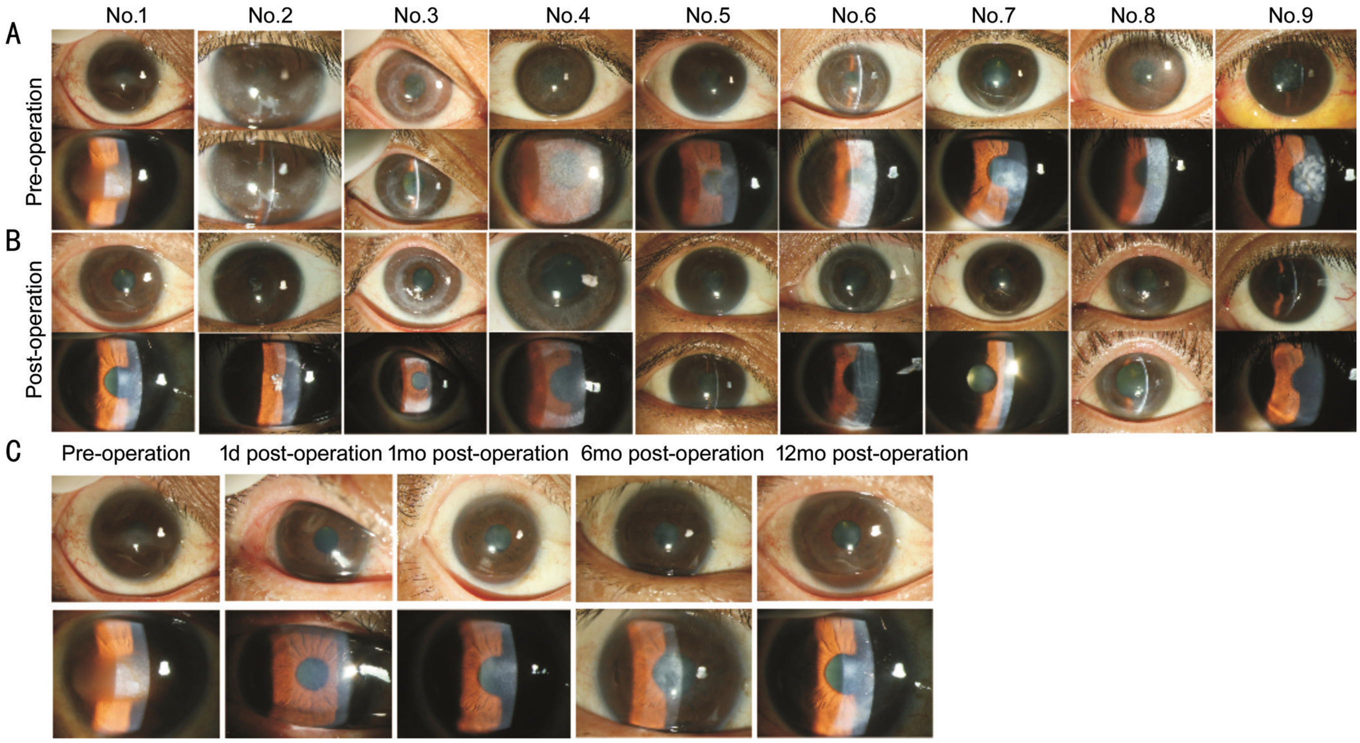

Figure 2 Pre- and post-operative anterior photographs for patients 1–9 obtained *via* slit-lamp microscopy A: The preoperative slit-lamp microscopy images of the nine patients showed banded or localized dense corneal opacity in patients 1, 2, 5, 7, and 9 and superficial granular and confluent deposits with diffuse stromal haze in patients 3, 4, 6, and 8; B: The slit-lamp microscopy images of the same patients at their final postoperative visit demonstrate how corneal opacities can be successfully removed from the optical zone of the cornea without corneal ulceration or neovascularization; C: The postoperative slit-lamp microscopy images of patient 1. The corneal tissue maintained its transparency over time with no visible tissue boundary.

Table 3 Pre- and post-operative visual and refractive data

No.	Preoperative			Postoperative		
	UDVA (logMAR)	SE (D)	CDVA (logMAR)	UDVA (logMAR)	SE (D)	CDVA (logMAR)
1	0.4	−1.25	0.1	0.3	−0.50	0.3
2	3.1	-	3.1	2.1	-	2.1
3	2.0	+15.00	0.8	0.7	-	0.7
4	1.7	-	1.7	1.0	-	1.0
5	1.3	+8.00	0.8	0.4	-	0.4
6	1.4	-	1.4	1.3	-	1.3
7	1.0	+2.00	1.0	0.9	−1.75	0.9
8	1.3	+1.75	1.0	1.3	-	1.3
9	1.3	+3.75	1.0	1.3	-	0.8

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; -: Did not improve; logMAR: Logarithm of the minimum angle of resolution.

(Figure 2A, 2B). All treated eyes had near-complete resolution of the corneal opacity. The nine patients' corneal transparency improved significantly postoperatively. A scar line was observed at the ablation margins, while the central region remained transparent. After 12mo of observation, the central area of corneal transparency decreased slightly postoperatively in patient 1 (Figure 2C), but no dense white spot occurred.

Corneal Densitometry The cornea was divided into three layers according to its depth: anterior (the most anterior 120 μm of the cornea), central, and posterior (the most posterior 60 μm). In each layer, the cornea was divided into four regions according to its diameter: 0–2, 2–6, 6–10, and 10–12 mm. The cornea's density was measured in each region of the three layers. Since the optical zone of the PTK procedure is <8 mm and the laser cutting depth was 100–170 μm, we compared the pre- and post-operative corneal densities of the 0–2 and 2–6 mm regions of the anterior corneal layer, the entire anterior corneal layer, and the four regions of the entire cornea (Figure 3). The densities of the entire cornea, the entire anterior corneal layer, and the 0–2 and 2–6 mm regions of the anterior corneal layer

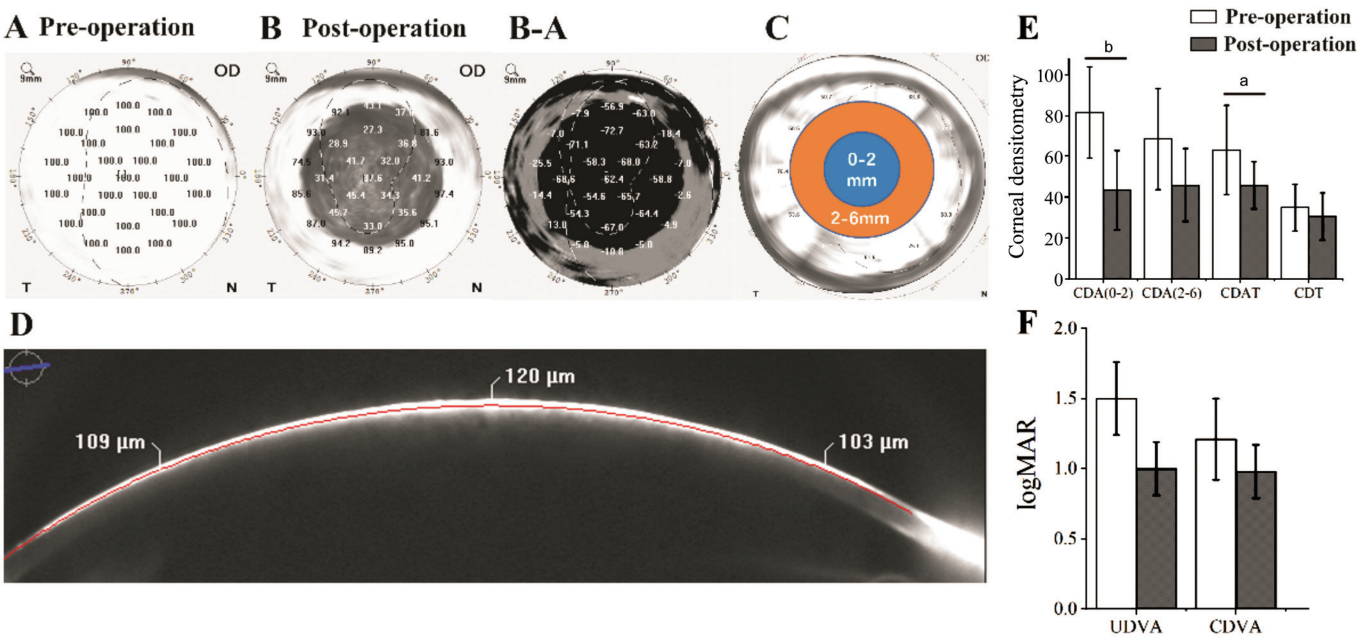

Figure 3 Pre and post-operative corneal densitometry measurements for patients 1–9 A: Preoperative corneal densitometry shows high corneal densities in the area of opacity; B: Postoperative corneal densitometry measurements show decreasing corneal densities in the operated area; B-A: Pre- to post-operative corneal densitometry differences; C: The cornea was divided into four regions based on its diameter: 0–2, 2–6, 6–10, and 10–12 mm; D: A cross-section of the cornea. The red line delineates the most anterior 120 μm of the cornea; E: Comparison of pre- and post-operative (final visit) corneal densitometry for all nine operated eyes. Density decreased significantly in the 0–2 mm region of the superficial cornea and the entire superficial cornea. It also decreased in the 2–6 mm region of the superficial cornea and the entire cornea. Data were presented as the mean±SEM. $^aP<0.05$; $^bP<0.01$. F: Comparison of pre- and post-operative (final visit) UDVA and CDVA for all nine operated eyes. Data were presented as the mean±SEM. UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SEM: Standard error of the mean; CDA (0–2): The density of the anterior corneal layers of 0–2 mm; CDA (2–6): The density of the anterior corneal layers of 2–6 mm; CDAT: The density of the total anterior corneal layer; CDT: The density of the total cornea.

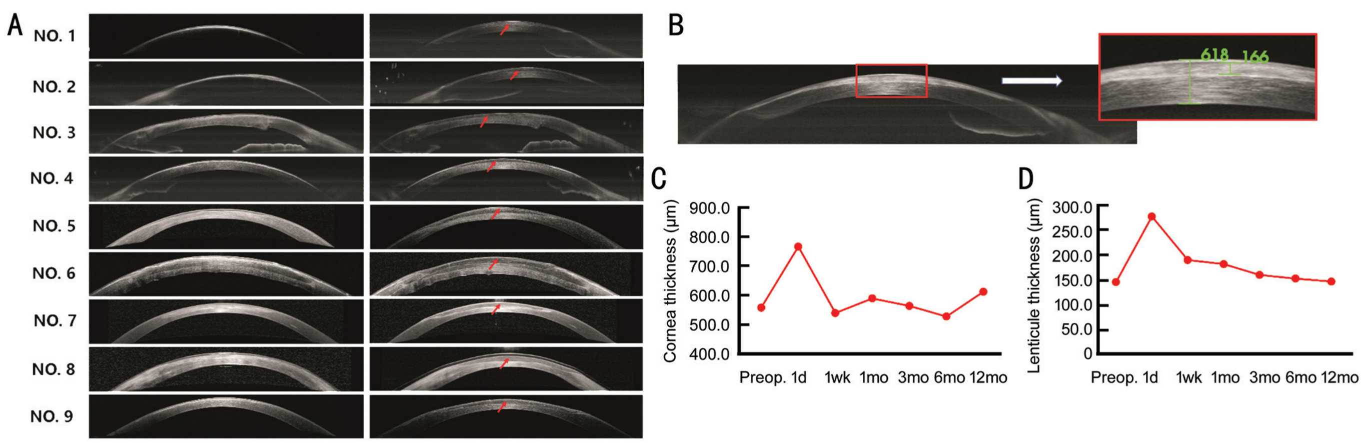

Figure 4 Representative corneal AS-OCT images A: Pre- and post-operative corneal AS-OCT images. The red arrowhead indicates the location of the lenticule; B: Measurement of the thickness of the cornea and the lenticule; C: The pre- and postoperative thickness of the lenticule; D: The pre- and postoperative thickness of the cornea. AS-OCT: Anterior segment optical coherence tomography.

decreased significantly from pre- to post-operative by 12.4% (35.05±11.45 *vs* 30.69±11.50, $P>0.05$), 27.5% (63.25±21.85 *vs* 45.87±11.51, $P<0.05$), 46.7% (81.59±22.24 *vs* 43.52±19.39, $P<0.01$), and 32.8% (68.55±24.79 *vs* 46.09±17.85, $P>0.05$), respectively (Figures 3E). The greater the preoperative corneal density, the greater the postoperative corneal density decrease.

Corneal Imaging with AS-OCT Pre- and post-operative images of the cornea were acquired by AS-OCT examination. The grafts were very clear, with the convex shape of the cornea thicker in the center and thinner around the periphery (Figure 4A). Central corneal thickness increased significantly on the first day and became stable one month postoperatively (Figure 4C, 4D). This change was also reflected in the corneal lens thickness.

Complications Patient 8 experienced delayed corneal epithelial healing, with a corneal epithelial defect of

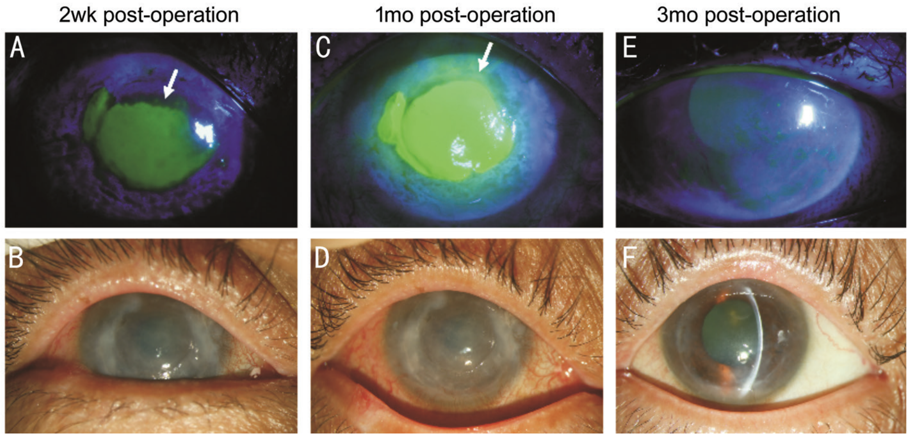

Figure 5 Delayed corneal epithelialization in patient 8 A, B: The corneal epithelial defect was noted at the 2wk postoperative follow-up (white arrows); C, D: The corneal epithelial defect had enlarged at the 1mo postoperative follow-up (white arrows); E, F: The ocular surface remained smooth and stable at the 3mo follow-up.

approximately 6×6 mm^2 (Figure 5C, 5D; white arrows) at one month postoperatively. The patient was treated with soft contact bandage lenses. Corneal epithelialization was completed one month later, and the corneal epithelium remained smooth and consecutive at the final follow-up (3mo).

DISCUSSION

This study demonstrated the efficacy of PTK combined with corneal lenticule transplantation in nine patients with corneal opacities. Corneal transparency and UDVA had improved within one year postoperatively. None of the operated eyes developed corneal ulceration, neovascularization, or host corneal rejection. Our findings suggest that PTK combined with corneal lenticule transplantation is a safe and efficient surgical approach that may prevent recurrence after PTK in patients with corneal opacity.

SMILE has been a popular area of research in corneal refraction since its introduction a decade ago. Its purported advantages include avoiding flap-related complications, reduced ocular surface disruption resulting in fewer dry eye symptoms, and improved short- and long-term biomechanical stability. Patients are fortunate to have this procedure available, and many human corneal stromal lenticules have been created. In recent years, our group and others worldwide have used wasted corneal stromal lenticules to correct refractive errors and treat corneal diseases such as presbyopia, hyperopia, keratoconus, corneal dystrophy, and corneal penetrating injury[23].

PTK has been the most beneficial option for treating corneal opacities, such as corneal scarring, dystrophies, degenerations, and recurrent corneal erosions, due to its rapid healing, better visual recovery, and provision of an optically smooth surface without significant injury to the unablated tissue. While hyperopic shifts have been documented after PTK, none of the nine patients in this study experienced a postoperative hyperopic shift[24]. In some patients, the change in refraction could not be measured because we could not obtain exact data via objective measurements. However, to some degree, PTK combined with corneal lenticule transplantation improved the hyperopic shift. In recent years, corneal stromal lenticules removed *via* SMILE have been used to correct refractive errors such as presbyopia and hyperopia. Studies have shown that it may be a potentially safe and effective alternative[19-21]. One potential weakness of this study is that the lens diopter could not be precisely calculated preoperatively.

Penetrating or lamellar keratoplasty results are satisfactory in most cases. However, the shortage of corneal donors, the constraints of availability, and the high cost of the procedure limit the use of fresh, high-quality corneal tissue for tectonic purposes. Lamellar or full-thickness keratoplasty is also complicated by immunological rejection, graft failure, irregular astigmatism, wound leakage, cataracts, and glaucoma[25]. Therefore, corneal stromal lenticules are much easier to acquire than corneas for penetrating or lamellar keratoplasty. In addition, different refractive corneal stromal lenticules can be selected, with varying options for corneal diameter, thickness, and diopter. Moreover, the problems of corneal rejection and infection caused by traditional penetrating or lamellar keratoplasty surgery can be avoided. Surgical SMILE lenticules are also biocompatible and biosafe after implantation, suggesting a remarkable prospect for their future use.

Kaufman[26] introduced epikeratophakia in 1979, where donor lenticules were sutured to the anterior surfaces of patients' corneas to correct different refractive errors, such as myopia, hyperopia, and keratoconus. The limitations of epikeratophakia were found to be uncontrolled epithelial recovery, interface scarring, reduced visual acuity, and poor refractive predictability and stability. In 2013, Reinstein et al. performed the first femtosecond laser-assisted, intrastromal implantation of a convex-shaped lenticule derived from a myopic SMILE procedure to treat hyperopia[14]. Our previous study[17-18] used small-incision, femtosecond, laser-assisted intracorneal, concave lenticule implantation to correct human keratoconus. In this study, porcine fibrin adhesive was first used to attach the corneal lenticule to the central position of the recipient's corneal surface after PTK treatment, which proved safe, effective, and simple to perform. Therefore, this procedure may provide a new treatment option for patients with corneal opacities in the future.

In this study, the central area of the cornea remained transparent, and recurrences were observed at the ablation margins with slit-lamp microscopy, which is consistent with Dogru *et al*[27]. Furthermore, the recurrences began from the ablation margins and progressed centrally in all patients, suggesting that decreases in corneal transparency may be caused by the characteristics of the underlying disease. However, since previous reports have not described using porcine fibrin sealant to implant corneal lenticules, stimulation caused by foreign substances could not be excluded.

Patient 8 experienced delayed corneal epithelial healing, which may be related to their history of diabetes and poor ocular surface function after corneal transplantation, which has guiding significance for the future indications of this surgery.

This study had some limitations, including its retrospective design, lack of a control group, small number of cases, and limited follow-up period. In particular, the short follow-up period was inadequate to determine whether corneal opacities would recur. Finally, the change in corneal refractive power was determined not only by the refractive power of the implanted corneal lenticules but also by the corneal curvature after PTK treatment. Therefore, further studies are needed to evaluate the final correction of the refractive powers of implanted corneal lenticules.

In conclusion, PTK combined with SMILE-derived corneal lens transplantation improves the visual acuity of patients with corneal opacity. This procedure represents a new, safe, and effective treatment for these patients. It also offers a novel approach for treating other ocular conditions.

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Authors' contributions: The study was designed by Zhong XW, Hu SS, and Ding H. Material preparation and data collection were performed by Hu SS, Meng XY, Ouyang BW, Yang ZD and Chen XD. Data analysis was performed by Hu SS. The manuscript was written by Hu SS, reviewed and edited by Zhong XW and Ding H. All authors read and approved the final manuscript.

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Conflicts of Interest: Hu SS, None; **Ding H,** None; **Meng XY,** None; **Ouyang BW,** None; **Yang ZD,** None; **Chen XD,** None; **Zhong XW,** None.

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