Two-Year Outcome of a Patient Treated With Phototherapeutic Keratectomy and Autologous SMILE Lenticule Transplantation for Flap-Related Complications Following LASIK

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ABSTRACT

PURPOSE: To describe a patient with flap complications after LASIK who was subsequently treated using phototherapeutic keratectomy (PTK) and an autologous lenticule transplant obtained via small incision lenticule extraction (SMILE).

METHODS: A 23-year-old man experienced free flap and partial flap loss in the left eye following LASIK, resulting in corneal stroma opacity 1 month later. The manifest refraction was -3.25 diopters sphere (DS)/-0.50 diopters cylinder (DC) × 100° in the right eye and +2.50 DS/-1.25 DC × 155° in the left eye. His left eye was treated with PTK and transplantation of an autologous lenticule obtained from his right eye using the SMILE procedure.

RESULTS: At the 2-year follow-up visit, the uncorrected distance visual acuity of the left eye had improved from 20/100 to 20/22 and the corrected distance visual acuity had improved from 20/25 to 20/18. Central corneal thickness had increased from 464 to 499 µm. The mean keratometry value had decreased from 45.00 diopters (D) at the 1-month follow-up visit to 39.40 D at the 2-year follow-up visit. Optical coherence tomography examination revealed that the lenticule remained transparent and exhibited a visible demarcation line.

CONCLUSIONS: The transplantation of an autologous lenticule obtained via SMILE combined with PTK improved uncorrected and corrected acuity in this patient with flap loss after LASIK.

LASIK is a popular treatment for the surgical correction of refractive errors. During LASIK, a corneal flap is created using a microkeratome or femtosecond laser, and in situ ablation of the exposed stromal bed is performed using an excimer laser.1-3 However, some intraoperative flap-related complications have been reported after mechanical LASIK, such as buttonholes and partial, thin, irregular, or free flaps.4 Such complications are usually treated conservatively using corticosteroid eye drops and specialized contact lenses. We describe a new technique for the treatment of partial flap loss and corneal opacity after LASIK in which an autologous lenticule transplant is performed via small incision lenticule extraction (SMILE) combined with phototherapeutic keratectomy (PTK).

CASE REPORT

A 23-year-old man was referred to our eye clinic due to blurred vision in the left eye. He had undergone LASIK for the correction of myopia in the left eye at another refractive surgery center 1 month prior to consultation. During the procedure, a microkeratome malfunction resulted in the creation of an incomplete and free corneal flap. One day after surgery, the central part of the free flap was lost due to unknown causes. The left eye was treated with 0.1% fluorometholone drops six times daily for 2 weeks. On evaluation at our clinic 1 month later, we observed corneal stromal opacity in his left eye. Further examination revealed an uncorrected distance visual acuity (UDVA) of 20/100 in his left eye and a corrected distance visual acuity (CDVA) of 20/25, with a manifest refraction of +2.50 diopters sphere (DS)/-1.25 diopters cylinder (DC) × 155°. Slit-lamp examination and Seidel testing using fluorescein staining revealed clear partial flap loss in the central cornea of his left eye and uncorrected and corrected acuity in this patient with flap loss after LASIK.

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ity) on anterior optical coherence tomography (OCT) images of the left eye (Figure 2A).

After 6 months, the patient experienced no improvement in visual symptoms and the corneal opacity remained unchanged, although the manifest refraction was stable. After the risks, benefits, and alternatives were explained and informed consent was obtained, the patient was scheduled for treatment via autologous lenticule transplantation and PTK in the left eye.

SMILE was first performed using the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) to correct myopia/astigmatism in his right eye. The thickness and diameter of the lenticule were 87 µm and 6.9 mm, respectively. The extracted lenticule was temporarily maintained in balanced salt solution to avoid dehydration. A hook was used to grasp the edge of the free flap and separate the incomplete flap from the underlying stromal bed. After the edge had been lifted 6 mm, non-toothed forceps were used to lift the incomplete flap gently from its stromal bed. The flap was then peeled back superiorly toward the hinge. The posterior surface of the flap was rough, exhibiting a central tissue defect, and annular opacities were observed in the center of both the stromal bed and flap. PTK to the residual stromal bed surface was then performed using the MEL 80 excimer laser (Carl Zeiss Meditec AG) with an intended ablation depth of 51 µm and optical zone of 6.75 mm. The interface was irrigated with balanced salt solution, immediately following which the lenticule extracted from his right eye was transplanted onto the stromal bed of the left eye. During transplantation, the patient was asked to focus on a blinking red light, and the center of the lenticule was mounted coaxially with the light beam under microscopic guidance. Each edge of the lenticule was carefully flattened and smoothed using a spatula and a sponge swab, followed by flap repositioning. A silicone hydrogel contact lens was

Figure 1. Corneal topographic images before and after surgery. (A) Preoperative. (B) One month after operation. (C) Two years after operation.

Figure 2. Anterior segment optical coherence tomography images (A) preoperatively and (B) 1 month and (C) 2 years after operation.
applied as a bandage after surgery and removed 10 days following the procedure. Postoperative medication was also prescribed for both eyes and consisted of an ophthalmic solution of levofloxacin four times per day for 1 week, a 0.1% fluorometholone solution tapered from eight times daily to one time daily over 1 month, and a preservative-free tear supplement four times daily for 1 month.

At the 1-month follow-up, the UDVA, manifest refraction, and CDVA of the left eye were 20/33, -0.50 DS/-2.50 DC × 150°, and 20/25, respectively. Corneal topography assessments revealed a CCT of 543 µm and mean keratometry value of 45.10 D (Figure 1B). OCT examinations demonstrated that epithelialization had been achieved, and the transplanted lenticule was attached to the stromal bed with visible demarcation lines (Figure 2B). No displacement or wrinkles were observed.

At the 2-year follow-up, the UDVA, manifest refraction, and CDVA of the left eye were 0.9 decimal (20/22 Snellen), -1.25 DC × 165°, and 1.0+2 decimal (20/18 Snellen), respectively. Corneal topography assessments revealed a CCT of 499 µm and mean keratometry value of 39.40 D (Figure 1C). OCT examinations demonstrated that the lenticule remained transparent with a visible demarcation line, and parts of the lenticule had been incorporated into the corneal stroma (Figure 2C). The small region of opacity at the periphery of the flap observed postoperatively had remained stable. Under slit-lamp examination, the cornea was clear with no flap striae, inflammation, epithelial ingrowth, or diffuse lamellar keratitis. The implanted lenticule was completely integrated with the adjacent stroma without visible boundaries (Figure 3).

**DISCUSSION**

Although the creation of a corneal flap is critical for successful LASIK, incomplete flaps can occur during the procedure due to failure of the microkeratome. The incidence of this complication ranges between 0.3% and 1.2%, although the rate of flap-related complications decreases with surgical experience and the application of a femtosecond laser. During SMILE, a refractive lenticule is extracted from the intrastromal cornea layer and subsequently transplanted as autologous or allograft tissue, resulting in successful treatment of hyperopia and various forms of anterior ocular disease.

To our knowledge, our report is the first to discuss the treatment of partial flap loss using an autologous lenticule obtained via the SMILE procedure.

In the current case, PTK was performed to remove the corneal opacity, followed by immediate transplantation of the lenticule from the patient’s right eye into the left eye for the treatment of partial flap loss. The patient experienced a favorable clinical outcome, wherein both the UDVA and CDVA had improved postoperatively and no complications were noted during the 2-year follow-up period. The first case of correction of iatrogenic hyperopia and high astigmatism after LASIK by the refractive lenticular transplantation was reported by Lazaridis et al. in 2016. They observed mild interface opacities at the 3-month postoperative examination and attributed
this to the remodeling of the stromal tissue. However, no interface problems such as haze, scarring, or rejection were present in the current case. The difference may be that we adopted autologous transplantation from the contralateral eye and a donor lenticule was used in their case.

At the 2-year follow-up, we observed that the CCT of the left eye had increased by 35 µm, which was nearly equal to the thickness of the intended PTK ablation depth subtracted from the thickness of the transplanted lenticule (87 µm – 51 µm = 36 µm). Previous studies have demonstrated that corneal thickness can be restored to preoperative levels following autologous lenticule re-implantation after SMILE surgery.\(^{11,12}\) The spherical equivalent refraction of the patient’s left eye was -0.63 D at the 2-year follow-up, indicative of a mild myopic shift. Pradhan et al.\(^6\) first reported implantation of an allogeneic lenticule obtained from a -10.50 D myopic donor via SMILE for the correction of high hyperopia in a young individual, although this procedure resulted in only 50% of the intended correction at the 1-year follow-up. Sun et al.\(^7\) reported that autologous lenticule transplantation may be safe, effective, and stable for the treatment of hyperopia in patients with ametropia, but that its refractive predictability should be improved in the future. In a pilot study,\(^9\) we evaluated the outcomes of 6 eyes with corneal dystrophy that had undergone PTK and an epikeratophakia procedure using donor lenticules obtained via SMILE. Our findings indicated that refraction ranged from -4.50 to -11.50 D in all eyes at the final follow-up.\(^9\) Thus, various studies have suggested that the refractive predictability and long-term effects of lenticule transplantation require further investigation.

Interestingly, in the current case, the mean keratometry value decreased from 45.00 D at the 1-month follow-up to 39.40 D at the 2-year follow-up, whereas the CCT decreased from 543 to 499 µm during the same period. We speculate that epithelial remodeling, posterior surface changes, and postoperative wound healing may have contributed to these changes. Moreover, we observed integration of the implanted lenticule and surrounding stroma on both slit-lamp and OCT images at the 2-year follow-up. Future studies should investigate the mechanisms underlying such alterations in histological ultrastructure.

Other alternatives for treating eye complications after LASIK are certainly used.\(^{13,14}\) Garcia-Gonzalez et al.\(^14\) demonstrated a case of central flap necrosis after a LASIK enhancement that was treated via surgical flap amputation and photorefractive keratectomy with mitomycin C. This approach has some disadvantages. First, irregular astigmatism can be induced by flap amputation. Second, the risk of haze or scar development in the stromal bed cannot be avoided even using mitomycin C. Third, the cornea is thinned and thus weakened after flap amputation and surface ablation. Conversely, the surgical technique applied in the current case restored corneal volume and thus may provide a solution for rare cases of excessive stromal tissue defect after LASIK, with subsequent correction of high hyperopia or hyperopic astigmatism. The addition of the lenticule and resulting increased corneal thickness may contribute to corneal strength and biomechanical properties. However, the refractive predictability was not satisfactory and the refractive error of the transplanted lenticule depends on that seen in the contralateral eye.

The findings of the current case demonstrate that the transplantation of an autologous lenticule obtained via SMILE combined with PTK improved uncorrected and corrected visual acuity with treatment of flap loss following LASIK. Future studies involving more cases are warranted to further delineate the clinical indications and outcomes for this new surgical procedure.

AUTHOR CONTRIBUTIONS

Study concept and design (JZ, FZ, XZ); data collection (JZ, FZ, JH, XZ, HX); analysis and interpretation of data (JZ, FZ, YC); writing the manuscript (JZ, FZ, JH, HX, YC); critical revision of the manuscript (JZ, FZ, XZ); administrative, technical, or material support (HX, XZ); supervision (XZ)

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