Customized transepithelial photorefractive keratectomy for iatrogenic ametropia after penetrating or deep lamellar keratoplasty

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PURPOSE: To evaluate the safety and efficacy of customized transepithelial photorefractive keratectomy (PRK) for the correction of iatrogenic ametropia after penetrating keratoplasty (PKP) or deep lamellar keratoplasty.

SETTING: Eye Clinic, Department of Neurological and Visual Sciences, University of Verona, Verona, Italy.

METHODS: This study comprised 9 patients who had irregular astigmatism from 2.0 to 8.0 diopters (D) after PKP or deep lamellar keratoplasty. The ametropia was corrected with customized transepithelial PRK and the Corneal Interactive Programmed Topographic Ablation (CIPTA) software program (LIGI). Complete ophthalmic examinations were performed before and after surgery.

RESULTS: The mean age of the patients was 39.2 years (range 31 to 59 years). All patients gained at least 2 Snellen lines of uncorrected visual acuity; 2 patients had an increase of at least 5 lines, and 3 patients had an increase of 8 lines. The mean refractive spherical equivalent changed from $-2.98~D~\pm~3.11$ (SD) (range -7.25 to +3.00~D) before PRK to $-0.58~\pm~0.84~D$ (range 0 to -2.50~D) at the last follow-up visit. One patient presented with grade 1 haze that did not improve with topical steroid therapy. No patient lost best spectacle-corrected visual acuity.

CONCLUSION: Customized transepithelial PRK with the CIPTA software was a safe and effective treatment for irregular astigmatism after PKP or deep lamellar keratoplasty.

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Excimer laser corneal ablation is 1 of the newest techniques to correct postkeratoplasty ametropia. 1–5 However, laser in situ keratomileusis (LASIK) and surface photorefractive keratectomy (PRK) are limited because of the irregularity of the corneal surface after transplantation. The major disadvantages of LASIK are related to the creation of the lamellar flap. Complications include free, incomplete, irregular, thin, or buttonholed flaps. The high incidence of corneal haze limits the use of PRK in these eyes. 6

Customized ablation is an effective, safe, and stable option to treat irregular astigmatism from various etiologies.⁷

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A topography-linked excimer laser is a potentially excellent approach to irregular ametropia after keratoplasty. However, the transplanted corneal epithelium may have different thickness as well as morphology and different patterns of reepithelialization in different areas of the cornea. This may limit the treatment's efficacy because the topography is performed on epithelium that was removed before laser treatment.

The purpose of this study was to evaluate the efficacy, predictability, safety, and stability of customized transepithelial PRK for irregular postkeratoplasty ametropia using the Corneal Interactive Programmed Topographic Ablation (CIPTA) software program (LIGI).

PATIENTS AND METHODS

This study comprised 9 eyes of 9 patients who had high ametropia with irregular astigmatism (range 2.00 to 8.00 diopters [D]) after penetrating keratoplasty (PKP) or deep lamellar keratoplasty. All patients were treated at the same time at the Eye Clinic of Verona University, Italy, by the same surgeon (E.P.) and were

followed for 12 months. All patients gave informed consent after the risks, benefits, and alternative treatment methods were described. This study was conducted according to the principles of the Helsinki Declaration and good clinical practices.

All the patients had keratoplasty at least 18 months and suture removal at least 6 months before PRK. They had stable refraction for at least 6 months and were intolerant to contact lenses.

Eight eyes had myopic ametropia with a mean spherical equivalent of -3.73 D \pm 2.30 (SD) (range 0 to -7.25 D). One 1 eye had hyperopic ametropia with a 3.00 D spherical equivalent (SE).

Clinical Examination

All patients had a complete preoperative ophthalmic examination including slitlamp biomicroscopy, Goldmann tonometry, indirect ophthalmoscopy, optic pachymetry, and endothelial cell count. The computer topography was performed with the Orbscan (Orbtek, Inc.).

Uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA) were determined preoperatively and at 2, 4, 6, 9, and 12 months. Cycloplegic refraction was measured preoperatively and postoperatively with the fogging (high plus) technique.

Corneal topography was acquired preoperatively and 2, 4, 6, 9, and 12 months after the treatment. The Alpin method of vector analysis of astigmatism was based on the refractive data. Subjective evaluation of visual quality was tested with a questionnaire that asked about halos, glare, and monocular diplopia.

Surgical Technique

Treatment began with the acquisition of 2 identical topographies with a maximum difference of 3 μ m between all the processed points in the 5.0 mm central zone of the cornea. This process provided reliable corneal surface data.

The elevation data obtained by the Orbscan topographer and the patient's manifest refraction were relayed to the CIPTA software program for processing. The customized ablation profile was transferred to the LSX excimer laser (LaserSight) for ablation at the corneal plane.⁷

All ablation profiles were calculated with corneal apex as the ablation center. This choice creates a postoperative cornea surface symmetrical with respect to the preoperative morphology of the

cornea, which will likely be more physiologically accepted by the patient. The postoperative curvature of the cornea was obtained by combining 2 methods: The cornea surface was standardized to the lowest preoperative keratometric reading by flattening the steepest axis. Then, the spherical component of the manifest refraction was added with a positive or negative sign to the standardized keratometric value to obtain the desired (ideal) postoperative surface. The system calculated the ablation profile as the difference, within the optical zone (defined by the scotopic pupil measured with 0.4 lux of illumination), between the ideal postoperative surface and the preoperative corneal shape. The transition zone was automatically calculated by the CIPTA program to create a constant gradient of curvature over the 360 degrees of the corneal surface. All treatments were performed as a 1-step procedure and aimed for emmetropia except for in 1 case (case 2), which was treated only for astigmatism because the fellow eye's refractive error was myopic (sphere -4.75 D).

All the ablation profiles were integrated with a transepithelial treatment that compensates for the epithelium removal; therefore, a constant ablation depth was added to the customized ablation. The transepithelial custom refractive treatment standardizes the technique, making it no-touch surgery.

After the ablation profile is transferred to the laser, it positions the laser beam and delivers the ablation in the correct location and depth at the cornea plane. To accomplish this, the CIPTA program sends the coordinates of each ablation point to the laser using the pupil center as the only reference point. In our study, 1 drop of lidocaine 4% was instilled every 5 minutes starting 20 minutes preoperatively.

One drop of formocortal–gentamicin (Formomicin) and a contact lens (Protek T&S, Contact Vision) were applied postoperatively. The postoperative regimen included netilmicin 0.3% (Nettacin) and hyaluronic acid 0.2% (Hyalistil) 4 times daily until the epithelium healed. After contact lens removal, fluorometholone 0.1% (Fluaton PVA) was prescribed 4 times a day for the first 3 months and then tapered by 1 drop every 30 days until 6 months. An amino acid agent (Trium) was used for 6 weeks after surgery, and artificial tears were prescribed 4 times a day for all patients during the follow-up. 11

RESULTS

The patients' data are shown in Table 1. The mean age of the 7 men and 2 women was 39.2 years (range 31 to 59

Table 1. Summary	of the preoperative	and postoperative	patient data.
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				Before CTPK			After CTPK		
Case	Age (Y)/Sex	Indication for Graft	Graft to CTPK (Mo)	UCVA	BSCVA	Refraction	UCVA	BSCVA	Refraction
1	30/M	Keratoconus	21	20/100	20/20	-6.00×180	20/20	20/20	Plano
2	59/M	Keratoconus	36	20/200	20/20	$-4.00 - 3.00 \times 107$	20/32	20/20	-2.50
3	31/M	Keratoconus	48	CF	20/20	-8.00×50	20/20	20/20	Plano
4	41/M	Keratoconus	102	20/200	20/20	-5.00×90	20/20	20/20	Plano
5	37/M	Perforating trauma	31	20/40	20/20	+1.00-2.00 imes100	20/20	20/20	Plano
6	31/M	Keratoconus	21	20/200	20/20	$-4.25 - 6.00 \times 180$	20/63	20/20	-2.00×90
7	45/F	Keratoconus	17	20/200	20/20	$-2.50 - 6.00 \times 60$	20/25	20/20	-1.00
8	37/M	Keratoconus	18	20/32	20/25	$-0.75 - 2.75 \times 20$	20/25	20/20	-1.50×100
9	42/F	Keratoconus	19	20/63	20/20	$+1.00 + 4.00 \times 170$	20/20	20/20	Plano

BSCVA = best spectacle-corrected visual acuity; CF = counting fingers (at 1 meter); CTPK = customized transepithelial photorefractive keratectomy; UCVA = uncorrected visual acuity

years). Two patients (cases 8 and 9) had deep lamellar keratoplasty with manual dissection of the recipient bed, and 6 patients (cases 1 to 4, and 6 and 7) had PKP for keratoconus. One patient (case 5) had a triple procedure after perforating trauma with an intraocular lens (IOL) implanted in the sulcus.

Eyes with a UCVA of 20/40 or better increased from 2 preoperatively to 8 postoperatively. No eye had a preoperative UCVA of 20/20; after treatment, 5 eyes had 20/20 UCVA. Mean preoperative SE was -2.98 ± 3.11 D (range -7.25 to +3.00 D); at the last postoperative visit, mean SE was -0.58 D \pm 0.84 D (range 0 to -2.50 D).

One patient (case 6) presented with grade 1 haze 6 months postoperatively that did not improve with topical steroid therapy. This case was probably the result of poor patient compliance with therapy. No patient lost lines of BSCVA. One patient (case 8) gained 2 lines of BSCVA. From 2 to 4 months, 5 eyes were within ± 0.50 D of the SE of the manifest refraction, 3 eyes were within ± 1.00 D, and 1 eye was within ± 1.50 D. From 4 to 9 months, 6 eyes were within ± 0.50 D of the SE of the manifest refraction and 3 eyes were within ± 1.00 D. These data were stable at

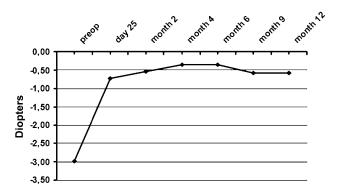


Figure 1. Mean SE over the entire follow-up.

the last follow-up visit. Figure 1 shows the course of the mean SE during the entire follow-up.

In the first 4 postoperative months, 1 eye (case 9) had a hyperopic shift that resolved to plano at the 6-month visit. All the eyes gained at least 2 Snellen lines of UCVA, and these data remained stable during the follow-up. One eye (case 6) had grade 1 haze during the follow-up. At the 12-month examination, all patients achieved 20/20 BSCVA. The correction of the ametropia was of 87%, and the index of success was 0.24 using the Alpin method of vector analysis. No patient received secondary surgery. Five patients reported glare and monocular diplopia, and 2 patients reported halos. All symptoms resolved after treatment. Figure 2 shows an example of preoperative and postoperative corneal topographies and the CIPTA pattern customized ablation.

DISCUSSION

The CIPTA software program was effective in reducing postkeratoplasty ametropia. In our series, the mean correction of the SE refractive error was 84% (range 64% to 100%), with a strong improvement in UCVA. One myopic patient (case 2) had an overcorrection of 0.50 D. In this case, the attempted correction was -3.00 D and we obtained -2.50 D. No patient lost any lines of BSCVA. Despite good BSCVA preoperatively, no patient could use spectacle correction because of the large amounts of ametropia.

Reports of LASIK for refractive error after PKP are promising, with a reduction in SE from 29% to 59%; however, perforation, endothelial cell loss, and bleeding can occur. ¹² Moreover, the irregular flap in post-PKP corneas and its unpredictable healing may induce irregularities that can affect visual outcome.

Customized ablation to smooth the corneal surface should provide better results. Ablating only the localized

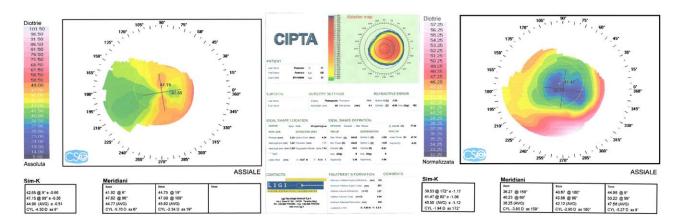


Figure 2. Left: Preoperative corneal topography. Center: Pattern of customized ablation. Right: Postoperative corneal topography (case 6).

defect removes less tissue than correcting a similar amount of regular astigmatism. This sparing of corneal tissue allows treatment of high levels of irregular astigmatism, simultaneously achieving a regular, smooth surface. Even if the eye is undercorrected, visual acuity is improved by smoothing the corneal surface (case 8). The CIPTA software is effective in treating irregular astigmatism. We believe that true customized treatment of transplanted corneas is possible only on the epithelium. In fact, the different thickness and morphology, together with the different pattern of reepithelialization of these corneas, can affect the customization's efficacy. 8

In our study, UCVA improved in all patients; 6 of 9 patients were within ± 0.50 D and all 9 patients were within ± 1.00 D of the desired SE correction, with no regression 12 months postoperatively. The 1 case of haze may have been the result of poor compliance with steroid therapy.

All stable post-PKP ametropia can be corrected with CIPTA software. Uncorrected visual acuity and refractive outcomes may be better with the software than with noncustomized laser treatment. In addition, our data show that treating directly on the epithelium is better than treating after epithelial debridement. One explanation is that customized transepithelial PRK regularizes stromal and epithelial defects, which may be important in visual acuity and in the final refraction in eyes with transplantation. In addition, manually removing epithelium may affect the final refractive result. The trauma of removing the epithelium from the underlying cornea may disrupt the original keratoplasty wound, inducing unquantifiable amounts of astigmatism.

In conclusion, the combination of topographic data and the customized flying-spot excimer laser ablation directly on the epithelium was an effective, predictable, safe, and stable option for correcting irregular ametropia after PKP and deep lamellar keratoplasty.

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