Topographically Supported Customized Ablation for the Management of Decentered Laser In Situ Keratomileusis

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• PURPOSE: To evaluate the efficacy, predictability, and safety of topographically supported customized ablations (TOSCAs) for decentered ablations following laser in situ keratomileusis (LASIK).

• DESIGN: Prospective nonrandomized clinical trial.

• METHODS: Nine patients (11 eyes) with LASIK-induced decentered ablations underwent TOSCA following flap lifting. Topographically supported customized ablation was performed using a corneal topographer to obtain a customized ablation profile, combined with a flying spot laser.

• RESULTS: Mean follow-up was 9.22 ± 2.82 months (range 6–12 months). No intra- or postoperative complications were observed. Manifest refraction (spherical equivalent) did not change significantly (pre-TOSCA: −0.14 ± 1.58 diopters [range, –1.75 to +3.00 diopters] to +0.46 ± 1.02 diopters [range, −1.00 to +1.75 diopters]; $P = .76$), whereas there was a statistically significant reduction in the refractive astigmatism (pre-TOSCA: –1.55 ± 0.60 diopters [range, −3.00 to −0.75 diopters] to −0.70 ± 0.56 diopters [range, −2.00 to −0.25 diopters]; $P = .003$). Mean uncorrected visual acuity improved significantly ($P < .001$) from 0.45 ± 0.16 (range, 0.2–0.7) to 0.76 ± 0.29 (range, 0.2–1.2) at last follow-up. Mean best-corrected visual acuity improved from 0.74 ± 0.22 (range, 0.4–1.0) to 0.95 ± 0.20 (range, 0.6–1.2; $P = .002$). Eccentricity showed a statistically significant reduction after TOSCA treatment (pre-TOSCA: 1.59 ± 0.46 mm [range, 0.88–2.23 mm]; post-TOSCA: 0.29 ± 0.09 mm [range, 0.18–0.44 mm]; $P < .001$).

• CONCLUSION: In our small sample, enhancement LASIK procedures with TOSCA appear to improve uncorrected and best-corrected visual acuity as well as eccentricity in patients with LASIK-induced decentered ablation. (Am J Ophthalmol 2004;137:806–811.

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ABLATION-RELATED COMPLICATIONS FOLLOWING refractive surgery present a problem for both the patient and surgeon and are a significant issue when considering an elective procedure and its alternatives.[1–3] It has been widely postulated that both decentric ablation and the diameter of the optical zone could compromise visual function following any keratorefractive procedure. An ablation is eccentric when its center does not correspond to the center of the optical axis.[4] This is a serious complication because it induces multifocallity of the optical zone and creates inevitable vision problems. In such cases, the shape of corneal meridians is modified from spherical to parabolic. The corneal meridian, connecting the pupillary to the treatment center, is most often affected, and on this meridian lies a transition zone from maximal to minimal dioptric power.

As several studies have shown, there is considerable variation in the incidence and amount of eccentric ablation following laser in situ keratomileusis (LASIK).[3–5] The amount of decentration correlates with greater attempted correction and with smaller ablation zones.[6] Excimer laser systems using mask techniques (for example, handheld rotating or erodible masks) or with smaller ablation zones are more likely to result in eccentric ablations. The incorporation of eye-tracking systems in the excimer laser units has substantially reduced, but not eliminated, the incidence of ablation zone decentration.[7] Nonetheless, several patients who have been treated with first- and second-generation laser systems require retreatment for correction of eccentric ablation. Furthermore, an active eye-tracking system alone cannot ensure proper centration. Additional factors may also affect the centra-

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tion of the ablation, including the surgeon's experience and patient-related factors such as cooperation, fixation, saccadic eye movement, and misalignment of the patient's head relative to the laser.[6]

Customized ablations have been shown to be effective for the treatment of corneal irregularities of various etiologies.[8–12] The purpose of this article is to evaluate prospectively the efficacy, safety, and predictability of a new customized topographically supported ablation technique (that is, TOSCA) for the treatment of eccentric post-LASIK optical zones.

METHODS

THE STUDY INCLUDED NINE CONSECUTIVE PATIENTS (11 eyes; seven men and two women, aged 21–37 years [mean age: 28.56 ± 5.77]) who had undergone eccentric LASIK (at the Vardinoyannion Eye Institute of Crete). Two patients had bilateral eccentric ablation, and the remaining patients had unilateral procedures. Factors that contributed to ablation decentration were patients' minimal cooperation, loss of eye fixation, and misalignment of the patients' head in relation to the laser.

All patients complained of halos and image distortion, occurring both at night and during the day. All patients had undergone LASIK treatment following the creation of a nasally hinged corneal flap 8.5 mm in diameter using an automated microkeratome (Flapmaker Disposable Microkeratome, Refractive Technologies, Cleveland, OH, United States). Mean preoperative spherical equivalent (SE) refraction was –5.50 ± 2.72 diopters (range, −8.25 to +1.50 diopters). Pre-LASIK uncorrected visual acuity was uniformly poor at counting fingers (CF). Best-corrected visual acuity averaged 0.89 ± 0.29 (range, 0.4–1.2). All treatments were performed as a one-step procedure, aimed at emmetropia. Intraoperative (after flap lifting) ultrasonic pachymetry was used in all eyes to determine flap and residual corneal bed thickness (mean flap thickness was 125.83 ± 20.96; range, 100–147 μm). The diameter ablation was 7.0 mm (MEL 70 G-Scan, excimer laser, Carl Zeiss-Meditec, Jena, Germany). The MEL-70 is a Gaussian scan flying spot excimer laser system that uses an artificial limbus ring, which is placed on the eye to serve as a target for the eye tracker. The eye tracker is logged on this ring, and fine centration adjustments are made via the laser system software. Decentration may result from either improper ring and head placement resulting from the surgeon's lack of experience or the patient's minimal cooperation and improper fixation.

The mean time between primary LASIK treatment and the TOSCA enhancement procedure was at least 7 months (mean time, 14.10 ± 5.43 months [range, 7–27 months]). In eight eyes (73%), a second procedure was performed more than 12 months after the initial LASIK, following stabilization of corneal curvatures as shown in topographic maps (that is, less than 1 diopter change in difference between two consecutive topographies and manifest refraction). A complete ophthalmologic examination was performed preoperatively to exclude ocular disease. Pre- and postoperative follow-up included examination for uncorrected visual acuity (decimal scale), best-corrected visual acuity (decimal scale), manifest refraction, higher order aberrations, and subjective symptoms. Corneal topography (Tomey, TMS-2N Corneal Topographer, Erlangen-Tennenlohe, Germany) was used to evaluate the ablation zone diameter, its decentration from the vertex normal, the pupil center, and the axis of decentration. Decentration was determined by calculating the distance between the center of the optical zone and the entrance pupil center using the difference elevation map (derived by subtracting the preoperative from the postoperative topographic map).

The WASCA aberrometer (Carl Zeiss-Meditec, Jena, Germany), which includes a Shack-Hartman wavefront, was used for recording low- and high-order aberrations of the eye. Root mean square (RMS, μm) wavefront error was used as a measure of optical quality before and following the TOSCA procedure, and 5-mm pupil area was used for analysis (two patients had 5.2-mm scotopic pupil diameter) to avoid the possible increase variance near the pupil margins and the effect of dilation drops.

Subjective symptoms such as glare, halos, ghost images, and monocular diplopia were also recorded. Postoperative visits were scheduled for days 1, 3, 15, and 30 and every 3 months thereafter.

All patients were appropriately informed before their participation in the study and gave their written informed consent in accordance with institutional guidelines, according to the Declaration of Helsinki.

The surgical procedure was performed under topical anesthesia. The cornea was marked with a corneal marker. A Sinskey hook was used to lift and dissect the peripheral edges of the flap, which was then peeled back nasally toward the hinge. Intraoperative ultrasonic pachymetry (50 m-Hz, Corneo-GAGE, Sonogage, Cleveland, Ohio) after flap lifting was performed in all eyes to determine flap and residual corneal bed thickness after stromal ablation (residual bed thickness after stromal ablation was greater than 250 μm in all eyes). Ablation was performed on the stromal bed by transferring (via floppy disk) the programmed ablation from the corneal topographic elevation map to the excimer laser. The flap was repositioned in the same manner as in the initial LASIK procedure.

All procedures were uneventful, and there were no disruptions of the LASIK flap in any patient. Postoperatively, all eyes received antibiotic-corticosteroid combination eye drops four times a day for 1 week and preservative-free artificial tears for 1 month.

Group differences for continuous variables were tested using the unpaired and paired Student *t* tests. Results are

TABLE 1. Pre- and Post-TOSCA Uncorrected (UCVA) and Best-Corrected Visual Acuity (BSCVA), Manifest Refraction (MR), Astigmatism, Root-Mean-Square Wavefront Error (RMS), Amount of Decentration (mm), and Subjective Symptoms

	Pre-TOSCA	Post-TOSCA	*P* Value
UCVA (decimal scale)	0.45 ± 0.16 (0.2 to 0.7)	0.76 ± 0.29 (0.2 to 1.2)	<.001
BSCVA (decimal scale)	0.74 ± 0.22 (0.4 to 1.0)	0.95 ± 0.20 (0.6 to 1.2)	.002
MR (spherical equivalent, diopters)	−0.14 ± 1.58 (−1.75 to +3.00)	+0.46 ± 1.02 (−1.00 to +1.75)	.76
Astigmatism (diopters)	−1.55 ± 0.60 (−3.00 to 0.75)	0.70 ± 0.56 (−2.00 to 0.25)	.003
RMS (μm)	0.611 ± 0.290	−0.370 ± 0.137	.04
Eccentricity (mm)	1.59 ± 0.46 (0.88 to 2.23)	0.29 ± 0.09 (0.18 to 0.44)	<.001
Subjective symptoms (number of eyes)	11	0	

presented as mean ± SD. A *P* value less than .05 was regarded as statistically significant.

RESULTS

MEAN FOLLOW-UP AFTER TOSCA WAS 9.22 ± 2.82 MONTHS (range, 6–12 months). The data of the last follow-up visit of each patient was recorded and selected for data analysis.

Mean uncorrected visual acuity significantly improved from 0.45 ± 0.16 (range, 0.2–0.7) to 0.76 ± 0.29 (range, 0.2–1.2) at the last follow-up examination ($P < .001$; Table 1). Of the 11 eyes, only one maintained preoperative uncorrected visual acuity; 10 eyes experienced 2 to 7 lines gain. Mean difference between preoperative and postoperative uncorrected visual acuity was a gain of 3.6 lines (range, unchanged uncorrected visual acuity to 7-line gain).

The mean best-corrected visual acuity significantly improved from 0.74 ± 0.22 (range, 0.4–1.0) to 0.95 ± 0.20 (range, 0.6–1.2; $P = .002$; Figure 1, A); there was no statistically significant change compared with pre-LASIK values (pre-LASIK: 0.89 ± 0.29 [range, 0.4 to 1.2]; post-TOSCA: 0.95 ± 0.20 [range, 0.6 to 1.2] $P = .28$; Table 1, Figure 1, B). Of the 11 eyes, two maintained pre-TOSCA best-corrected visual acuity, and the rest (nine eyes), experienced a gain of 1 to 5 lines (Figure 1, A). Mean difference between pre-TOSCA and last follow-up after TOSCA was a gain of 2.0 ± 1.6 lines (range, unchanged to 5 lines gain).

Topographic analysis showed that the average decentration was reduced from 1.59 ± 0.46 mm (range, 0.88–2.23 mm) to 0.29 ± 0.09 mm (range, 0.18–0.44 mm; $P < .001$; Figure 2; Table 1). Treatment depths were 41.78 ± 9.20 μm (range, 30–60 μm). Spherical equivalent did not change significantly after TOSCA (pre-TOSCA: −0.14 ± 1.58 diopters [range, –1.75 to +3.00 diopters] to +0.46 ± 1.02 diopters [range, −1.00 diopters to +1.75 diopters]; $P = .76$) at last follow-up (Table 1). There was a statistically significant reduction in astigmatic error: –1.55 ± 0.60 diopters (range, −3.00 to –0.75 diopters) to –0.70 ± 0.56 diopters (range, −2.00 to 0.25 diopters; $P = .003$).

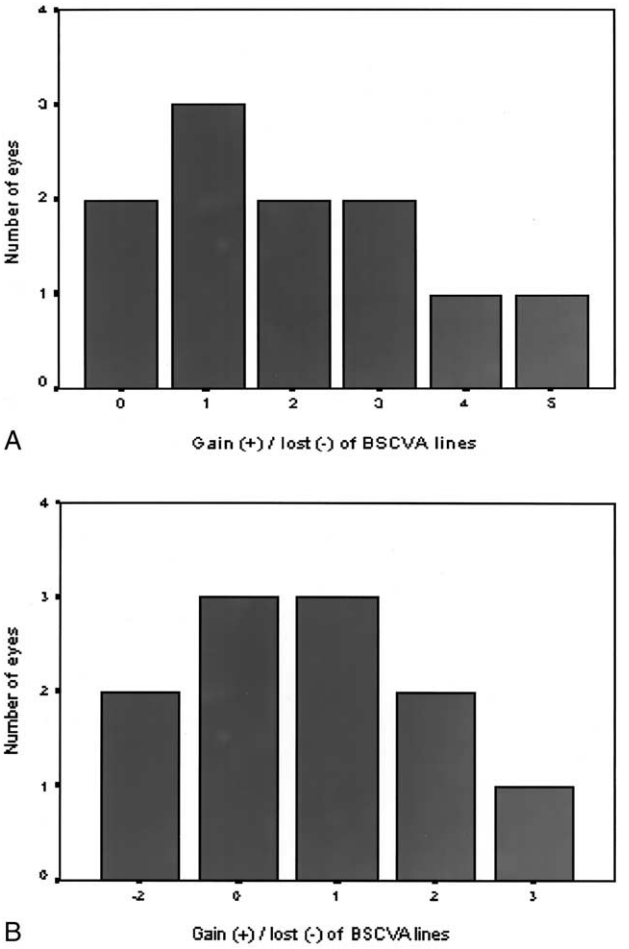

FIGURE 1. Changes in best-corrected visual acuity (decimal scale) after topographically supported customized ablation (TOSCA) treatment compared with pre-TOSCA (A) and pre-LASIK (B) values.

There was a statistically significant decrease in the higher-order wavefront aberrations after TOSCA correction for the 5-mm pupil diameter (RMS: pre-TOSCA: 0.611 ± 0.290 to post-TOSCA: 0.370 ± 0.137, $P = .04$). Specifically, a significant reduction of

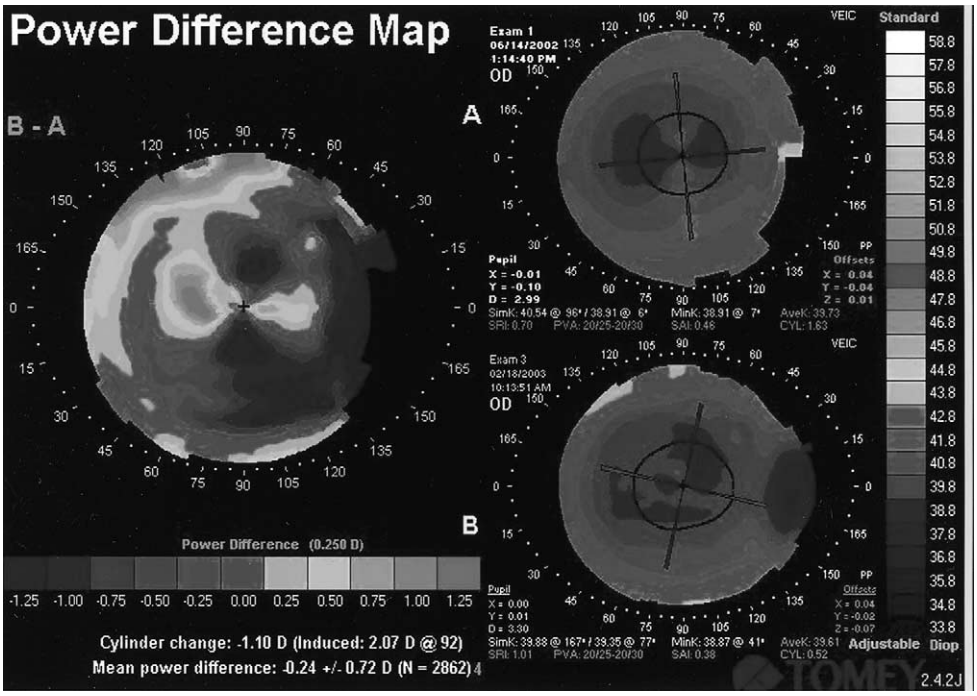

FIGURE 2. Topographic maps (A) before (showing an eccentric ablation with irregular astigmatism) and (B) after topographically supported customized ablation treatment (showing a uniform and recentered ablation); difference map reveals the planned ablation.

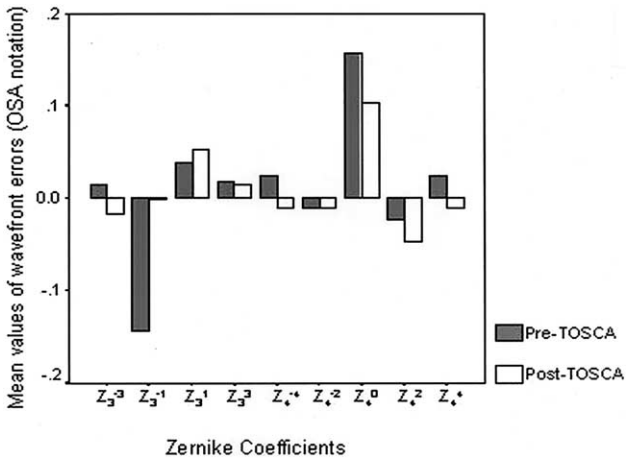

FIGURE 3. Mean values of wavefront errors (Optical Society of America [OSA] notation) before and after topographically supported customized ablation.

2third-order coma along vertical axis (Z_3^{-1}) was found (pre-TOSCA: −0.143 ± 0.327 μm [range −0.72 to 0.19] to post-TOSCA: −0.001 ± 0.132 μm [range −0.28 to 0.08]; Figure 3).

Subjective symptoms (glare, halos, ghost images, and monocular diplopia) were present preoperatively in all eyes, while none of them were reported postoperatively. Monocular diplopia, present in three eyes (27%) preoperatively, was resolved after TOSCA treatment.

DISCUSSION

THE NUMBER OF REFRACTIVE OPERATIONS INCREASES EVery year, and these procedures have gained worldwide acceptance for their safety. With accumulating experience and the application of more sophisticated techniques, the safety and efficacy of refractive surgery has increased considerably in recent years. In addition, patient satisfaction and complications, together with surgeons' clinical suggestions, are being evaluated to determine the maximum efficacy following refractive surgery.

Laser in situ keratomileusis for the surgical correction of myopia is rapidly becoming the most common refractive surgical procedure worldwide. Quick visual rehabilitation, minimal postoperative discomfort, and the ability to correct high degrees of myopia with slight postoperative complications are among the reasons for LASIK's popularity over other refractive surgical options.

Low values of decentrations (eccentrations of 0.5–1.0 mm) could affect low-contrast visual acuity[13] and induce wavefront higher-order aberrations.[14] When a significant decentration (more than 1.0 mm) occurs, visual performance is highly compromised; symptoms such as glare, asymmetric halos (due to a prismatic effect that is more pronounced at night), and diplopia (mainly due to induced multifocality of the cornea) have been reported.[15] In addition, eccentric optical zone may produce ghost images, which further reduce visual acuity, particularly when the

central zone of the uniform power is restricted to a small portion of the corneal surface.

Several attempts have been made to correct eccentric ablations.[16–18] Management of this complication aims to restore a normal topographic map, either with enlargement of the central ablated area using arcuate cuts[16] or with supplemental ablation post–photorefractive keratectomy, which can be diagonal or masked.[17] Retreatment of decentered ablation by means of a second photorefractive keratectomy procedure (opposite of the initial ablation) is suggested by Seiler and associates,[17] whereas Pallikaris and associates[16] treated eccentric post-LASIK ablations using arcuate cuts. They suggested that the smaller the optical zone of the cuts, the more effective they were. In cases of severe decentered ablation, however, a longer arcuate cut (90 degrees) was recommended. The disadvantages of these methods are that diametral ablation can only be performed in previous PRK eccentrations, and arcuate cuts result in regression of their effect, especially in younger patients, and are effective only in small eccentric ablations.[16,17]

Recently, several topographically driven customized ablations have been performed for corneal irregularities treatment, with varied results.[8–12] The visual benefits of customized ablation include reduction in irregular astigmatism, improvement of visual acuity, and reduction of preoperative symptoms. Knorz and Jendritza[10] and Wiesinger-Jendritza and associates[19] reported a high incidence of undercorrection and regression after topographically driven customized ablations, whereas other studies have reported satisfactory results from this procedure in eccentric myopic photorefractive keratectomy[8] and for the correction of postkeratoplasty astigmatism.[9]

In our study, the average decentration was significantly reduced, resulting in an overall improvement in visual acuity. The amount of eccentricity following TOSCA treatment was less than 0.5 mm. This includes the upper limit, beyond which decentrations have an influence on postoperative visual function.[20] Furthermore, there was a statistically significant reduction in higher-order aberrations and in patients' subjective symptoms.

There were no statistically significant differences in manifest refraction (spherical equivalent) following TOSCA treatment, although a statistically significant reduction in astigmatism was observed. This is an important finding, especially with regard to emmetropic patients, because it allows us to correct eccentric ablations with a reduced risk of overcorrection.

An important advantage of this method is that in contrast with wavefront-guided customized ablation, patients with large decentrations and increased amounts of high-order aberrations (out of dynamic range of many aberrometers) may be good candidates for TOSCAs.

Several questions arise from this case series. When is the proper time to perform retreatment with TOSCA? In our studies, the minimum time since previous LASIK was at least 7 months. Another issue involves comparison of recutting the cornea versus lifting the flap. If cutting of the cornea with a microkeratome induces any topographic alterations, this method would be inappropriate for customized ablations.

Corneal healing after surgery may also affect treatment outcome and should be taken into consideration.[21] Although stromal remodeling is considered minimal after LASIK, hyperplasia of the corneal epithelium may occur, which may be responsible for refractive regression during the first months following LASIK.

Although the TOSCA procedure was shown to be safe in our series of patients, this remains to be confirmed in prospective trials with larger samples. Once it has been proven a safe and effective procedure, topographically guided LASIK may be applicable to posttrauma eyes and to eyes with irregular astigmatism.

REFERENCES

1. Sugar A, Rapuano CJ, Culbertson WW, et al. Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. Ophthalmology 2002;109:175–187.
2. Swawi AU, Steinert RF, Osborne WE, White AA. Rotational malposition during laser in situ keratomileusis. Am J Ophthalmol 2002;133:561–562.
3. Pallikaris IG, Kymionis GD, Astyrakakis NI. Corneal ectasia induced by laser in situ keratomileusis. J Cataract Refract Surg 2001;27:1796–1802.
4. Webber SK, McGhee NJ, Bryce IG. Decentration of photorefractive ablation zones after excimer laser surgery for myopia. J Cataract Refract Surg 1993;22:299–303.
5. Pallikaris IG, Siganos DS. Excimer laser in situ keratomileusis and photorefractive keratectomy for correction of high myopia. J Refract Corneal Surg 1994;10:498–510.
6. Tsai YY, Lin JM. Ablation centration after active eye-tracker-assisted photorefractive keratectomy and laser in situ keratomileusis. J Cataract Refract Surg 2000;26:28–34.
7. McDonald MB, Carr JD, Frantz JM, et al. Laser in situ keratomileusis for myopia up to −11 diopters with up to −5 diopters of astigmatism with the summit autonomous LADAR Vision excimer laser system. Ophthalmology 2001; 108:309–316.
8. Alessio G, Boscia F, La Tegola MG, Sborgia C. Topography-driven excimer laser for the retreatment of decentralized myopic photorefractive keratectomy. Ophthalmology 2001; 108:1695–1703.
9. Alessio G, Boscia F, La Tegola MG, Sborgia C. Corneal interactive programmed topographic ablation customized photorefractive keratectomy for correction of postkeratoplasty astigmatism. Ophthalmology 2001;108:2029–2037.
10. Knorz MC, Jendritza B. Topographically-guided laser in situ keratomileusis to treat corneal irregularities. Ophthalmology 2000;107:1138–1143.
11. Knorz MC, Neuhann T. Treatment of myopia and myopic astigmatism by customized laser in situ keratomileusis based on corneal topography. Ophthalmology 2000;107: 2072–2076.
12. Alessio G, Boscia F, La Tegola MG, Sborgia C. Topography-driven photorefractive keratectomy: results of corneal inter-

active programmed topographic ablations software. Ophthalmology 2000;107:1578–1587.
13. Verdon W, Bullimore M, Maloney RK. Visual performance after photorefractive keratectomy; a prospective study. Arch Ophthalmol 1996;144:1465–1472.
14. Mrochen M, Kaemmerer M, Mierder P, Seiler T. Increased higher-order optical aberrations after laser refractive surgery; a problem of subclinical decentration. J Cataract Refract Surg 2001;27:362–369.
15. Doane JF, Cavanaugh TB, Durrie DS, Hassanein KM. Relation of visual symptoms to topographic ablation zone decentration after excimer laser PRK. Ophthalmology 1995; 102:42–47.
16. Pallikaris IG, Xirafis ME, Naoumidis LP, Siganos DS. Arcuate transverse keratotomy with a mechanical arcutome based on videokeratography. J Refract Surg 1996;12:S296–S299.
17. Alkara N, Genth U, Seiler T. Diametral ablation—a technique to manage decentered photorefractive keratectomy for myopia. J Refract Surg 1999;15:436–440.
18. Pallikaris I, Panagopoulou S, Katsanevaki V. The PALM technique: photoablated lenticular modulator. In: Pallikaris I, Siganos D, editors. LASIK. Thorofare, NJ: Slack, 1997: 277–278.
19. Wiesinger-Jendritza B, Knorz MC, Hugger P, Liermann A. Laser in situ keratomileusis assisted by corneal topography. J Cataract Refract Surg 1998;24:166–174.
20. Amano S, Tanaka S, Shimizu K. Topographical evaluation of centration of excimer laser myopic photorefractive keratectomy. J Cataract Refract Surg 1994;20:616–619.
21. Mitooka K, Ramirez M, Maguire LJ, et al. Keratocyte density of central human cornea after laser in situ keratomileusis. Am J Ophthalmol 2002;133:307–314.