

Two-step LASIK With Topography-guided Ablation to Correct Astigmatism After Penetrating Keratoplasty

Alessandro Mularoni, MD; Gian Luca Laffi, MD; Leona Bassein, Cstat; Giorgio Tassinari, MD

ABSTRACT

PURPOSE: To assess the efficacy, predictability, stability, and safety of a two-step LASIK procedure using topography-guided ablation to correct astigmatism after penetrating keratoplasty.

METHODS: Fifteen eyes of 15 patients underwent a two-step LASIK procedure at the Maggiore Hospital of Bologna, Italy. In the first step, a flap was created using the Hansatome microkeratome. In the second step, topography-guided ablation using the LaserSight LSX was planned with interactive software (CIPTA) once topographical and refractive stabilization had been obtained. Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), cylindrical correction, gain of lines of BSCVA, spherical equivalent refraction, and complications were analyzed.

RESULTS: Minimum follow-up was 12 months (range: 12 to 30 months). Uncorrected visual acuity improved in all 15 (100%) eyes. At the last postoperative examination, 11 (73%) eyes had UCVA \geq 20/40. Nine (60%) eyes were within 1.0 diopter (D) of the attempted correction. Mean postoperative astigmatism was -1.67 (range: -3.5 to 0 ; standard deviation: 1.26). Index of success of astigmatic correction was 0.26 . No patient lost Snellen lines of BSCVA. Intraoperative complications included two buttonhole flaps, and postoperative complications included one flap retraction. No further laser treatment was needed.

CONCLUSIONS: The two-step LASIK procedure using topography-guided ablation reduces spherical and cylindrical refractive error due to penetrating keratoplasty. Topography-guided ablation also proved to be effective in correcting irregular astigmatism. [*J Refract Surg.* 2006;22:67-74.]

Several studies have considered the safety and effectiveness of excimer laser use after penetrating keratoplasty.¹⁻⁴ Photorefractive keratectomy (PRK) was successful in treating myopia and astigmatism, but showed a high incidence of complications (eg, reactivation of herpes simplex keratitis and corneal graft rejection) when performed after penetrating keratoplasty.^{1,2,5}

Photorefractive keratectomy following penetrating keratoplasty is associated with increased incidences of irregular astigmatism, corneal scarring, and regression.³ In a multicenter trial, Maloney et al⁶ reported a 29% rate of loss of two or more lines of visual acuity in eyes treated with PRK after anterior segment ocular surgeries. Other authors consider LASIK safe and effective in correcting refractive error after penetrating keratoplasty.⁷ Over time it became clear that the lamellar cut may modify the corneal shape, hence some authors⁸⁻¹² suggested a two-step technique. Topography-guided ablation has been shown to be an effective procedure to treat irregular astigmatism.^{4,13,14} The use of both techniques seems to be a logical approach to treating highly irregular refractive defects. This article evaluates the efficacy, predictability, stability, and safety of two-step LASIK using topography-guided ablation in consecutive eyes that had undergone penetrating keratoplasty.

PATIENTS AND METHODS

Fifteen eyes of 15 consecutive patients (6 women and 9 men) with significant postoperative refractive errors after penetrating keratoplasty were included in the study. The grafts were performed for keratoconus in 9 eyes, bullous keratopathy in 2 eyes, corneal scarring after herpetic keratitis in 2 eyes, corneal scarring after penetrating injury in 1 eye, and corneal scarring after PRK in 1 eye. Only eyes unsatisfied

From the Department of Ophthalmology, Maggiore Hospital, Bologna, Italy.

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Correspondence: Alessandro Mularoni, MD, Maggiore Hospital, L. Nigrisoli, 2 - 40133 Bologna, Italy. Tel: 39 051 6478608; Fax: 39 051 6478945; E-mail: alessandro.mularoni@ausl.bologna.it

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TABLE

Pre- and Postoperative Data of 15 Patients Who Underwent Two-step LASIK

Patient No./ Sex/Age (y)	Eye	Diagnosis	Graft-ablation Interval (mos)	Preoperative		
				UCVA	BSCVA	Refraction
1/M/38	Right	Keratoconus	132	CF	20/25	+3.0 -9.0 × 45
2/M/40	Right	Keratoconus	30	CF	20/25	+1.0 -13.0 × 145
3/F/36	Right	Leukoma	17	CF	20/40	-7.0 -6.0 × 140
4/M/40	Right	Keratoconus	72	20/63	20/25	-1.25 -5.0 × 30
5/M/29	Left	Keratoconus	30	20/100	20/32	-1.5 -5.5 × 20
6/M/45	Left	Leukoma	30	20/100	20/32	-2.0 -5.0 × 110
7/M/52	Left	Keratoconus	30	20/400	20/40	+5.0 -11.0 × 115
8/F/33	Left	Keratoconus	36	20/400	20/32	-1.0 -4.0 × 125
9/M/58	Right	Bullous keratopathy	16	20/63	20/25	+3.5 -6.0 × 110
10/M/24	Left	Leukoma	30	20/100	20/40	+6.0 -9.0 × 150
11/F/67	Right	Bullous keratopathy	30	CF	20/200	0.00 -10.0 × 120
12/F/43	Left	Keratoconus	168	20/400	20/25	-0.5 -8.5 × 100
13/M/29	Left	Keratoconus	66	20/400	20/25	-3.0 -4.5 × 180
14/F/29	Right	Keratoconus	20	20/200	20/25	-5.0 -1.0 × 5
15/F/64	Left	Leukoma	25	20/200	20/32	-8.0 -2.75 × 25

UCVA = uncorrected visual acuity, BSCVA = best spectacle-corrected visual acuity, CF = counting fingers

with spectacle or contact lens correction were considered for LASIK. All eyes enrolled for the study were examined at the Maggiore Hospital in Bologna, Italy after informed consent was obtained.

Average patient age at the time of LASIK was 42 years (range: 22 to 66 years). All eyes had clear corneal grafts and stable refractive errors after all sutures were removed (range: 4 to 80 months). Minimum time from penetrating keratoplasty to LASIK was 16 months (range: 16 months to 6 years). Elevation maps were obtained using Orbscan II (Bausch & Lomb, Rochester, NY). Two acquisitions were required whose height difference in the corneal central zone (5 mm) did not differ more than 3 μm . The pupil diameter was measured under scotopic conditions using the infrared camera of the laser eye tracker. The Corneal Interactive Programmed Topographic Ablation (CIPTA) computer program (Ligi, Taranto, Italy) was used for planning the ablation projects to exclude those eyes with a calculated corneal bed thickness <250 μm . Exclusion criteria were wound ectasia or corneas having steep anterior meridian power >53 diopters (D) and corneas with significant vascularization. Mean follow-up was 21 months (range: 12 to 30). No patients exited from this study.

Pre- and postoperatively all eyes underwent a full

ocular examination including medical history, uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA), corneal topography, keratometry, ultrasonic pachymetry (Optikon 2000; Rome, Italy), manifest and cycloplegic refraction with cyclopentolate by autorefractometry (Topcon RM 8000; Topcon Corp, Nagoya, Japan), applanation tonometry, slit-lamp microscopy, and fundus examination.

SURGICAL TECHNIQUE

Surgery was performed under topical anesthesia (oxybuprocaine). The Hansatome microkeratome (Bausch & Lomb) was used to create a superiorly hinged corneal flap with a diameter of 8.5 or 9.5 mm and a thickness of 160 or 180 μm depending on the case. The flap was lifted with a spatula to check its integrity; ultrasonic pachymetry was done and the flap was replaced. After refractive stabilization, intended as a difference in manifest refraction spherical equivalent to <1.0 diopter (D) in two consecutive examinations, the flap was lifted again and the stromal bed was treated with the LaserScan LSX (LaserSight Technologies, Winter Park, Fla) in a topography-guided ablation pattern. The main laser characteristics were: Gaussian spot type, flying spot 0.8 mm, 200 Hz repetition rate, and active video eye tracker.

After Lamellar Cut			After Excimer Ablation			Follow-up (mos)
UCVA	BSCVA	Refraction	UCVA	BSCVA	Refraction	
CF	20/25	+3.0 -8.0 × 43	20/25	20/20	+2.0 -2.0 × 130	15
CF	20/25	+1.0 -11.75 × 140	20/20	20/20	Plano	30
CF	20/40	-7.0 -7.0 × 135	20/100	20/25	-2.75 -1.5 × 150	26
20/63	20/25	+1.0 -5.0 × 30	20/20	20/20	Plano	24
20/100	20/32	0.00 -3.5 × 18	20/40	20/20	+0.5 -2.5 × 170	22
20/100	20/40	-2.5 -5.0 × 110	20/40	20/25	-1.25 -3.0 × 105	21
20/400	20/40	+5.0 -11.0 × 115	20/100	20/25	+4.0 -3.5 × 150	24
20/400	20/25	-1.0 -4.0 × 125	20/40	20/25	-0.5 -0.75 × 105	22
20/63	20/25	+3.0 -6.0 × 100	20/25	20/20	0.00 -1.5 × 110	30
20/100	20/40	+6.0 -7.5 × 150	20/80	20/40	+3.75 -2 × 150	19
20/400	20/100	-1.0 -8.0 × 115	20/200	20/100	0.00 -3.5 × 130	20
20/400	20/25	0.00 -8.5 × 95	20/63	20/25	0.00 -2.75 × 95	13
20/80	20/25	-3.0 -3.5 × 5	20/25	20/20	-1.0 -0.5 × 130	15
20/200	20/25	-5.0 -2.5 × 5	20/32	20/20	-0.5 -1.0 × 150	12
20/100	20/50	-8.0 -3.5 × 10	20/32	20/32	Plano	15

CIPTA was used to prepare the ablation pattern. CIPTA is an interactive software program that links data obtained with use of the elevation Orbscan tomography to those of a flying-spot excimer laser to develop a topography-guided ablation pattern. It uses the topographic altimetric data, as well as parameters relating to refraction and transition intended as the area linking treated with untreated cornea. Topography-guided ablation, especially because it takes pre-existing irregular astigmatism into account, aims at making the cornea as regular as possible.

The apex of the cornea was chosen as the center of the ablation. The minimum optical zone was selected according to the scotopic pupil diameter. The postoperative asphericity index was 0. The lowest keratometric reading in the scotopic pupil area was selected and its value was used together with the eye refraction to calculate the desired postoperative keratometry. The transition zone was selected to obtain a mean constant slope in radial direction on 360°.

Each eye was examined at the slit-lamp 1 to 2 hours after surgery to check for debris and misalignment of the corneal flap before discharge from the hospital with a transparent shield.

Patients were instructed to use tobramycin/dexa-

methasone 4 times daily for 15 days and then 2 times daily for 15 more days, and diclofenac 4 times daily for the first 3 days.

Routine postoperative examinations including UCVA and BSCVA were scheduled at 1 day, 3 days, 1 week, and 1, 2, 3, 6, 9, and 12 months.

STATISTICAL ANALYSIS

Data were collected using specially designed forms (StatXact; Cytel Software Corp, Cambridge, Mass). A basic analysis was planned to include all eyes up to the required 12-month minimum follow-up interval for all patients.

Blyth-Still-Casella confidence intervals were used for the binomial distribution and for proportions. Vector analysis of astigmatism, according to Alpíns' method,¹⁵ was based on the refractive data.

RESULTS

After lamellar cut, topographic and refractive stabilization were obtained in all 15 eyes within a mean of 45 days (range: 22 to 104 days; standard deviation [SD] 19). Pre- and postoperative data are shown in the Table. Minimum follow-up was 12 months (range: 12 to 30 months; SD 6).

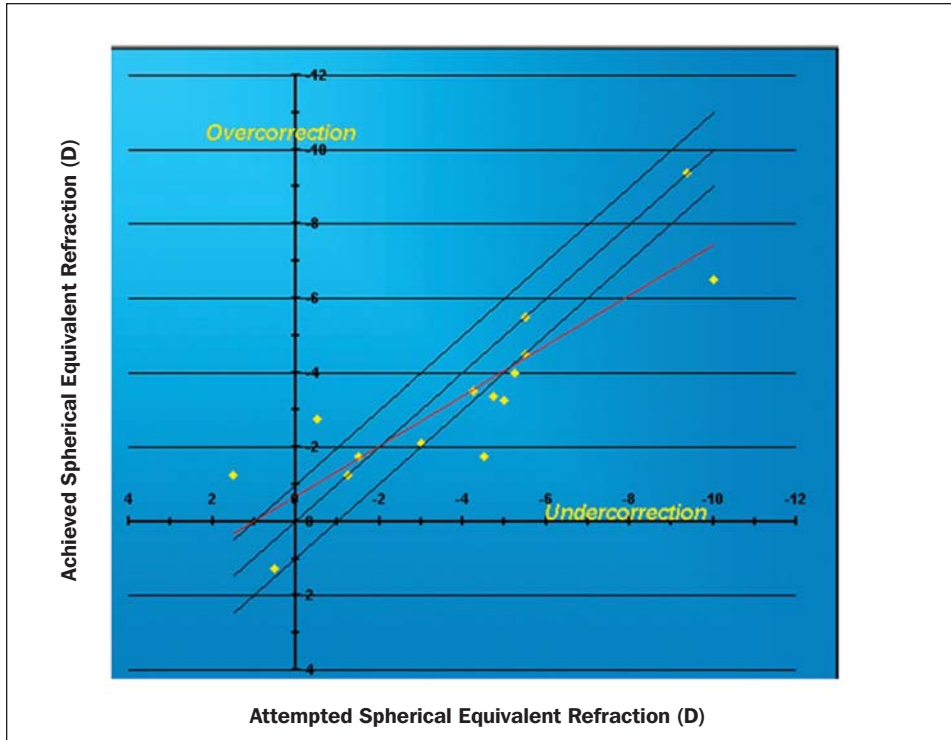


Figure 1. Predictability. Spherical equivalent refraction during postoperative follow-up (12 months).

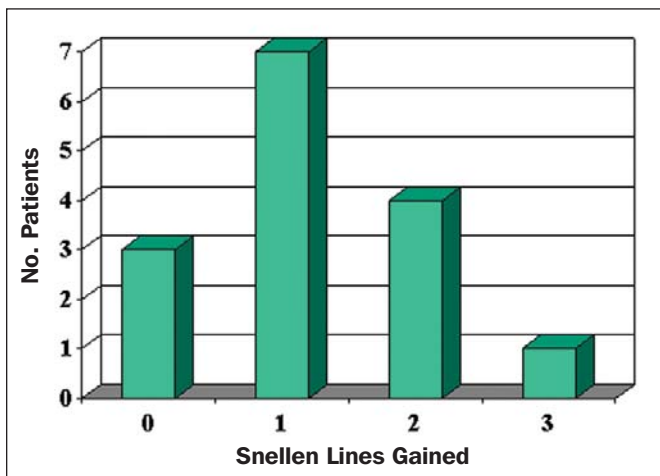


Figure 2. Safety. Changes in BSCVA at 12 months.

Uncorrected visual acuity improved in all eyes from 20/160 preoperatively (range: counting fingers to 20/63) to 20/40 at 12-month follow-up (range: 20/200 to 20/20). At 12-month follow-up, 10 (66.6%) eyes had UCVA \geq 20/40, 2 (13.3%) eyes had UCVA of 20/20, 2 (13.3%) eyes had UCVA of 20/100, and 1 (6.6%) eye had UCVA of 20/200; no eyes had preoperative UCVA of 20/20.

PREDICTABILITY

Mean preoperative spherical equivalent refraction was -3.86 D (range: -10.0 to $+1.5$ D; SD 3.27). At 12-month follow-up, mean spherical equivalent refraction

was -0.58 D (range: -3.5 to $+2.75$ D; SD 1.62); 8 (53.3%) eyes were within 1.0 D of the attempted correction and 14 (93.3%) eyes were within 2.75 D (Fig 1).

Mean preoperative refractive cylinder was -6.68 D (range: -1.0 to -13.0 D; SD 3.29). At 12-month follow-up, mean postoperative refractive cylinder was -1.67 D (range: 0 to -3.5 ; SD 1.26). The mean percentage of cylindrical correction was 75% of the attempted correction.

Target induced astigmatism (ie, the desired target correction) was 6.68 D (SD 3.22). Surgical induced astigmatism (ie, the achieved astigmatic outcome) was 6.13 D (SD 3.6). The magnitude of error, which is the difference between surgical induced astigmatism and target induced astigmatism, was -0.47 (SD 1.37). The magnitude of error is positive when the vector of the surgical induced astigmatism is higher than the vector of the target induced astigmatism correction and negative when it is lower. The angle of error, which is the angle described by the vectors of achieved correction (surgical induced astigmatism) versus intended correction (target induced astigmatism), was 2.8 (SD 8.4). The angle of error is positive if the achieved correction is on an axis counterclockwise to where it was intended and negative if the achieved correction is clockwise to its intended axis. Difference vector (ie, the induced astigmatic change that would enable the initial surgery to achieve its intended target) was 1.46 (SD 1.13). The index of success, calculated by dividing the difference vector by the target induced astigmatism, was 0.26.

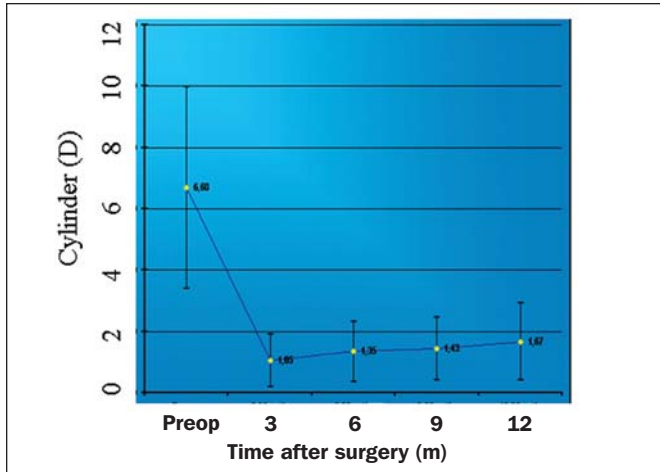


Figure 3. Cylinder stability over time. Error bars indicate standard deviation.

SAFETY

None of the eyes lost Snellen lines of BSCVA (95% confidence interval [CI], 78.7% to 100%) (Fig 2). Mean BSCVA improved from 20/32 (range: 20/200 to 20/25) preoperatively to 20/25 (range: 20/100 to 20/20) postoperatively.

STABILITY

Spherical equivalent refraction from 1- to 6-month follow-up was stable within 1.0 D in 14 (93.3%) eyes, but changed from plano to -1.25 D in 1 (6.7%) eye (patient 13). From 6- to 12-month follow-up, 13 (86.6%) eyes were stable within 1.0 D, 1 eye (patient 3) changed from -1.75 D to -3.5 D and 1 eye (patient 10) changed from $+1.5$ D to $+2.75$ D (Figs 3 and 4).

COMPLICATIONS

Intraoperative complications included two button-holes (patients 3 and 5). In these cases, the average keratometric values were 52 and 52.5 D, respectively. The flap was immediately repositioned, and 3 months passed before repeating the lamellar cut with 180- μ m of thickness. The second flap was created without complications.

Postoperative complications included cellular interface debris without diffuse lamellar keratitis, making it necessary to relift and irrigate the interface (patient 8). Flap retraction, probably due to dehydration in a thin flap, occurred in patient 6, who had a long ablation time and poor cooperation. No eye needed laser retreatment.

CASE REPORT

A 40-year-old man (patient 2) underwent penetrating keratoplasty in 1998 for keratoconus. Preoperative UCVA was counting fingers and BSCVA was 20/25

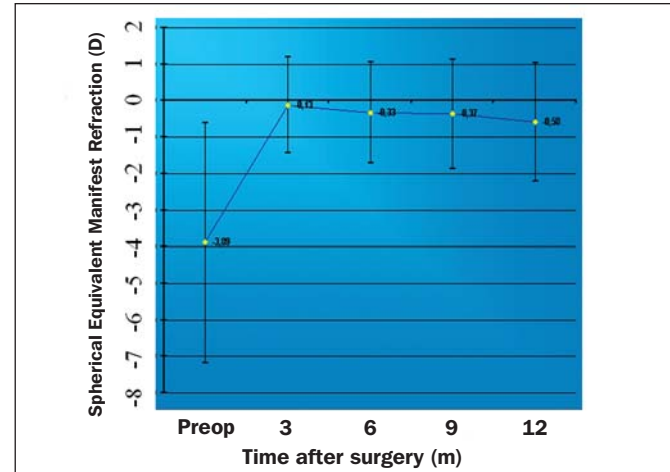


Figure 4. Spherical equivalent refraction stability over time. Error bars indicate standard deviation.

with $+1.0 -13.0 \times 145$. In May 2000, lamellar cut was performed and 45 days postoperatively, UCVA was counting fingers and BSCVA was 20/25 with $+0.75 -11.75 \times 140$. At this time, the flap was lifted and a topography-guided laser ablation was performed to correct astigmatism (Figs 5 and 6). No complications occurred, and 3 months after laser ablation UCVA was 20/20 with no refractive error, which remained unchanged over 2 years.

DISCUSSION

Penetrating keratoplasty has become a common and successful procedure.¹ Unfortunately, regular and irregular astigmatism, as well as spherical refractive error, remain major limitations to visual rehabilitation. Many studies cite a mean astigmatism of 4.0 to 6.0 D (range: 0 to ≥ 20 D) and significant anisometropia after penetrating keratoplasty.¹⁶⁻¹⁸ Three diopters of anisometropia, which induce image size disparity, and astigmatism >1.5 to 3.0 D will not be tolerated by most eyes.^{3,19} Anisometropia in an undercorrected eye may result in headache, photophobia, burning, tearing, diplopia, and blurred vision.³

Eyes that cannot be rehabilitated with spectacle or contact lens correction can be helped by means of an additional surgical procedure. Various types of corneal resections or relaxing incisions have been used including combined arcuate and semiradial incisions, circumferential relaxing incisions, and compression sutures, but poor predictability represents a major limitation for all of these procedures.^{20,21}

Toric intraocular lenses are of limited use due to the fact that available cylinder includes only 2.0, 3.5, and 4.0 D. Other disadvantages include the possible occurrence of rotation,²² and the fact that good results are possible only for regular astigmatism.

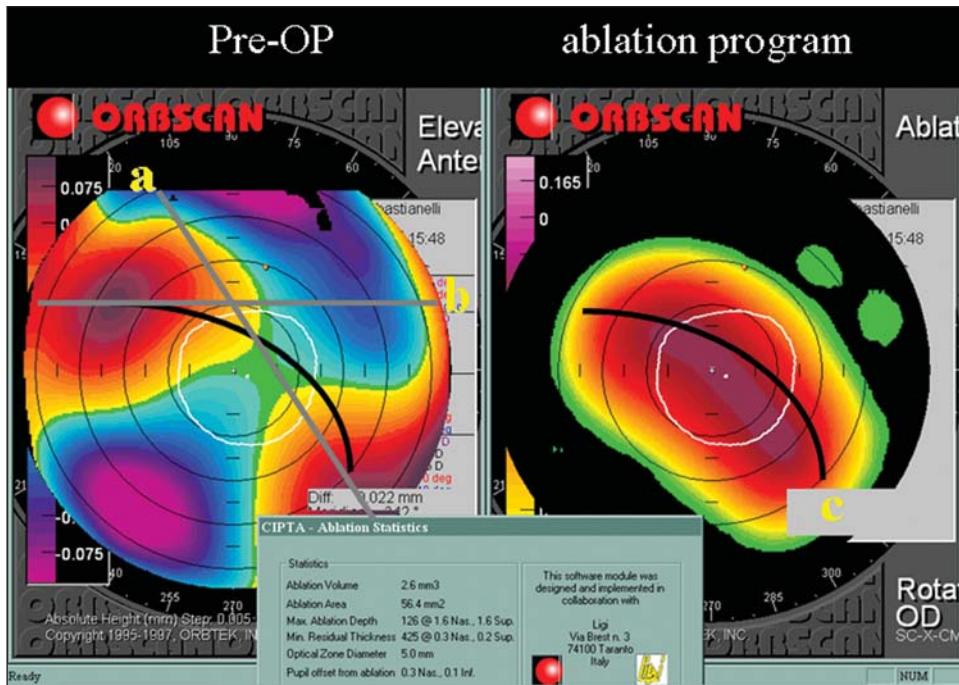


Figure 5. Patient 2. The pretreatment map (left) shows an irregular astigmatism. The gray lines (a and b) show the different astigmatism axis in two halves of the cornea. The true astigmatic axis of this cornea is an arch line (black line). The ablation program map (right) describes the pattern ablation along the arch line. The following information is indicated in the box at the bottom of the image: ablation volume, ablation area, maximal ablation depth, minimal residual thickness, optical zone diameter, and pupil offset from ablation.

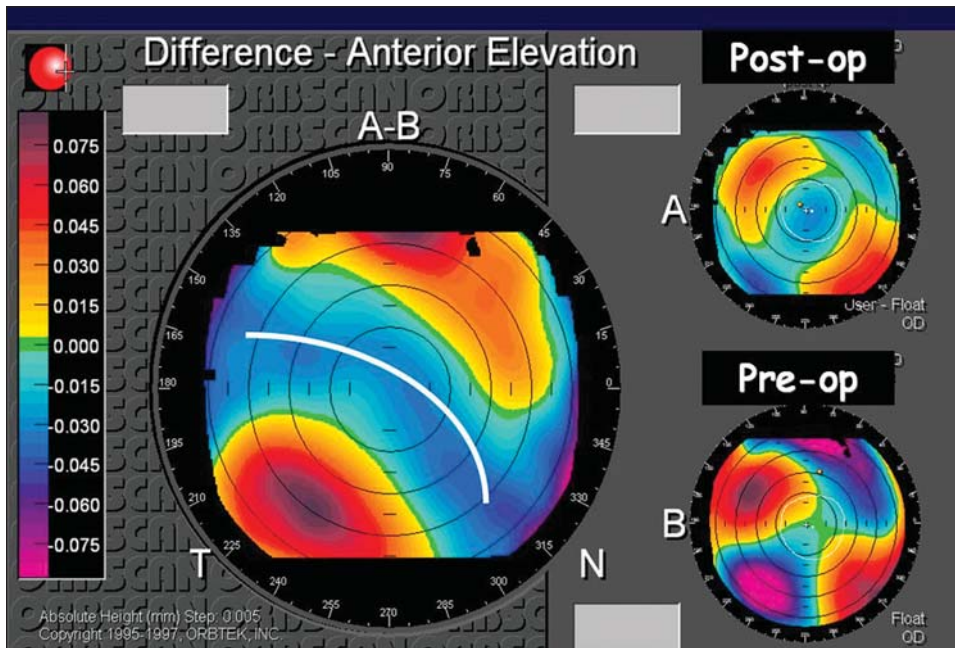


Figure 6. Patient 2. Differential elevation map shows the right curve profile of the ablation. The white line is similar to the main axis of planned ablation. The preoperative map is located on the bottom right and the postoperative map is located on the top right. The main image represents the differential map, which shows that the result of the ablation has the same shape as the ablation program.

Photorefractive keratectomy without topography-guided ablation has been shown to be effective in reducing post-penetrating keratoplasty astigmatism, improving both UCVA and BSCVA. The percentage of reduction in astigmatism has been reported to be between 31% and 67% of refractive value.³ Disadvantages of PRK include variable and unstable results if not topographically linked,¹ scarring,³ reactivation of herpes simplex keratitis and corneal graft rejection, corneal haze, and regression.³

Laser in situ keratomileusis has recently been in-

troduced as another procedure for the correction of post-penetrating keratoplasty spherical and cylindrical error.^{7,23-29} Several studies cite a decrease in the percentage of astigmatism between 0% and 58%.^{23,30,31} Other studies excluded eyes with irregular astigmatism, which frequently occurs after penetrating keratoplasty.

Disadvantages of LASIK are insignificant and generally related to the creation of the lamellar flap. Intraoperative complications included paracentral perforation of the flap²³ and buttonhole.²⁴ Postoperative complications included flap displacement,²³ interface epithelial

ingrowth at the periphery,²⁴ and pseudophakic retinal detachment 2 years after LASIK.²⁴

Our intraoperative complications included two buttonholes—in both cases, the final result was satisfied with improvement of BSCVA. Postoperative complications included cellular interface debris, resolved by cleaning the interface, and flap retraction; however, no loss of Snellen lines of BSCVA occurred.

Laser treatment can be performed at the same time as lamellar cut or when the corneal changes induced by lamellar cut have stabilized.⁸⁻¹²

Our technique is effective and safe. The mean cylindrical reduction was 5.0 D (SD 1.67) with a 75% reduction of astigmatism. The vector analyses method revealed an index of success of 0.26. Target induced astigmatism was 6.68 D (SD 3.22) and surgical induced astigmatism was 6.13 (SD 3.6), demonstrating a tendency towards low astigmatic undercorrection. Magnitude of error was -0.47 (SD 1.37) and indicates a tendency towards astigmatic undercorrection. The angle of error was 2.8 (SD 8.4) and demonstrates a good centration of alignment. Our results may be a consequence of the combination of two-step LASIK and topography-guided ablation based on the corneal shape following the keratome cuts.

Other studies have shown that creating the flap can change the shape of the cornea and thus influence refraction.¹² In the present study, after creating the flap, the cylinder correction changed more than 1.0 D and the axis changed as well in five eyes. The mean pre-cut refractive cylinder was -6.68 D (SD 3.29) and the mean post-cut refractive cylinder was -6.32 D (SD 2.82). Mean spherical equivalent refraction changed from 3.86 D pre-cut to 3.68 D post-cut. Because the shape of the cornea continues to evolve after lamellar cut, it is preferable to wait for topography and refraction to stabilize. Topography-guided ablation after calculating the new shape of the cornea with the Orbscan videokeratoscope has the following advantages:

- Irregular astigmatism, which cannot be corrected with standard techniques, can be corrected.
- The transition zone size can be topography-guided so as to maintain a constant minimum slope around 360° to avoid regression phenomena.
- Regular and smooth corneal surfaces can be obtained, thus improving visual acuity (BSCVA improved in 12 eyes in the present study).
- Microns of ablation can be saved compared to standard ablation.

This technique is shown to be safe: no eyes lost lines of BSCVA. No cases of graft-host wound dehiscence or laser retreatment occurred. All corneal grafts remained clear during the entire postoperative follow-up period.

Limitations of our technique include exclusion of eyes with excessively steep corneas (>53 D), the acquisition time needed to obtain the elevation map, possible cyclotorsion of the eye under the laser, efficiency of the laser eye-tracker, and the inability to consider non-corneal astigmatism.

Our results confirm that the two-step LASIK procedure using topography-guided ablation reduces the spherical errors in regular and irregular astigmatism following penetrating keratoplasty. Topography-guided ablation proved to be effective in correcting irregular astigmatism. Such results in virtually all cases qualifies this technique as a suitable solution for correcting astigmatism after penetrating keratoplasty.

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