

Transepithelial, Topography-guided Ablation in the Treatment of Visual Disturbances in LASIK Flap or Interface Complications

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ABSTRACT

PURPOSE: To evaluate the efficacy and safety of a single-step, transepithelial, topography-guided surface ablation in the treatment of visual disturbances including irregular astigmatism and light scattering caused by LASIK flap or interface complications.

METHODS: Seventeen eyes of 16 patients with LASIK flap or interface complications and central residual stromal thickness $\geq 300 \mu\text{m}$ were treated with a topography-guided custom transepithelial “no touch” (cTEN) technique using the iVIS Suite 1-kHz excimer laser (iVIS Technology). Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refraction, corneal irregularity, ocular higher order aberrations (HOAs), and visual symptoms were analyzed.

RESULTS: Mean 15.9 ± 11.0 months after surgery, mean UDVA improved from 20/87 to 20/25. Mean CDVA improved from 20/28 to 20/19 ($P < .001$), with 64.7% of eyes gaining two or more lines of CDVA. Mean corneal irregularity index decreased from 25.82 to $20.36 \mu\text{m}$ ($P = .009$). Mean root-mean-square (RMS) of total HOAs decreased from 1.30 to 0.49 ($P = .042$), whereas RMS of the odd-order (3rd and 5th) and even-order (4th and 6th) HOAs decreased from 0.85 to 0.38 ($P = .001$) and 0.43 to 0.24 ($P = .036$), respectively. All patients claimed their visual symptoms were better (8 eyes) or cured (9 eyes).

CONCLUSIONS: Corneal regularization and removal of the underlying flap or interface pathology by cTEN ablation appears to be an effective treatment for LASIK flap or interface complications associated with visually disturbing irregular astigmatism and light scattering in cases with sufficient residual stromal thickness. [*J Refract Surg.* 2012;28(2):120-126.]

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Laser in situ keratomileusis (LASIK) is currently the most common surgical technique in refractive surgery and has an excellent safety record.¹ However, although rare, flap or interface complications such as incomplete, decentered, buttonholed or lacerated flaps; improperly replaced free-cap; striae; wrinkles or folds; along with diffuse lamellar keratitis (DLK) or recurrent epithelial ingrowth, can lead to visually irregular astigmatism and/or optical scattering.² These complaints are difficult to manage with common techniques such as flap relift, recut, or traditional surface ablation; however, epithelial removal with phototherapeutic keratectomy followed by topography-guided ablation may be an option.

Recently, we presented a case report using a novel single-step, transepithelial, topography-guided custom ablation technique for the treatment of recurrent epithelial ingrowth.³ We have now applied this technique to treat different types of LASIK flap or interface complications. The aim of the current study was to evaluate the efficacy and safety of this technique in treating visually disturbing irregular astigmatism and light scattering caused by various LASIK flap or interface complications.

PATIENTS AND METHODS

PATIENTS AND OPHTHALMIC EXAMINATIONS

This retrospective study comprised 17 consecutive symptomatic eyes of 16 patients with LASIK flap or interface com-

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plications, with residual stromal thickness ≥ 300 μm and no topographic signs suggestive of keratectasia. Nine eyes had previous unsuccessful retreatments by commonly used techniques such as flap relift or recut, followed by wavefront-guided custom ablation. The current treatments were performed at SynsLaser Clinic in Tromsø or Oslo, Norway, from January 2007 through April 2010. Mean interval time between the previous LASIK surgery and topography-guided custom transepithelial “no touch” technique (cTEN) treatment was 59.3 ± 38.8 months (range: 12 to 120 months). Mean patient age was 48.0 ± 9.8 years (range: 29 to 63 years). Mean preoperative manifest refraction spherical equivalent (SE) was $+0.25 \pm 2.84$ diopters (D) (range: -6.25 to $+4.75$ D), and mean preoperative cylindrical error was 1.50 ± 1.14 D (range: 0.25 to 3.75 D). Halos, glare, starburst, and decreased corrected distance visual acuity (CDVA) were reported in 100% (n=17), 88% (n=15), 47% (n=8), and 76% (n=13) of eyes, respectively. The refractive surgical history of all eyes is listed in Table 1. All patients provided written informed consent and the study was approved by the regional ethics committee.

Patients underwent ophthalmic examinations pre- and postoperatively, consisting of slit-lamp microscopy, Scheimpflug-based corneal topo-/tomography (Precisio; iVIS Technology, Taranto, Italy), Placido disk-based topography and wavefront aberrometry (OPD-Scan II; NIDEK Co Ltd, Gamagori, Japan), dynamic pupillometry (pMetrics, iVIS Technology), uncorrected distance visual acuity (UDVA)/CDVA (NIDEK RT 2100 system, NIDEK Co Ltd), and tonometry (Icare tonometer; Revenio Group Corp, Helsinki, Finland). The assessment of the quality of vision was achieved by patients' subjective evaluation of whether their visual disturbances remained unchanged, became worse/better, or were cured after cTEN treatment.

SURGICAL PLAN SIMULATION AND SURGICAL TECHNIQUE

cTEN ablation was performed by iVIS Suite, an integrated system consisting of the Precisio (Scheimpflug-based) topo-/tomographer, pMetrics pupillometer, Corneal Interactive Programmed Topographic Ablation (CIPTA) planning software, and iRES excimer laser (iVIS Technology).

The refraction, corneal anterior elevation and pachymetry map, pupillometry, as well as the pupil, iris, and scleral vessel registration information of the patient are imported into the CIPTA software, with the aim of reshaping the detected irregular corneal surface into a regular aspheric surface within a treatment zone suggested by pupillometry. The curvature of the targeted surface is determined by subtracting the amount of desired spherocylindrical dioptric change from the

preoperative curvature. The detailed principles of the concept have been described elsewhere.⁴ In general, the current topography-guided, transepithelial surface ablation consists of a refractive part, which regularizes the corneal surface, and a lamellar part (programmed according to the estimated depth of the pathology to be removed), which “translates” the regularized surface into the stroma below the pathology to achieve a “healthy” regular surface. The two parts are summed and executed in a single, uninterrupted ablation. The ablation is performed through the epithelium, anterior stroma, and in some cases, through the entire flap if required by the underlying pathology and if the amount of the residual corneal tissue is sufficient.

The ablation plan is executed by a 0.6 mm/250 mJ/cm² dual-flying-spot laser (iRES), which delivers a maximum effective frequency of up to 1 kHz (2 \times 500 Hz) at the corneal plane and uses a synchronized eye-tracking system for x, y, and cyclotorsional tracking. The iRES also features a delivery of constant local frequency of 4 pulses per second per mm² to control the thermal effect.

After registration of the iris and scleral vessels by the laser's x, y, and cyclotorsional tracker, the corneal surface is gently dried with a lint-free, presoaked merocel sponge (Medtronic Inc, Mystic, Connecticut) to achieve a reflective, homogeneous, “dry” surface upon which the laser ablation is performed. To prevent haze, 0.02% mitomycin C is applied to the cornea for 12 or 30 seconds after treatment with maximum stromal ablation depth <100 or >100 μm , respectively. Finally, a bandage contact lens (Acuvue Oasys; Johnson & Johnson, New Brunswick, New Jersey) is applied and worn for 7 days or until complete reepithelialization is achieved. The detailed surgical protocol is described elsewhere.⁵

OUTCOME ANALYSIS

All visual acuity values were recorded as Snellen values and converted to logMAR for statistical analysis and then converted back to Snellen values for presentation purposes. Pre- and postoperative topography were analyzed using Precisio irregularity index (maximum height difference between the real cornea and best-fit aconic surface within the central 6-mm zone) as well as by measuring the orthogonal curvature asymmetry within the central 4 mm. Statistical analysis was performed using SPSS 11.0 (SPSS Inc, Chicago, Illinois). The paired *t* test was used to assess the changes in UDVA, CDVA, and higher order aberrations (HOAs).

RESULTS

Eyes were available for postoperative evaluation at 15.9 ± 11.0 months (range: 6 to 45 months) after the cur-

TABLE 1
Preoperative Data for 17 Eyes That Underwent cTEN Treatment for Postoperative LASIK Flap/Interface Complications

Eye/Sex/ Age (y)	LASIK Complication	UDVA (Decimal)	Refraction	CDVA (Decimal)	IRI (μ m)	Asymmetry (D)	Visual Disturbances			
							Halos	Glare	Starburst	Decreased CDVA
1/M/62	Free cap	0.20	+3.75 -0.75 \times 163	1.00	18	1.36	Yes	Yes	No	No
2/F/40	Microfolds	0.40	-1.00 -0.25 \times 150	0.80	8	0.68	Yes	Yes	Yes	Yes
3/F/40	Microfolds	0.40	-1.25 -0.25 \times 10	1.00	7	0.63	Yes	Yes	Yes	No
4/M/47	Microfolds	0.30	+3.25 -3.75 \times 90	0.80	29	4.75	Yes	Yes	Yes	Yes
5/M/45	Buttonhole	0.02	-6.25 -1.50 \times 8	0.80	9	0.76	Yes	Yes	Yes	Yes
6/F/44	Decentered flap	0.20	+0.50 -2.50 \times 165	0.80	28	6.44	Yes	Yes	No	Yes
7/F/41	Epithelial ingrowth	0.30	+3.50 -3.50 \times 164	0.80	61	7.91	Yes	Yes	No	Yes
8/M/63	Small flap	0.10	-1.50 -1.50 \times 122	0.50	22	1.70	Yes	Yes	No	Yes
9/F/58	Decentered flap	0.70	+0.50 -0.25 \times 90	0.70	14	2.24	Yes	Yes	No	Yes
10/F/43	Epithelial ingrowth	0.40	-1.25 -0.25 \times 90	0.70	31	4.57	Yes	Yes	No	Yes
11/F/60	DLK scarring	0.15	+4.75 -3.00 \times 100	0.70	20	5.42	Yes	Yes	No	Yes
12/M/45	DLK, epithelial ingrowth	0.70	+1.25 -1.75 \times 132	1.00	17	3.00	Yes	Yes	No	No
13/F/29	DLK scarring	0.10	+0.50 -0.75 \times 55	0.50	24	2.10	Yes	Yes	No	Yes
14/M/62	Lacerated flap	0.04	-4.00 -2.00 \times 180	0.30	—	—	Yes	Yes	Yes	Yes
15/M/40	Double flap interface	0.30	-1.00 -1.25 \times 75	0.90	—	—	Yes	No	Yes	Yes
16/M/50	DLK scarring	0.50	+2.50 -1.50 \times 5	1.00	20	1.60	Yes	No	Yes	No
17/M/48	Epithelial ingrowth, microfolds	0.30	0.00 -0.75 \times 160	0.40	—	—	Yes	Yes	Yes	Yes

cTEN = topography-guided custom transepithelial "no touch" technique, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, IRI = irregularity index, DLK = diffuse lamellar keratitis

rent surgery, of which 82.4% (n=14) were evaluated at 12 months or later. In 29.4% (n=5) of eyes (eyes 8, 9, 11, 12, and 17), a secondary cTEN treatment was performed mainly to treat the residual refractive error. No intra- or postoperative complications were observed. Pre- and postoperative patient data are listed in Tables 1 and 2, respectively. The mean maximum ablation depth (including the epithelium) for the cTEN treatment was 162 \pm 48 μ m (range: 121 to 313 μ m). Postoperatively, all 15 eyes aimed for emmetropia achieved UDVA of 20/40 or better, whereas 26.7% (4/15) of eyes achieved UDVA of 20/20 or better (Fig 1).

The mean postoperative spherical equivalent refractive (SE) adjusted by intended SE was 0.09 \pm 0.81 D (range: -1.13 to +2.25 D). Of all eyes, 47% were with-

in \pm 0.50 D of the intended refraction and 88% were within \pm 1.00 D of the intended refraction (Figs 2 and 3). The refraction remained stable at 12 months postoperatively (Fig 4). Mean CDVA improved from 20/28 (logMAR 0.15) to 20/19 (logMAR -0.02) (P<.001). Regarding CDVA, 64.7% (n=11) of eyes gained 2 or more lines, 11.8% (n=2) of eyes remained unchanged, and no eyes lost lines of CDVA (Fig 5). Figure 6 shows the pre- and postoperative refractive astigmatism in the treated eyes.

Eleven of the 17 eyes had irregular astigmatism with irregularity index >10 and orthogonal curvature asymmetry >1.00 D within the central 4 mm. In these eyes, preoperative irregularity index changed from 25.82 \pm 12.82 μ m (range: 14 to 61 μ m) to

TABLE 2
Postoperative Data for 17 Eyes That Underwent cTEN Treatment for Postoperative LASIK Flap/Interface Complications

Eye	Ablation Depth* (μm)	Desired Refractive Outcome	Time Point (mo)	UDVA (Decimal)	Refraction	CDVA (Decimal)	IRI (μm)	Asymmetry (D)	Visual Symptoms†	
									Better	Cured
1	157	+1.00	12	0.30	+3.50 -0.50 \times 140	1.00	15	1.33		X
2	121	Emmetropia	43	1.00	+0.25 -0.50 \times 10	1.50	13	2.50		X
3	135	Emmetropia	35	1.20	0.00 -0.25 \times 160	1.50	11	2.65		X
4	157	Emmetropia	6	0.50	+1.25 -1.00 \times 175	0.90	17	1.86	X	
5	165	Emmetropia	12	0.90	-0.25 -0.25 \times 175	1.00	28	3.68		X
6	150	Emmetropia	36	1.20	Plano	1.20	20	3.26		X
7	313	Emmetropia	13	0.80	-0.50 -0.75 \times 85	1.00	48	4.29		X
8	130	-5.00 -1.00 \times 120	12	0.05	-5.00 -2.75 \times 170	1.00	15	2.20	X	
9	127	Emmetropia	12	0.90	+1.00 -0.25 \times 35	1.10	7	0.58	X	
10	131	Emmetropia	15	0.60	+1.25 -1.25 \times 80	1.00	24	1.98	X	
11	212	Emmetropia	14	0.60	-0.50 -0.25 \times 90	0.80	28	3.90	X	
12	130	Emmetropia	6	0.90	+0.50 -0.50 \times 125	1.00	15	1.60	X	
13	199	Emmetropia	12	0.50	-0.25 -0.75 \times 105	0.60	19	1.90	X	
14	202	Emmetropia	12	0.80	+0.50 -0.50 \times 80	0.90	—	—		X
15	132	Emmetropia	12	0.80	-0.75 -0.75 \times 135	1.40	—	—	X	
16	143	Emmetropia	12	1.00	0.00 -0.50 \times 60	1.20	16	0.90		X
17	144	Emmetropia	6	0.80	0.75 -0.75 \times 85	1.20	—	—		X

cTEN = topography-guided custom transepithelial "no touch" technique, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, IRI = irregularity index

*Maximum ablation depth including the epithelium.

†No patient had worse or unchanged visual symptoms.

$20.36 \pm 10.64 \mu\text{m}$ (range: 7 to 48 μm) ($P=.009$), whereas asymmetry changed from $3.74 \pm 2.22 \text{ D}$ (range: 1.36 to 7.91 D) to $2.16 \pm 1.19 \text{ D}$ (range: 0.58 to 4.29 D) ($P=.004$). Figure 7 shows the pre- and postoperative corneal anterior elevation maps, as well as the ablation maps of 16 of 17 eyes from the current study.

Pre- and postoperative HOAs could be reliably measured in 9 of 17 eyes. The quality/repeatability of the preoperative HOA measurements was poor in 8 eyes and was not used in analysis. In the 9 measured eyes, the average total HOA root-mean-square (RMS) measured at 5-mm diameter decreased by 62.3% from 1.30 to 0.49 ($P=.04$), the average odd-order (3rd and 5th orders) RMS and even-order (4th and 6th orders) RMS decreased by 55.3% from 0.85 to 0.38 ($P=.001$) and by 44.2% from 0.43 to 0.24 ($P=.36$), respectively.

The patients' subjective evaluation at a mean of 15.9 months (range: 6 to 43 months) after cTEN surgery showed that in 47.1% (8/17) and 52.9% (9/17) of eyes, visual symptoms were claimed to be better and cured, respectively. No eyes were claimed to be unchanged or

worse. The pathology causing the decrease of transparency was removed by the current ablation in all eyes, and none of the treated eyes developed haze.

DISCUSSION

Visual disturbances occurring with LASIK flap or interface complications can be traced to the inferior optical performance of the cornea, due either to irregular astigmatism caused by the underlying pathology (irregular flap, striae, wrinkles, folds, scarring after DLK, epithelial ingrowths, etc) or to the effect of optical scattering within the flap, LASIK interface, or both, caused by the same pathology. Hence, the current treatment concept is: 1) regularize the cornea and treat the irregular astigmatism, and 2) ablate the underlying anatomical substrate and remove a potential source for scattering.

Symptomatic postoperative LASIK eyes with irregular corneas show greatly increased HOAs that correlate to their irregular corneal topography.⁶ The topography-guided custom ablation was used in the current study

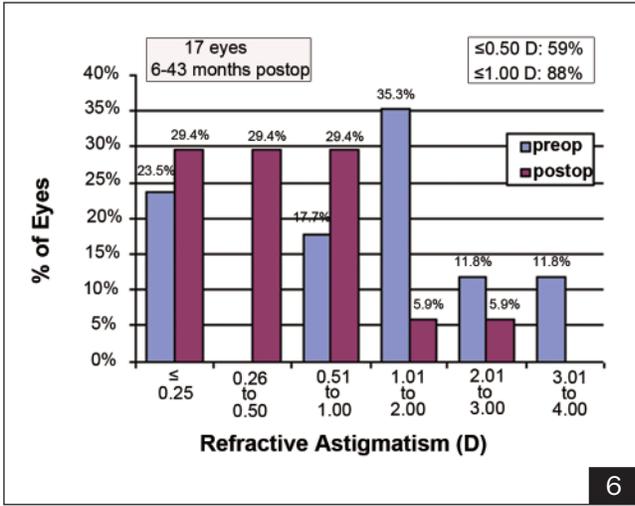
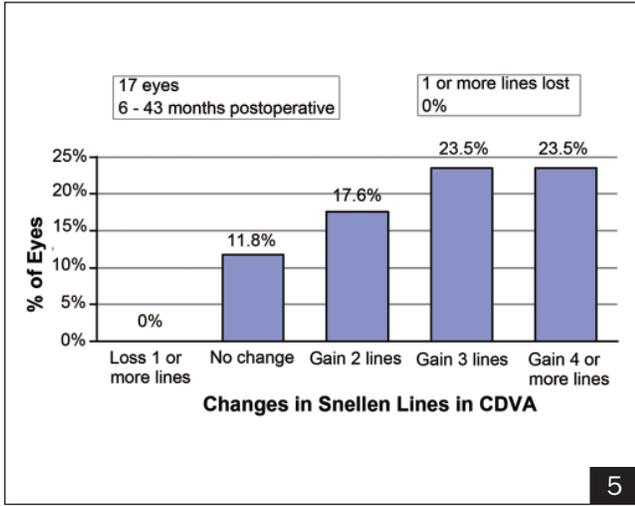
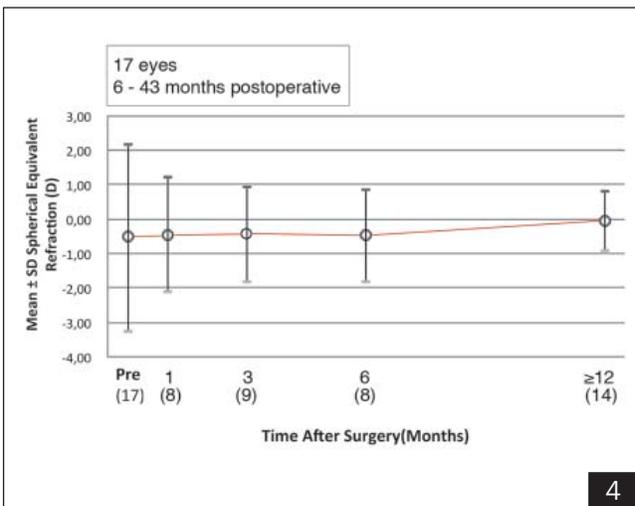
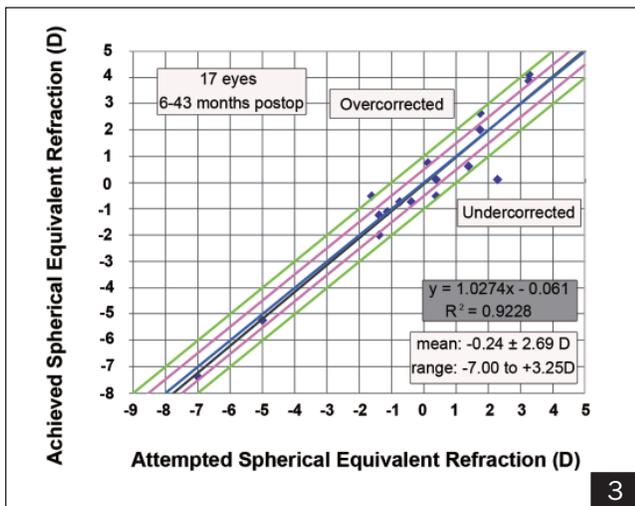
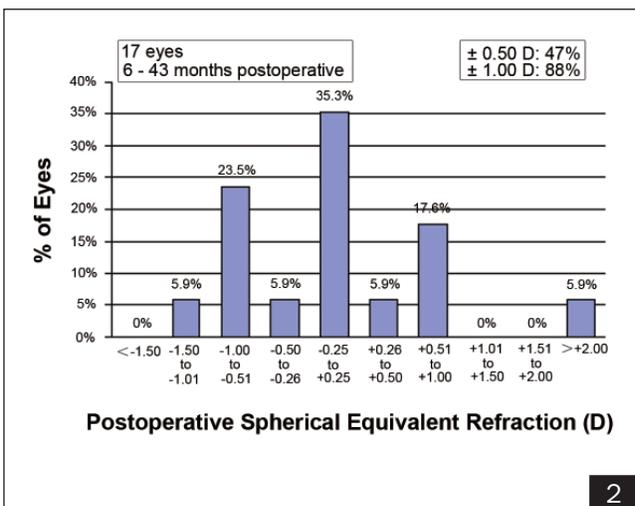
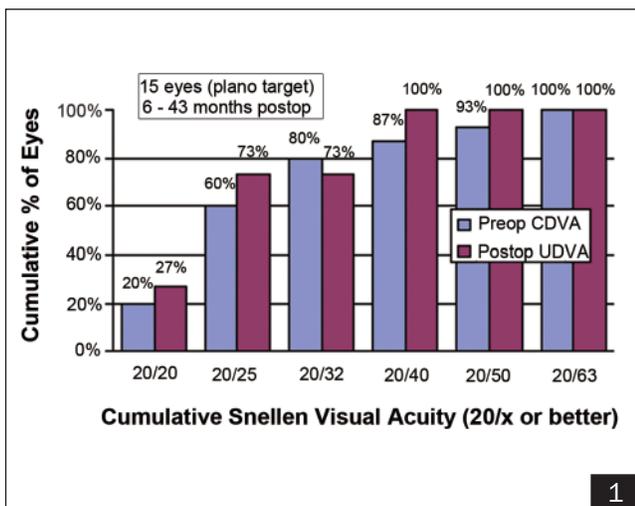


Figure 1. Uncorrected distance visual acuity (UDVA) after cTEN treatment (CDVA = corrected distance visual acuity). **Figure 2.** Predictability of spherical equivalent correction after cTEN treatment. **Figure 3.** Attempted versus achieved spherical equivalent refraction. **Figure 4.** Stability of spherical equivalent refraction with cTEN treatment (SD = standard deviation). **Figure 5.** Gain/loss of corrected distance visual acuity (CDVA) at the last follow-up examination. **Figure 6.** Refractive astigmatism.

because it measures the corneal morphological irregularities that represent the substrate for the aberrations. Regularization of the corneal topography and decrease in the amount of HOAs after treatment in the current study showed the efficacy of this approach.

Various types of surface ablation on top of the flap are used for treatment of irregular astigmatism caused by LASIK complications.⁷⁻⁹ This approach saves corneal tissue and does not significantly compromise corneal biomechanical stability.¹⁰ Furthermore, surface ablation on top of the flap addresses the scattering problem if the flap or interface pathologies are included in the tissue to be ablated. However, epithelial remodeling (thickening over depressed stroma and thinning over elevated stroma) will occur in irregular astigmatism^{11,12} due to the irregular stromal surface and must be addressed if surface ablation is used. The remodeling compensates in some degree for the irregular astigmatism, meaning that the irregularity seen and measured on topography is only a part of the stromal irregularity, implying a mismatch between the epithelial and stromal surfaces. Therefore, a topography-guided ablation based on the preoperative measurements of the epithelial surface applied to the stroma can only correct the irregularity that has not been compensated by the epithelium. It also means that as a consequence of epithelial remodeling, mechanical or alcohol-assisted epithelial removal used with traditional surface ablation techniques (advanced surface ablation, laser epithelial keratomileusis, epi-LASIK) will reveal an irregular stromal surface that does not match the preoperative corneal topography. This may represent a source of potentially significant ablation error when topography-guided surface ablation is used. To circumvent this issue, we chose the approach integrating topography-guided ablation and epithelial removal. The high speed of the iVIS-Suite's 1-kHz high-frequency excimer laser, together with its minimized ablation rate difference between the epithelium and stroma by use of a proprietary laser algorithm based on optimization of fluence, laser beam profile, ablation pattern, and the local ablation rate, make integrated transepithelial custom ablation realistic. In this way, the deepithelialization area fits exactly the edge of the refractive part of the ablation, thus generating less corneal trauma compared to mechanical epithelial removal, potentially resulting in faster and less painful reepithelialization.

The current study generally showed good refractive outcomes. Two eyes in the current study were not aimed for emmetropia; one due to lack of available corneal tissue, the other to achieve isometropia. Five eyes required retreatment for residual refractive

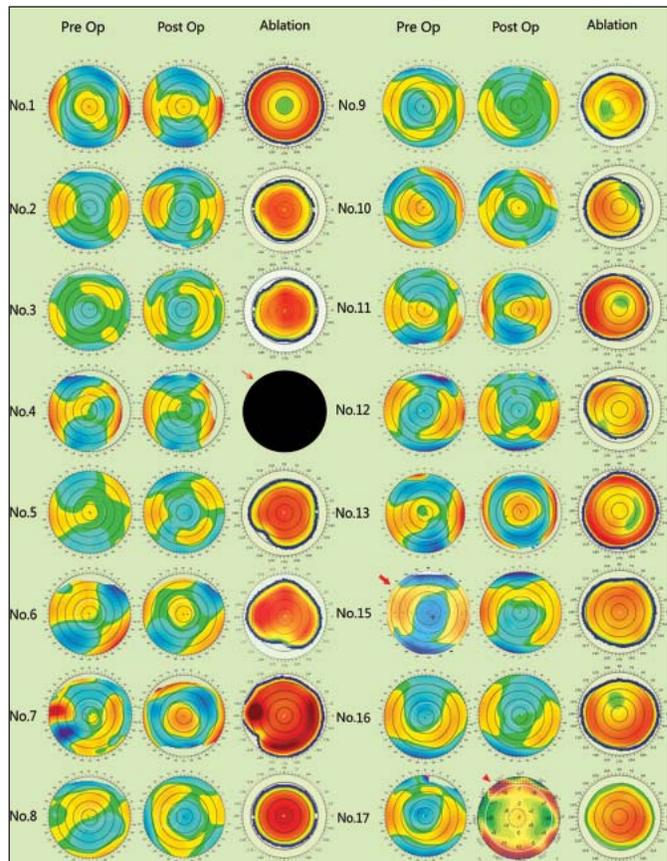


Figure 7. Pre- and postoperative Preciso (iVIS Technology, Taranto, Italy) corneal anterior elevation maps (left and middle) and CIPTA ablation map (right) (the ablation map was unavailable in eye 4, preoperative elevation map is by Orbscan [Bausch & Lomb, Rochester, New York] in eye 15, and postoperative elevation map is by Pentacam [Oculus Optikgeräte GmbH, Wetzlar, Germany] in eye 17).

error, which may be attributed to: error in planning of the spherocylindrical correction due to the influence of the HOAs on the measured amount of the preoperative sphere and cylinder¹³; and epithelial remodeling, which occurs after the current treatment, affecting the final refractive outcome. Thus, a more precise preoperative refraction measurement and better knowledge and control of the postoperative epithelial healing/remodeling process may improve the refractive outcome. The other improvement to the current approach would be an increase of accuracy of measurements of the depth of the pathology in the LASIK flap or interface, which were estimated by analysis of Scheimpflug images in the current study. In that way, more accurate flap or interface pathology depths could be determined and programmed into the cTEN ablation.

The cTEN technique appears to be safe and effective in the treatment of optically disturbing LASIK flap or interface irregularities, when a sufficient amount of corneal tissue is available.

AUTHOR CONTRIBUTIONS

Study concept and design (X.C., A.S.); data collection (X.C., A.S., W.Z.); analysis and interpretation (X.C., A.S., W.Z., T.P.U., F.S., Q.W.); drafting of the manuscript (X.C., A.S., W.Z., F.S.); critical revision of the manuscript (X.C., A.S., W.Z., T.P.U., F.S., Q.W.); statistical expertise (X.C.); administrative, technical, or material support (A.S., Q.W.); supervision (A.S.)

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