articles

Induced optical aberrations following formation of a laser in situ keratomileusis flap

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Purpose: To determine how refractive error, visual acuity, and high-order aberrations (3rd- and 4th-order) are affected by the formation of a lamellar corneal flap during laser in situ keratomileusis (LASIK).

Setting: University refractive surgery center.

Methods: The effect of lamellar corneal flap formation was analyzed in 15 myopic eyes (mean preoperative refraction −4.72 diopters [D] [range −1.25 to −7.25 D]). The flap was created using a 2-step procedure: (1) a nasally hinged lamellar corneal flap was created; (2) the flap was lifted and stromal ablation performed 2 months after the flap was made. A Hartmann-Shack aberrometer was used to measure the aberrations.

Results: There was no significant change in the refractive error (spherical equivalent pre-flap −4.72 ± 1.99 D and post-flap −4.62 ± 1.99 D [*P* = .28]) or visual acuity (pre-flap uncorrected visual acuity [UCVA] 0.07 and best corrected visual acuity [BCVA] 0.96; post-flap UCVA 0.08 and BCVA 0.95 [*P* = .16 and *P* = .33, respectively]). A statistically significant increase in total higher-order wavefront aberrations was observed following flap formation (root mean square pre-flap 0.344 ± 0.125 and post-flap 0.440 ± 0.221 [*P* = .04]).

Conclusion: Flap formation during LASIK can modify the eye's existing natural higher-order aberrations (especially spherical and coma-like aberrations along the axis of the flap's hinge), while visual acuity and refractive error remain unaffected.

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Advancements in refractive surgery have been in the forefront of ophthalmology's development over the past decade. As refractive surgery has become more accepted and popular, the ophthalmic investigative community has increased efforts to develop more sophisticated techniques for correcting visual errors. The hope is to not only address spherical and cylindrical refractive errors (low-order aberrations) but also to modify a spectrum of higher-order ocular aberrations to maximize the quality of vision.

The concept of wavefront error has moved from the research field to clinical application.[1–7] There is evidence to support the idea that refractive procedures (such as laser in situ keratomileusis [LASIK] and photorefractive keratectomy [PRK]) may increase naturally occurring higher-order aberrations and irregular astigmatism of the eye, resulting in deterioration in the quality of the retinal image.[8,9] Understanding the manner in which these optical aberrations vary after the formation of a LASIK flap is a fundamental element in the development of aberration-free guided ablations.

Our review found only 1 report that directly investigated the induction of ocular aberrations caused by the formation of a lamellar corneal flap during a LASIK procedure.[10] Due to the study's limitations, which in-

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clude the use of different microkeratomes, variable hinge positions (superior and nasal), and inconsistent flap thickness, we could not obtain sufficient and comparable results.

In this prospective study, we used a simple 2-step LASIK procedure to investigate the effect of the lamellar corneal flap on refraction, visual acuity, and higher-order ocular aberrations (3rd and 4th order).

Patients and Methods

Fifteen eyes scheduled for myopic LASIK were enrolled in this prospective study. Patients were excluded if they had active anterior segment disease; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery; history of herpes keratitis; diagnosed autoimmune disease, systemic connective tissue disease, or atopic syndrome; or corneal topographic and pachymetric findings suspicious for keratoconus. All patients were appropriately informed before their participation in the study and provided written informed consent in accordance with institutional guidelines, according to the Declaration of Helsinki.

The mean spherical equivalent of the preoperative refraction was −4.72 diopters (D) ± 1.99 (SD) (range −1.25 to −7.25 D) and the mean refractive astigmatism, −1.37 ± 1.44 D (range 0.00 to −3.75 D).

Laser in situ keratomileusis was performed in 2 steps. It was similar to a standard LASIK procedure except that the ablation to the stromal bed was performed in a second step. In the first step, an 8.5 mm nasally hinged corneal flap was created with an automated microkeratome (Flapmaker disposable microkeratome, Refractive Technologies). The flap was repositioned while standard medical treatment was administered to all eyes. Of the 19 eyes initially included in the study, 4 with flap irregularities (thin flaps, flap striae, epithelial defects or ingrowth) were excluded from the study.

A mean 57 ± 18 days (range 30 to 90 days) after creation, the flap was lifted, ultrasound pachymetry (DGH 5100 Technology) was recorded (flap thickness extrapolated), and the stromal bed was ablated (Asclepion-Meditec Mel 70 excimer laser) according to the new measurements.

Before each step, a comprehensive preoperative examination was performed. This included uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), corneal topography (EyeSys Premier, version 3.1, EyeSys Technologies), slitlamp and fundus examinations, and wavefront measurement of optical aberrations.

The Asclepion-Meditec wavefront analyzer WASCA, which comprises a Hartmann-Shack sensor capable of displaying 3rd- and 4th-order Zernike polynomials with a resolution of 210 μm at the corneal plane, was used for all measurements. The WASCA uses a ray of light focused on the retina (retinal spot) and then resolves the reflected wavefront pattern to provide nearly instantaneous, high-precision measurements of primary and higher-order ocular aberrations. In addition to the Hartmann-Shack sensors, the WASCA, mounted on a normal *x-y-z* base, comprises 2 extra cameras. These cameras display the iris and the retinal spot on the computer monitor and serve to precisely align the eye being examined. This feature allows wavefront analysis with simultaneous alignment control for fine adjustments.

The root-mean-square (RMS) wavefront error was used as a measure of the optical quality before and after formation of the lamellar flap. The RMS system of measurement is principally based on assessing numerous points along the optical surface and then extrapolating a single number that is a statistical measure of the deviation of that surface from the ideal form.

The Zernike coefficients were estimated for 6.0 mm and 4.0 mm pupil diameters and are given in the notation of Born and Wolf.[11]

Statistical Analysis

Group differences for continuous variables were tested using the unpaired and paired Student *t* test and the 1-way analysis of variance for normally distributed data. Differences for categorical variables were tested using the chi-square or Fisher exact test for independence. Ninety-five percent confidence interval limits were calculated for differences in mean results. A *P* value less than 0.05 was regarded as statistically significant.

Results

Refractive Outcome

There was no significant change in the mean refraction between the preoperative examination and the post-flap follow-up (−4.72 ± 1.99 D [range −1.25 to −7.25 D] and −4.62 ± 1.99 D [range −1.00 to −7.25 D], respectively [*P* = .28]).

There was no statistically significant surgically induced astigmatism (SIA) by magnitude or by axis (*P* = .3). The cumulative vector of SIA, suggested by vector analysis, was +0.28 × 18.

Visual Outcome

Uncorrected visual acuity changed slightly from 0.07 ± 0.14 (range counting fingers [CF] to 0.4) to 0.08 ± 0.15 (range CF to 0.4) (*P* = .16) after flap formation as did BSCVA, from 0.96 ± 0.24 (range 0.5 to 1.2) to 0.95 ± 0.25 (range 0.5 to 1.2), respectively (*P* = .33).

Wavefront Aberrations

There was a statistically significant increase in total higher-order wavefront aberrations after flap formation for the 6.0 mm pupil (RMS pre-flap 0.344 ± 0.125 to post-flap 0.440 ± 0.221 [P = .04]). Similar findings were not found for the 4.0 mm pupil (0.097 ± 0.039 to 0.115 ± 0.035, respectively [P = .11]).

Table 1 shows the pre- and post-flap Zernike coefficient for the 6.0 mm and 4.0 mm pupils. For the 6.0 mm pupil, the mean spherical aberrations (Z_4^0) increased significantly from 0.174 before to 0.246 after flap creation (P = .034). There was a statistically significant increase in 3rd-order coma along the horizontal axis (Z_3^{-1}) (pre-flap 0.248 to post-flap 0.453 [P = .007]) (Figure 1); a similar finding was not observed along the vertical axis (Z_3^1) (pre-flap 0. 571 to post-flap 0. 700 [P = .422]). The induced aberrations after flap creation for Z_3^{-1} and Z_4^0 remained statistically significant for the 4.0 mm pupil.

Other Findings

There was a significant increase in corneal thickness following flap formation: pre-flap 539.1 ± 26.9 μm (range 470 to 571 μm) to post-flap 549.9 ± 27.6 μm (range 485 to 591 μm) (P < .001).

Discussion

Several studies have demonstrated an increase in optical aberrations after refractive surgery, suggesting a degradation of overall retinal image quality. Oshika and coauthors[5] found an increase in higher-order corneal aberrations (2.7-fold in LASIK and 2.3-fold in PRK) compared to the preoperative values. While they did not find differences between LASIK and PRK in the introduction of coma-like aberrations, there was a significant increase in the induction of spherical-like aberrations in the LASIK group. Other studies[12,13] report that PRK may increase ocular aberrations, impairing overall visual performance of the treated eye, while Moreno-Barriuso et al.[14] propose that LASIK increases total wavefront error (RMS), with the largest increase occurring in spherical aberrations.

In our study, the creation of a corneal flap induced changes to the 3rd- and 4th-order aberrations of the eye. The largest increase was in spherical and coma-like aberrations along the horizontal axis, while similar results were not appreciated along the vertical axis. The increase in spherical aberrations could be due to the changes in corneal asphericity following the creation of a flap, and a supporting factor for this hypothesis may be the statistically significant increase in post-flap corneal pachymetry measurements. In addition, the increase in coma-like aberrations in the horizontal axis following flap formation could be due to the wound-healing process along the flap edges. These alterations appear to be influenced by hinge position (nasal in our patients), resulting in a less symmetric cornea. It also appears that a nasally positioned flap hinge has less effect on induced 3rd-order coma aberrations along the vertical axis.

Table 1. Wavefront errors in 15 eyes before and after flap creation for 6.0 mm and 4.0 mm pupils.

	6.0 mm Pupil			4.0 mm Pupil		
Zernike Coefficient (μm)	**Pre-flap**	**Post-flap**	***P***	**Pre-flap**	**Post-flap**	***P***
Third order						
Z_3^{-3} (triangular astigmatism-trefoil with base on *x*-axis)	0.375	0.316	.136	0.112	0.091	.118
Z_3^{-1} (3rd order coma along *x*-axis)	0.248	0.453	.007	0.076	0.125	.018
Z_3^1 (3rd order coma along *y*-axis)	0.571	0.700	.422	0.168	0.177	.808
Z_3^3 (triangular astigmatism trefoil with base on *y*-axis)	0.371	0.434	.185	0.109	0.129	.175
Fourth order						
Z_4^{-4} (4th foil)	0.084	0.135	.087	0.018	0.027	.110
Z_4^{-2} (4th-order astigmatism on *y*-axis)	0.062	0.089	.259	0.013	0.020	.180
Z_4^0 (spherical aberration)	0.174	0.246	.034	0.032	0.049	.032
Z_4^2 (4th-order astigmatism along *x*-axis)	0.141	0.178	.167	0.027	0.031	.427
Z_4^4 (4th foil)	0.118	0.110	.805	0.026	0.022	.513

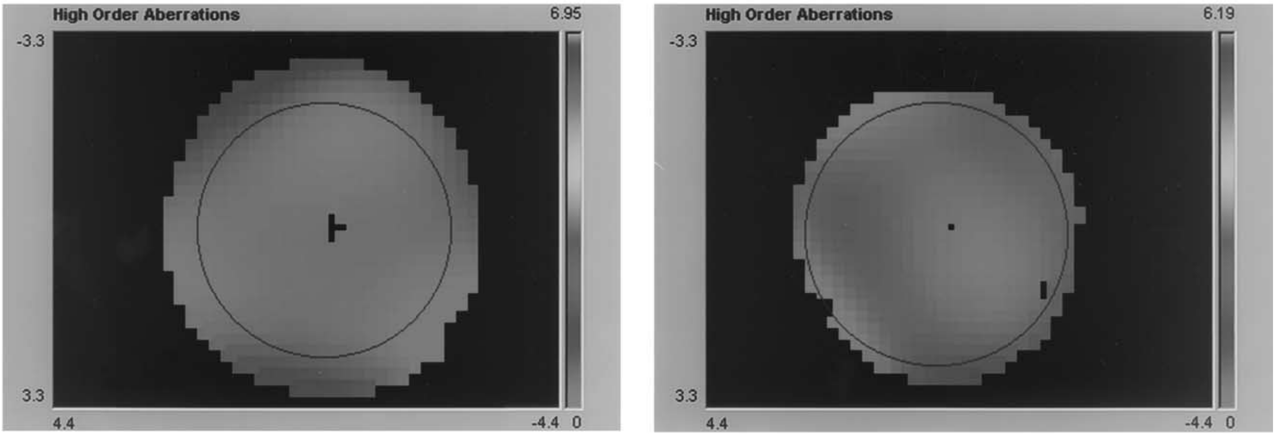

Figure 1. (Pallikaris) Wavefront analyzer map before (*left*) and 2 months after (*right*) creation of a corneal lamellar flap, demonstrating the induction of optical aberrations (especially the induced third-order coma along the horizontal axis, Z_3^{-1}).

Hersh and Abbassi[15] report that induced astigmatism was generally less and more random in axis in LASIK than in PRK. In addition, Huang et al.[16] note that the flap formation reduces preexisting corneal astigmatism and produces a relative steepening of the hinge meridian. In both studies, the authors used indirect methods to conclude that the flap had induced astigmatism without isolating the contribution of the stromal ablation component, neglecting the possibility that the laser system generated astigmatism even when programmed to perform only a spherical ablation. The only article to have studied the direct effects of a lamellar flap formed in a 2-step procedure is a case report by Dada et al.[17] The authors describe the reduction in post-penetrating-keratoplasty (PKP) astigmatism following the creation of a lamellar corneal flap. The limitation of this study is that the contractile forces in a post-PKP cornea with high astigmatism (7.3 D) are different from those in a cornea that had LASIK, so its conclusion could not be reliably expanded to LASIK procedures. In our study, we found no statistically significant SIA after flap formation by magnitude or by axis, while a general trend toward against-the-rule SIA was observed.

In conclusion, our results appear to illustrate that a lamellar corneal cut made by an automated microkeratome does not significantly alter existing refractive error or visual acuity. It does, however, appear to increase corneal higher-order aberrations. Logically, these should be taken into consideration when devising future wavefront-guided aberration-free or customized LASIK systems. Additional prospective studies with more cases and using various types of microkeratomes (and hinge positions) will help uncover the optical role played by LASIK flaps. This will allow us to provide our patients with the ultimate in vision quality.

References

1. Mrochen M, Kaemmerer M, Seiler T. Clinical results of wavefront-guided laser in situ keratomileusis 3 months after surgery. J Cataract Refract Surg 2001; 27:201–207
2. McLellan JS, Marcos S, Burns SA. Age-related changes in monochromatic wave aberrations of the human eye. Invest Ophthalmol Vis Sci 2001; 42:1390–1395
3. Applegate RA, Thibos LN, Hilmantel G. Optics of aberroscopy and super vision. J Cataract Refract Surg 2001; 27:1093–1107
4. Mrochen M, Kaemmerer M, Mierdel 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
5. Oshika T, Klyce SD, Applegate RA, Howland HC. Changes in corneal wavefront aberrations with aging. Invest Ophthalmol Vis Sci 1999; 40:1351–1355
6. MacRae SM. Supernormal vision, hypervision, and customized corneal ablation. (editorial) J Cataract Refract Surg 2000; 26:154–157
7. MacRae SM, Williams DR. Wavefront guided ablation. (editorial) Am J Ophthalmol 2001; 132:915–919
8. Martínez CE, Applegate RA, Klyce SD, et al. Effect of pupillary dilation on corneal optical aberrations after photorefractive keratectomy. Arch Ophthalmol 1998; 116:1053–1062
9. Oshika T, Klyce SD, Applegate RA, et al. Comparison of corneal wavefront aberrations after photorefractive kera-

tectomy and laser in situ keratomileusis. Am J Ophthalmol 1999; 127:1–7
10. Panagopoulou SI, Pallikaris IG. Wavefront customized ablations with the WASCA Asclepion workstation. J Refract Surg 2001; 17:S608–S612
11. Born M, Wolf E. Principles of Optics, 7th ed. Cambridge, Cambridge University Press, 1999
12. Seiler T, Kaemmerer M, Mierdel P, Krinke H-E. Ocular optical aberrations after photorefractive keratectomy for myopia and myopic astigmatism. Arch Ophthalmol 2000; 118:17–21
13. Mierdel P, Kaemmerer M, Krinke H-E, Seiler T. Effects of photorefractive keratectomy and cataract surgery on ocular optical errors of higher order. Graefes Arch Clin Exp Ophthalmol 1999; 237:725–729
14. Moreno-Barriuso E, Merayo Lloves J, Marcos S, et al. Ocular aberrations before and after myopic corneal refractive surgery: LASIK-induced changes measured with laser ray tracing. Invest Ophthalmol Vis Sci 2001; 42:1396–1403
15. Hersh PS, Abbassi R. Surgically induced astigmatism after photorefractive keratectomy and laser in situ keratomileusis; Summit PRK-LASIK Study Group. J Cataract Refract Surg 1999; 25:389–398
16. Huang D, Sur S, Seffo F, et al. Surgically-induced astigmatism after laser in situ keratomileusis for spherical myopia. J Refract Surg 2000; 16:515–518
17. Dada T, Vajpayee RB, Gupta V, et al. Microkeratome-induced reduction of astigmatism after penetrating keratoplasty. Am J Ophthalmol 2001; 131:507–508

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