

Comparison of Epi-LASIK and Off-Flap Epi-LASIK for the Treatment of Low and Moderate Myopia

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Purpose: To compare the early postoperative course and the 1-year clinical results of off-flap Epi-LASIK and Epi-LASIK for the treatment of low and moderate myopia.

Design: Pilot double-masked, randomized, comparative study.

Participants: Fifty-six patients (112 myopic eyes).

Methods: Epithelium was separated in all eyes with the use of Centurion SES epikeratome (Norwood Abbey EyeCare, Vic, Australia). The first eye treated and surgical method in the first eye were randomized. One eye of each patient underwent standard Epi-LASIK, whereas in the contralateral eye, the epithelial sheet was not retained on the photoablated stroma (off-flap Epi-LASIK eyes). Mean preoperative spherical equivalent was -3.50 ± 1.22 diopters (D; range, -1.75 to -6.37 D) in Epi-LASIK eyes and -3.61 ± 1.22 D (range, -1.50 to -6.50 D) in off-flap Epi-LASIK eyes ($P > 0.05$, paired Student *t* test). Excimer laser corneal ablation was performed using the Allegretto 200Hz (Wavelight Laser Technologie AG, Erlangen, Germany). Patients were followed up daily until the epithelial healing was complete and at 1, 3, 6, and 12 months.

Main Outcome Measures: Epithelial healing time, subjective pain score, and uncorrected visual acuity (UCVA) were evaluated during the first postoperative days. Uncorrected visual acuity, spherical equivalent refraction, best spectacle-corrected visual acuity, haze scores, and wavefront aberrations were recorded at all subsequent intervals.

Results: Time of epithelial healing did not differ significantly in Epi-LASIK and off-flap Epi-LASIK eyes (4.76 ± 0.84 days in Epi-LASIK eyes vs. 4.54 ± 0.93 days in off-flap Epi-LASIK eyes). No significant difference in UCVA was found after the 2 techniques during the first postoperative days. Subjective pain score was lower in off-flap Epi-LASIK eyes at 2 postoperative hours, whereas no significant difference in pain scores was noted between the 2 techniques at the other intervals. There was no significant difference in spherical equivalent, line gain or loss, haze scores, and higher-order aberrations between Epi-LASIK and off-flap Epi-LASIK eyes at any interval. Uncorrected visual acuity was significantly better in Epi-LASIK eyes only at 6 months (-0.05 ± 0.08 in Epi-LASIK eyes vs. 0.00 ± 0.07 in off-flap Epi-LASIK eyes). Preoperative wavefront aberrations did not change significantly 1 year after either procedure.

Conclusions: Epi-LASIK and off-flap Epi-LASIK had equal visual and refractive results for the treatment of low and moderate myopia in this study.

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Epi-LASIK is a new surface ablation procedure that is reported to be safe, efficient, and predictable for the treatment of low and moderate myopia.^{1–3} In Epi-LASIK, the epithelium is separated as a sheet with the use of an automated device, the epikeratome, and then is repositioned on the photoablated stroma. The preserved epithelial sheet (morphologically intact for the first 24 postoperative hours⁴) theoretically may represent a barrier that protects the photoablated corneal stroma from a postoperative inflammation cascade. Like laser epithelial keratomileusis (LASEK),^{5,6} in which the epithelial separation is achieved with the use of alcohol solutions on the cornea, the goal of Epi-LASIK is to overcome the limitations of conventional photorefractive keratectomy (PRK) such as slow visual recovery and postoperative pain, as well as the risk of corneal haze.

The theoretical advantages of the epithelial sheet repositioning on the ablated stroma have not yet been studied. The purpose of the present randomized, contralateral, pilot study is to compare pain, epithelial healing, visual recovery, and refractive results of Epi-LASIK-treated eyes with the fellow eyes of the same patients in which the epithelium was separated by the same epikeratome but was not retained on the stroma (an approach called off-flap Epi-LASIK).

Patients and Methods

Fifty-six patients were included in this pilot randomized, double-masked comparative study. Inclusion criteria were myopic spherical equivalent less than -6.50 diopters (D), age older than 18 years, and stable refraction as documented by previous glass

prescriptions. Exclusion criteria were previous refractive surgery, anisometropia of more than 2 D, and ocular or systemic disease that could affect the epithelial healing. Institutional review board approval was obtained, and patients were informed about the study protocol and gave a written informed consent according to the Declaration of Helsinki before their participation in the study. All participants and the examiners were not aware of which method was performed in each eye.

The first eye treated and the surgical method used (Epi-LASIK, in which the epithelial sheet was repositioned after the photoablation, or off-flap Epi-LASIK, in which the epithelial sheet was removed) in the first eye were randomized with a flip of a coin. In cases in which a total epithelial sheet was separated in the Epi-LASIK-assigned eye (4 eyes [7%]), the epithelial sheet was not preserved in that eye, whereas in the fellow eye, the epithelium was preserved.

The preoperative examination of the enrolled eyes included manifest and cycloplegic refraction, corneal topography (Technomed C-Scan, Technomed GmbH, Baesweiler, Germany), measurement of wavefront aberrations at pupil diameter of 6 mm (Wave-Analyzer, Wavelight, AG, Erlangen, Germany), ultrasonic corneal pachymetry, mesopic pupil size measurement (Colvard pupillometer, Glendora, CA), slit-lamp biomicroscopy, applanation tonometry, and dilated funduscopy.

Surgical Technique

All surgical procedures were performed by the same surgeon (IGP). Epithelial separations were performed with the use of Centurion Epi Edge Epikeratome (Norwood Abbey, EyeCare, Vic, Australia), as has been described.¹ The diameter of epithelial sheet was 9 mm, whereas the length of the hinge was 2 to 4 mm. In off-flap Epi-LASIK eyes, the epithelial sheet was separated with the use of the same epikeratome and was removed after its separation with the use of a beaver on the hinge, except for total or free epithelial sheets, which were removed with no additional manipulations.

All excimer laser corneal treatments of the reported series were performed with the use of the Allegretto 200 Hz (Wavelight Laser Technologie AG) laser platform, attempting to achieve emmetropia in treatment zones ranging from 6.5 to 7 mm according to the patient's mesopic pupil size.

Postoperative Treatment and Follow-up

Patients received the same treatment for both eyes. In the current series, plano Focus Night & Day bandage contact lenses (CIBA Vision Ophthalmics, Duluth, GA) were used. Postoperative medication included diclofenac sodium 0.1% 4 times daily (Denacof Novartis International AG, Basel, Switzerland) for 2 days in all

eyes as well as combined eye drops of tobramycin and dexamethasone 4 times daily (TobraDex, Alcon Laboratories, Inc, Fort Worth, TX), until the removal of the therapeutic lens. After the removal of the lens, all treated eyes received fluorometholone eye drops 4 times daily (FML; Allergan, Irvine, CA) in a tapered dose for 5 weeks. Artificial tears (Refresh; Allergan, Irvine, CA) were prescribed to be used at patient discretion.

Patients were examined daily until the removal of the therapeutic lens. Early follow-up included recording of uncorrected visual acuity (UCVA), subjective pain score, and biomicroscopy. Pain scores were evaluated according to a predetermined scale ranging from 0 to 4, as follows: 0, no discomfort or pain; 1, mild discomfort; 2, moderate burning pain; 3, burning pain that required oral medication (nimesulide; Mesulid; Boehringer Ingelheim GmbH, Ingelheim, Germany); and 4, severe constant or sharp pain. On the day of the operation, patients were asked to record pain scores every 2 hours for a total of 5 records. The same scale was used in the following daily visits when a single pain and discomfort score was obtained from each enrolled patient.

All the enrolled patients then were scheduled to be examined at 1, 3, 6, and 12 postoperative months. The postoperative assessment included uncorrected and best spectacle-corrected visual acuity, manifest refraction, biomicroscopy, topography, measurement of higher-order aberrations, and applanation tonometry. Subepithelial haze was graded according to a predetermined scale⁷ as following: 0, clear cornea; 1, trace haze that could be seen only with broad beam illumination; 2, mild haze visible by slit-beam illumination; 3, moderate haze somewhat obscuring iris details; and 4, marked haze obscuring iris detail.

Doctors (MIK) evaluating all measurements and patients were unaware of the surgical procedure performed in each eye.

Statistical Analysis

Statistical analysis was performed with the use of SPSS software version 16.0 (SPSS, Inc., Chicago, IL). Group differences for continuous variables were tested using the paired Student *t* test. Results are presented as mean \pm standard deviation. Epithelial healing time, pain scores, line gain or loss, and haze scores were evaluated with the use of the Pearson chi-square test with tables of contingency, whereas the Wilcoxon signed-rank test was used to compare UCVA and best spectacle-corrected visual acuity (BSCVA) between the 2 groups. A *P* value of less than 0.05 was regarded as statistically significant.

Results

The epithelial separation was achieved successfully in all eyes that were included in the study. Mean patient age was 26.6 ± 8.29 years

Table 1. Preoperative Data of the Operated Eyes

	Epi-LASIK	Off-Flap Epi-LASIK	P Value*
No. of eyes (right/left)	32/24	24/32	
Mean spherical equivalent (D; range)	-3.50 ± 1.22 (-1.75 to -6.37)	-3.61 ± 1.22 (-1.50 to -6.50)	0.1 (<i>t</i> test)
Mean BSCVA (logMAR)	0.002 ± 0.14 (0.1 to -0.20)	-0.02 ± 0.05 (0.1 to -0.20)	0.1 (Wilcoxon signed-rank test)
Mean corneal pachymetry (μ m)	550.27 ± 33.36 (485–613)	551.85 ± 31.4 (470–610)	0.28 (<i>t</i> test)
Mean keratometry (D)	42.97 ± 1.31	42.92 ± 1.31	0.32 (<i>t</i> test)

BSCVA = best spectacle-corrected visual acuity; D = diopters; logMAR = logarithm of the minimum angle of resolution.

*Power of statistical difference between the 2 groups.

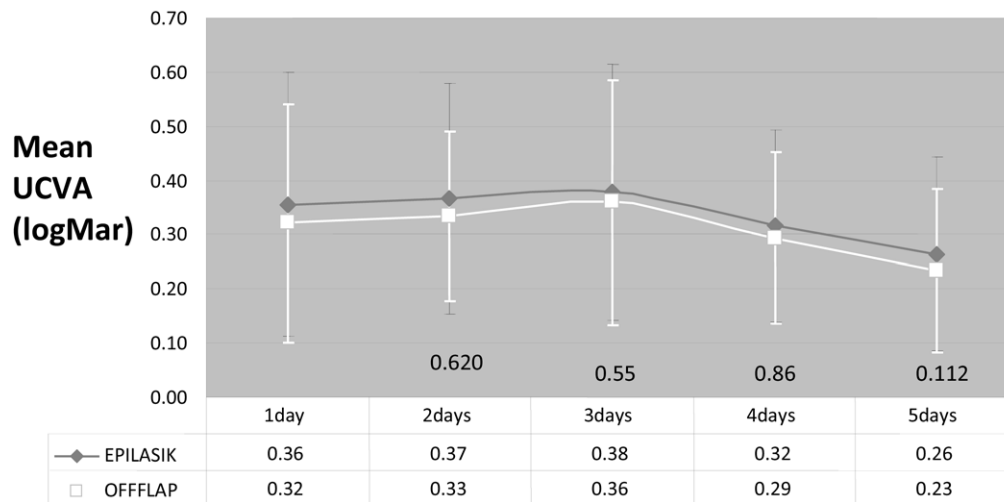


Figure 1. Graph showing the changes in uncorrected visual acuity (UCVA) in logarithm of the minimum angle of resolution (logMAR) units (mean value±standard deviation) during the first postoperative days after both procedures. Mean values are presented in the boxes below the graph. P values (in the chart area) represent the power of statistical difference between the 2 eyes of the same patient at all intervals (Wilcoxon signed-rank test).

(range, 18–54 years). Thirty-four patients were men and 22 were women. Mean preoperative spherical equivalent was -3.50 ± 1.22 D (range, -1.75 to -6.37 D) in the Epi-LASIK-treated eyes and -3.61 ± 1.22 D (range, -1.50 to -6.50) in the off-flap Epi-LASIK-treated eyes. There was no statistically significant difference in the attempted corrections between the 2 groups ($P = 0.1$, paired Student *t* test). Table 1 shows the preoperative data of the treated eyes.

Early Postoperative Period

The mean time of epithelial healing was 4.76 ± 0.84 days (range, 3–6 days) in the Epi-LASIK-treated eyes and 4.54 ± 0.93 days (range, 3–6 days) in the off-flap Epi-LASIK-treated eyes. No significant difference was noted in epithelial healing time between the 2 eyes of the same patient ($P > 0.05$, Pearson chi-square test). In 8 patients (14.28%), the off-flap Epi-LASIK eye healed first, whereas in 2 patients (3.57%) the Epi-LASIK eye healed first. In the rest of the patients, the epithelium healed and the contact lenses were removed on the same postoperative day in both eyes.

Figure 1 summarizes the daily records of the mean logarithm of the minimum angle of resolution UCVA of all eyes until the day of reepithelization. Off-flap Epi-LASIK eyes had better UCVA in the first postoperative days, but this difference was not statistically significant at any interval ($P > 0.05$, Wilcoxon signed-rank test). On day 3, a decrease in UCVA was noted after both techniques. By the day of reepithelization, the mean logarithm of the minimum angle of resolution UCVA was 0.24 ± 0.14 (range, 0.70–0.1) in the Epi-LASIK eyes and 0.21 ± 0.13 (range, 0.52–0.1) in the off-flap Epi-LASIK eyes.

Table 2 summarizes the percentage of eyes with subjective pain scores from 0 through 4 during the first postoperative hours. More Epi-LASIK eyes had discomfort (pain score 1) and a burning sensation (score 2) during the first 8 postoperative hours, with the difference being significant at 2 hours after surgery ($P = 0.04$, Pearson chi-square test). At 10 hours after surgery and on the first postoperative day, more discomfort was noted in the off-flap Epi-LASIK eye. Except for the first 2 hours, the differences were not significant at any other postoperative interval ($P > 0.05$, Pearson chi-square test).

Table 2. Percentages of Eyes with Subjective Pain Scores of 0 through 4 during the First Postoperative Hours

Time (hrs)	Procedure	Pain Score					P Value*
		0	1	2	3	4	
2	Epi-LASIK	14%	29%	33%	17%	7%	0.043
	Off-flap Epi-LASIK	44%	24%	22%	7%	2%	
4	Epi-LASIK	31%	45%	17%	2%	5%	0.206
	Off-flap Epi-LASIK	49%	40%	7%	5%		
6	Epi-LASIK	51%	27%	17%	5%		0.774
	Off-flap Epi-LASIK	55%	29%	12%	2%	2%	
8	Epi-LASIK	44%	41%	12%	2%		0.630
	Off-flap Epi-LASIK	44%	49%	5%	2%		
10	Epi-LASIK	64%	29%	5%		2%	0.381
	Off-flap Epi-LASIK	65%	23%	5%	7%		
24	Epi-LASIK	89%	11%				0.230
	Off-flap Epi-LASIK	74%	19%	6%			

*Asymptotic significance, 2-sided Pearson chi-square test.

Stability of Refraction

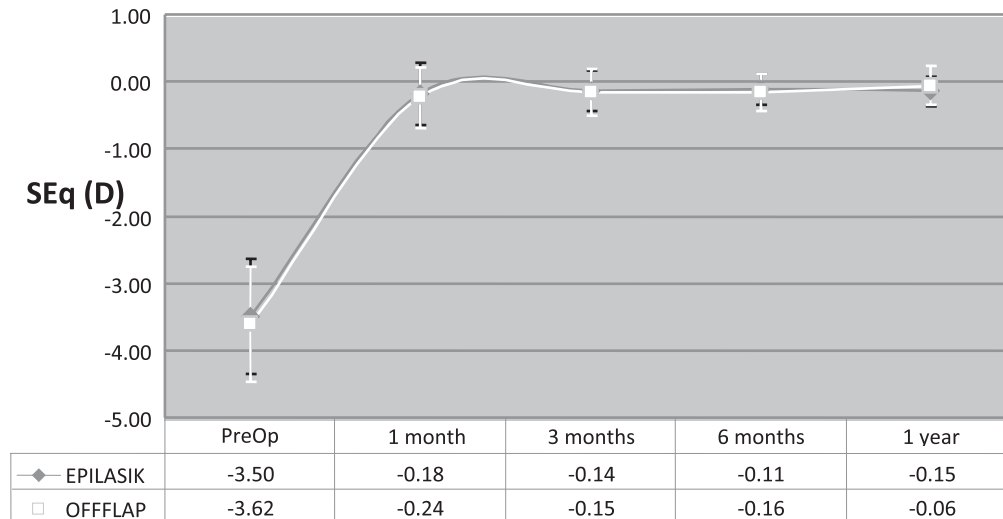


Figure 2. Graph showing the changes in mean spherical equivalent (mean value±standard deviation) in Epi-LASIK and off-flap Epi-LASIK eyes during the follow-up. Mean values are presented in the boxes below the graph. D = diopters; PreOp = before surgery; SEq = spherical equivalent.

Refractive Results

All 56 patients completed 1 year of follow-up.

Predictability and Stability. There was no statistically significant difference in spherical equivalent between the 2 eyes of the same patients at any postoperative interval ($P>0.05$, paired Student *t* test; Fig 2). At 1 postoperative year, 90% (50 eyes) of Epi-LASIK and off-flap Epi-LASIK eyes were ± 0.50 D of target refraction, whereas all (100%) Epi-LASIK eyes and 95% ($n = 53$) of off-flap Epi-LASIK eyes were ± 1.00 D of target refraction.

Efficacy. Figure 3 shows changes in UCVA in the Epi-LASIK and off-flap Epi-LASIK eyes during the follow-up. The UCVA did not differ between the 2 groups of treated eyes ($P>0.05$, Wilcoxon signed-rank test), except for the 6-month interval, when the Epi-LASIK eyes had significantly better UCVA ($P = 0.01$).

Safety. At 1 postoperative month, 21% of the Epi-LASIK eyes and 20% of the off-flap Epi-LASIK eyes gained 1 or 2 lines of BSCVA, whereas 25% of the Epi-LASIK and 20% of the off-flap Epi-LASIK eyes lost 1 or 2 lines of BSCVA. The BSCVA improved with time during follow-up after both procedures. At 1 year, 57% of Epi-LASIK and 46% of off-flap Epi-LASIK eyes gained 1 or 2 lines of BSCVA (Fig 4). There was no statistical difference in line gain or loss between the 2 groups at any interval ($P>0.05$, Pearson chi-square test).

Haze Scores. There was no significant difference in corneal haze between the 2 groups at any postoperative interval ($P>0.05$, Pearson chi-square test; Table 3). At the third postoperative month, 1 patient (1.79%) had moderate haze (stage 3) in the Epi-LASIK eye, which improved to trace haze at 6

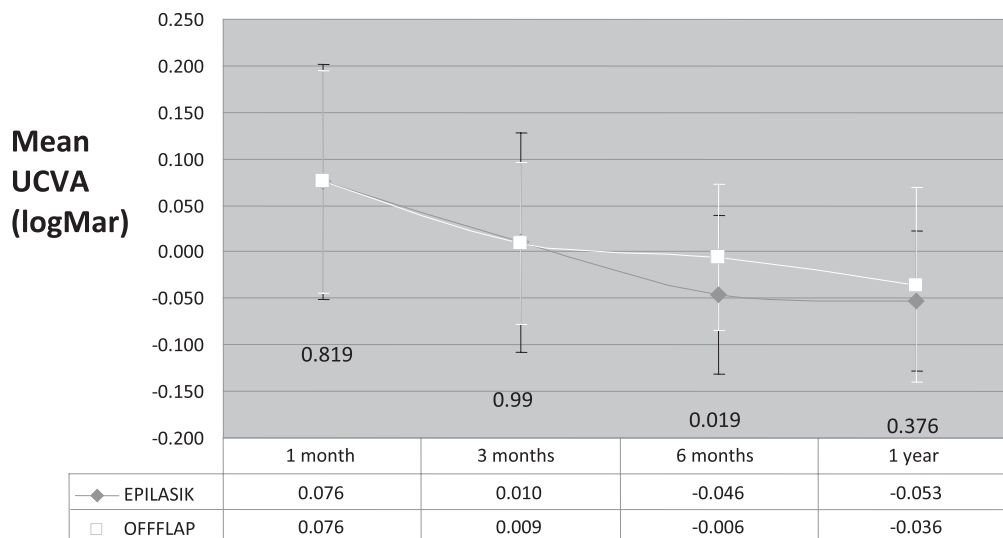
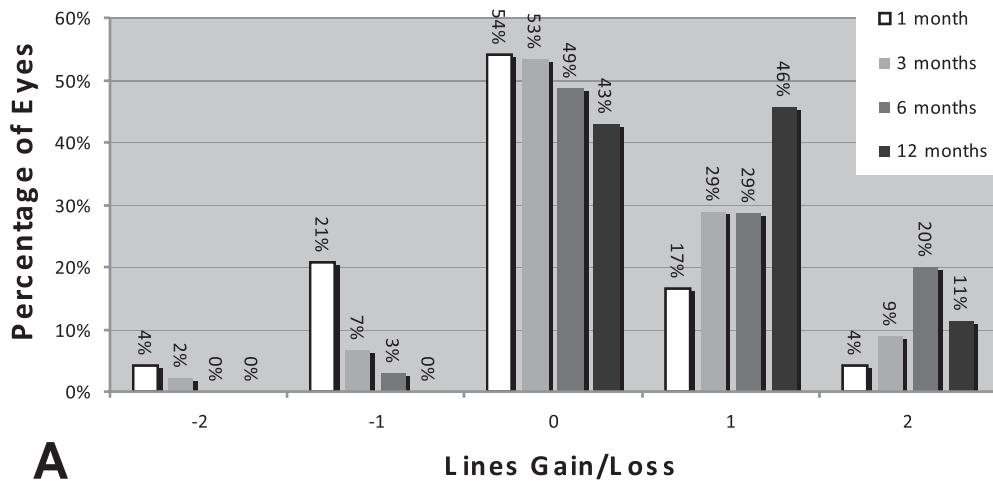


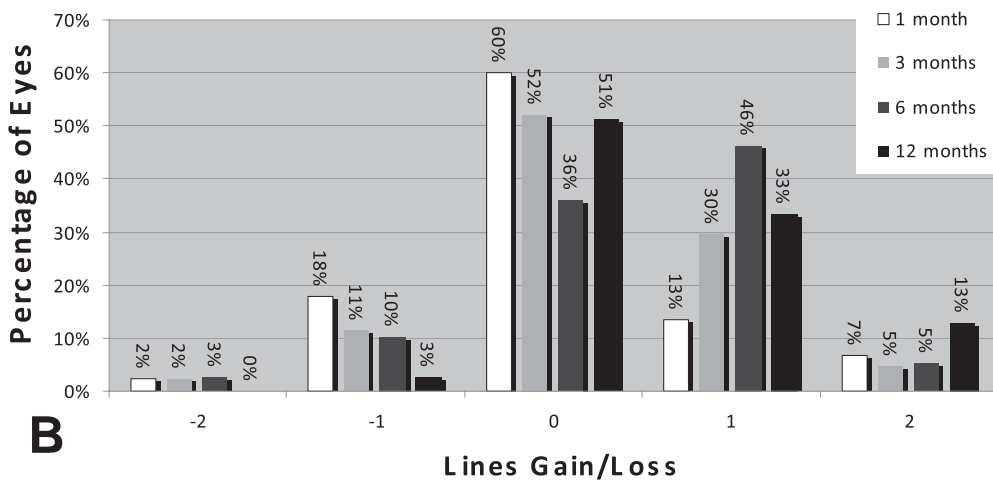
Figure 3. Graph showing the changes in uncorrected visual acuity (UCVA) in logarithm of the minimum angle of resolution (logMAR) units (mean±standard deviation) in Epi-LASIK and off-flap Epi-LASIK eyes. Mean values are presented in the boxes below the graph. *P* values (in the chart area) represent the power of statistical difference between the 2 eyes of the same patient at all intervals (Wilcoxon signed-rank test).

Changes in Best Corrected Visual Acuity in EpiLASIK treated eyes



A

Changes in Best Corrected Visual Acuity in off-flap EpiLASIK treated eyes



B

Figure 4. (A) Bar graph showing the percentage of Epi-LASIK eyes that gained or lost 1 to 2 lines of best-corrected visual acuity during the follow-up. (B) Percentage of off-flap Epi-LASIK eyes that gained or lost 1 to 2 lines of best-corrected visual acuity during the follow-up.

months, whereas the contralateral eye was clear during the follow-up. At 1 month, 10 patients (17.85%) had more haze in the Epi-LASIK eye and 6 patients (10.71%) had more haze in the off-flap Epi-LASIK eye. At the other postoperative intervals, the number of patients with more haze in the Epi-LASIK eye was the same as the number of patients with more haze in the off-flap Epi-LASIK eye.

Wavefront Aberrations. Of 31 patients who were evaluated, the total higher-order root mean square increased after both techniques, although not significantly ($P > 0.05$, paired Student *t* test; Table 4). No significant difference was noted in third- and fourth-order root mean square and, more particularly, in spherical aberration and coma between the 2 groups of eyes at any postoperative interval.

Discussion

Among others, a rotating brush, a blunt blade (beaver), alcohol application, and transepithelial laser or laser-scrape technique have been used for epithelial removal before PRK.⁸⁻¹⁰ In many cases, the mechanical removal was found to result in defects in the Bowman layer, an irregular anterior stromal surface, and retained islands of residual epithelium.^{11,12} Apart from this, the time required for the debridement can be long, and this may cause stromal dehydration secondary to evaporation and may affect refractive predictability.¹³ Alcohol-assisted deepithelialization was shown to be faster than mechanical debridement and led to a more

Table 3. Percentages of Eyes with Haze Scores of 0 through 3 during Follow-up

Time (mos)	Procedure	Haze Score				P Value*
		0	1	2	3	
1	Epi-LASIK	65%	33%	2%		0.646
	Off-flap Epi-LASIK	73%	25%	2%		
3	Epi-LASIK	87%	13%			0.592
	Off-flap Epi-LASIK	89%	11%			
6	Epi-LASIK	75%	23%		2%	0.962
	Off-flap Epi-LASIK	75%	25%			
12	Epi-LASIK	86%	14%			0.722
	Off-flap Epi-LASIK	86%	14%			

*Asymptotic significance, 2-sided, Pearson chi-square test.

circumscribed and reproducible epithelial defect at the end of surgery.^{14,15} The problems of potential toxicity of alcohol¹⁶ on corneal stroma and the varying application times needed for the loosening of the epithelial layer¹⁷ can be overcome by the use of an epikeratome for the epithelial separation. The epikeratome separates the epithelium as a sheet in an automated way under the level of epithelial basement membrane.¹⁸ In Epi-LASIK, the epithelial sheet then is repositioned on the photoablated stroma. Studies have reported satisfying refractive and visual results of Epi-LASIK.¹⁻³ In a modified technique called off-flap Epi-LASIK, the epithelium is separated with the use of the epikeratome and is removed before photorefractive correction. In the present study, the early postoperative course and the 1-year clinical results of off-flap Epi-LASIK eyes were examined and compared with those of the fellow Epi-LASIK-treated eyes of the same patients.

No significant difference was noted in the epithelial healing time between the 2 eyes of the same patient, although in 14.28% of the patients, the off-flap eye healed first, whereas in 3.57% of the patients, the Epi-LASIK eye healed first. Previous studies showed conflicting results. Torres et al¹⁹ found that Epi-LASIK-treated eyes needed more time for epithelial healing (4.75 ± 1.44 days; range, 3–7 days) than PRK-treated eyes (3.95 ± 1.39 days; range, 3–6 days), whereas in another

study,²⁰ Epi-LASIK-treated eyes healed faster. In off-flap Epi-LASIK, the epikeratome leaves a smooth corneal surface for photoablation, as compared with the potentially irregular stromal bed after conventional mechanical epithelial removal techniques, which may hamper epithelial healing. In the present study, however, the time of epithelial healing was longer than that reported in conventional PRK.¹⁹ This may be explained by the relatively large diameter of the epithelial sheet separated by the epikeratome (9 mm), which resulted in a large initial deepithelialized area.

Visual recovery did not differ significantly between the 2 eyes of the same patients, although off-flap Epi-LASIK eyes were recorded to have better UCVA during the first postoperative days. This is probably because of the hazy appearance of the repositioned epithelial flap on the second and third postoperative day in Epi-LASIK eyes.¹

Regarding symptoms in the early postoperative period, off-flap Epi-LASIK-treated eyes had significantly less discomfort only at the first 2 postoperative hours. At the other intervals, there was no statistical difference between the 2 methods. Previous studies found different results regarding pain levels after surface ablation procedures. O'Doherty et al,²⁰ comparing pain levels after Epi-LASIK, PRK, and LASEK, found that Epi-LASIK-treated eyes had significantly less pain only in the first 2 hours, whereas after that period, all patients had the same level of pain. Torres et al¹⁹ found that Epi-LASIK-treated eyes had similar postoperative pain as PRK eyes on the first postoperative day, but more pain on the third and sixth days, which may be explained by the appearance of central islands of hazy epithelium in Epi-LASIK-treated eyes at that point. The discrepancy of present results with previous studies may be explained by the epikeratome-assisted epithelial removal used in the off-flap Epi-LASIK eyes in the present study. As compared with conventional methods of epithelial removal before photoablation in PRK, such as the mechanical debridement with a rotating brush or a beaver and alcohol-assisted epithelial removal, the separation of the epithelial sheet with the use of the epikeratome may leave a smoother stromal surface with more regular borders for photoablation, which may decrease postoperative discomfort.

As for the refractive and visual results, Epi-LASIK and

Table 4. Changes in Higher-Order Aberrations at 12 Months after Surgery in Epi-LASIK and Off-Flap Epi-LASIK Eyes

Procedure	Interval	Total Higher-Order Root Mean Square (µm), Mean (Standard Deviation)	Third-Order Root Mean Square (µm), Mean (Standard Deviation)	Fourth-Order Root Mean Square (µm), Mean (Standard Deviation)	Coma Root Mean Square (µm), Mean (Standard Deviation)	Spherical Aberration Root Mean Square (µm), Mean (Standard Deviation)
Epi-LASIK (n = 31 eyes)	Before surgery	0.27 (0.10)	0.22 (0.11)	0.12 (0.04)	0.17 (0.11)	0.06 (0.05)
	12 months after surgery	0.35 (0.15)	0.29 (0.15)	0.15 (0.09)	0.21 (0.14)	0.11 (0.10)
	P Value*	0.06	0.09	0.14	0.29	0.06
Off-flap Epi-LASIK (n = 31 eyes)	Before surgery	0.32 (0.12)	0.27 (0.12)	0.14 (0.05)	0.19 (0.11)	0.08 (0.05)
	12 months after surgery	0.38 (0.22)	0.31 (0.20)	0.17 (0.10)	0.24 (0.18)	0.10 (0.08)
	P Value*	0.23	0.33	0.12	0.26	0.16

*Power of statistical difference between preoperative and 12-month postoperative value (paired, Student t test).

off-flap Epi-LASIK were found to be equally efficient and predictable for the correction of myopic spherical equivalent of less than -6.50 D. The UCVA was found better in the Epi-LASIK-treated eyes at 6 postoperative months, but the 2 groups did not differ at the other intervals. Comparing UCVA 3 months after 3 surface ablation techniques, PRK, LASEK, and Epi-LASIK, O'Doherty et al²⁰ found no significant difference between Epi-LASIK and LASEK eyes, but a better level of vision in the PRK group.

Regarding corneal haze, no significant difference was noted between groups during the follow-up. At 1 postoperative month, more patients had more haze in their Epi-LASIK eye. One patient (1.79%) had moderate haze at 3 postoperative months in the Epi-LASIK eye, whereas the fellow off-flap eye had a clear cornea. However, a larger sample of patients, as well as larger attempted corrections may reveal smaller differences in haze levels, if in fact such differences exist.

To evaluate the quality of vision after both techniques, higher-order aberrations were measured in 31 patients (56%). Total higher-order aberrations and, more particularly, coma and spherical aberration increased after both techniques, but this increase was not statistically significant as compared with preoperative values. Higher-order aberrations of off-flap Epi-LASIK eyes did not differ significantly from those of Epi-LASIK eyes at any postoperative interval.

In conclusion, Epi-LASIK and off-flap Epi-LASIK had equal refractive and visual results, and they did not differ regarding their early postoperative course. To determine the potential benefit of the epikeratome-assisted epithelial removal as compared with other ways of removing the epithelium in PRK, this method has to be compared regarding epithelial healing with other epithelial removal techniques before photorefractive corrections.

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