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Long term results of Epi-LASIK and LASEK for myopia☆

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ABSTRACT

Purpose: To evaluate the long term clinical and confocal results of mechanical (Epi-LASIK) versus alcohol-assisted laser epithelial keratomileusis (LASEK) for correction of myopia.
Setting: Gazi University Medical School, Department of Ophthalmology, Ankara, Turkey.
Design: Retrospective study.
Methods: Twenty-two eyes treated with LASEK and twenty eyes treated with Epi-LASIK were evaluated with a mean follow-up duration of 45 months. Mechanical separation of the epithelium was performed with Lasitome epithelial separator, and alcohol-assisted separation with 25 s application of 18% alcohol. Laser ablation was performed with the ESIRIS laser. All patients were examined daily until epithelial closure; at 1, 3, 6, and 12 months; and every year subsequently. Main outcome measures were uncorrected visual acuity (UCVA), manifest refraction, haze, and gray scale value in confocal microscopy, efficacy and safety indexes.
Results: Preoperative myopic spherical equivalent refraction was -4.65 ± 1.74 D in the LASEK and -3.87 ± 1.30 D in the Epi-LASIK-treated eyes ($p = 0.36$). Of both LASEK and Epi-LASIK-treated eyes, 95% achieved 20/25 or better final UCVA. The grade of haze and mean gray scale value in confocal microscopy were similar in LASEK and Epi-LASIK-treated eyes at all postoperative periods. The efficacy index was 0.94 in LASEK group and 0.96 in Epi-LASIK group ($p = 0.44$). The safety index was 1.01 in LASEK group and 1.02 in Epi-LASIK group ($p = 0.42$).
Conclusions: Both LASEK and Epi-LASIK offer safe and effective correction of myopia in the long term.

1. Introduction

Treatment of ametropia and improvement of vision are main areas of interests of ophthalmologists for over a century.

Most procedures to treat refractive error are based on laser surgery in a chronological order: PRK (photorefractive keratectomy), LASIK (laser in situ keratomileusis, LASEK (laser-assisted subepithelial keratectomy), Epi-LASIK (epithelial LASIK) and most recently, Epi-LASEK (epithelial LASEK).

The rapidly developing technology for refractive surgery requires comparative studies of different surgeries to define best technique in terms of simple, effective, minimally invasive, safe, and comfortable.

Also, for any surgical procedure, it is important to continually monitor long-term stability and efficacy. Long-term follow-up provides more objective suggestions about refractive and mechanical stability of the cornea after excimer laser.

Laser epithelial keratomileusis (LASEK) and epipolis LASIK (Epi-LASIK) are the most recent surface ablation techniques, and the term of "advanced surface ablations" used to describe advantages on corneal wound healing [1]. Recently, there is an increasing trend for histopathological comparison of the epithelial flaps created by these techniques. Different epithelial separation levels have a major impact on the accuracy of the intended ablation, wound healing that is related with corneal haze and so the final refractive outcome [2].

In this study we aimed to review long-term results of clinical and confocal microscopic findings after Epi-LASIK and LASEK for correction of myopia.

2. Materials and methods

This retrospective nonrandomized clinical study included eyes of patients having LASEK and Epi-LASIK. The study was performed with the approval and under the supervision of the local ethical board. All patients provided informed consent after they received a thorough explanation of the procedures and their potential risks.

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Twenty-two eyes treated with LASEK (13 women, 3 men), twenty eyes treated with (14 women, 2 men) Epi-LASIK were studied.

Other inclusion criteria were age older than 18 years, stable refraction of at least 1 year, and normal corneal topography. Daily-wear soft contact lenses were removed at least 2 weeks before the preoperative examination.

The preoperative examination of the enrolled eyes included manifest and cycloplegic refractions, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BCVA), slit-lamp biomicroscopy, applanation tonometry, dilated ophthalmoscopy, corneal topography, ultrasonic corneal pachymetry, esthesiometry, and Schirmer testing (with topical anesthetic drops). Exclusion criteria were previous refractive surgery, unstable refraction, ocular and systemic diseases (collagen vascular diseases, dry eye, corneal diseases, diabetes) that could affect the epithelial healing, glaucoma, topographical evidence of keratoconus.

2.1. Surgical technique

Both procedures were performed under sterile conditions in an operating room under topical anesthesia with proparacaine 0.5% (Alcaine®, Alcon, Ft Worth, Texas, USA). A drape and lid speculum were inserted after the treatment of eyelids with 10% povidone-iodine.

In Epi-LASIK treated eyes, Lasitome epithelial separator (Gebauer, Neuhausen, Germany) was used to create an epithelial flap with a nasal hinge (9 mm, hinge 0.5 mm). In LASEK treated eyes, the epithelium was incised with an 8-mm trephine placed centrally, and 18% alcohol was applied for 25 s. A cellulose sponge was used to remove the alcohol and the ocular surface was irrigated with BSS. The flap edges were dried with a sponge and the epithelial flap detached with a crescent blade, leaving a hinge at the 12 o'clock position.

Laser ablation was performed with the ESIRIS excimer laser (SCHWIND, Kleinostheim, Germany). Spherical and cylindrical ablations were performed according to manifest refraction without any reduction using the SCHWIND ORK-CAM aspheric profile. The ablation diameter was 6.5 mm with a 0.75 mm transition zone in all eyes. Following the ablation, stroma was washed with BSS and the flap gently repositioned. A drop of tobramycin 0.3% (Tobrex®, Alcon, Ft Worth, TX, USA) and dexamethasone 0.1% (Maxidex®, Alcon, Ft Worth, TX, USA) were instilled. The epithelial flap was allowed to dry for 2 min, and a cooled soft contact lens (Focus Night & Day; Ciba Vision, Duluth, Ga) was placed over the cornea with sterile forceps. The eyelid speculum and drape were removed.

2.2. Postoperative follow-up

Patients were examined daily until epithelial closure and 1, 3, 6, 12 months and then followed up yearly. Postoperative medication until epithelial closure included topical tobramycin and dexamethasone five times daily. Diclofenac 50 mg (Voltaren®, Novartis) was prescribed to all patients, and they were advised take it orally once or twice per day if required.

The contact lenses were removed after epithelial closure. Topical tobramycin was discontinued following epithelial closure. Dexamethasone was administered four times daily for 1 month followed by fluorometholone 0.1% (FML®, Allergan, Irvine, CA, USA) four times daily for another 1–2 months depending on refraction and haze level. All medications were discontinued after 3 months.

Postoperative haze was graded as follows: +0.5, barely visible corneal opacity; +1, reticular subepithelial opacities not affecting visual acuity; +2, punctuate or coalesced subepithelial opacities affecting visual acuity; +3, confluent subepithelial opacities affecting visual acuity and partially obscuring iris detail; and +4, dense opacities completely obscuring iris detail.

Table 1
Patient data.

	LASEK	Epi-LASIK	
Eyes (*n*)	22	20	
Age (y)			$p = 0.36$
Mean	33.4 ± 7.12	34.5 ± 8.4	
Range	24–49	24–49	
Sex			
Female	13	14	
Male	3	2	
Myopic SE[a] (D)			$p = 0.36$
Mean	−4.65 ± 1.74 D	−3.87 ± 1.30 D	
Range	−1.75 to −7.25 D	−2.00 to −6.375 D	

[a] SE: spherical equivalent.

Table 2
Refractive results.

	LASEK	Epi-LASIK	
UCVA[a] 20/25 or better (% of eyes)	95	95	$p = 0.39$
Efficacy index	0.94	0.96	$p = 0.44$
Safety index	1.01	1.02	$p = 0.42$

[a] UCVA: uncorrected visual acuity.

Gray scale value of the anterior stroma immediately beneath the epithelium was evaluated with the Confoscan 3 confocal microscope (NIDEK Technologies, Padova, Italy) at 1, 3, 6, 12 months and yearly.

The other outcome measures were efficacy index ($UCVA_{postoperative}/BCVA_{preoperative}$) and safety index ($BCVA_{postoperative}/BCVA_{preoperative}$).

Statistical analysis was performed using SPSS 16.0 software (SPSS, Chicago). Statistical comparisons were done with the chi-square test for categorical variables, and *t* test for continuous variables. Statistical significance was considered at $p < 0.05$.

3. Results

22 eyes were treated with LASEK and 20 eyes were treated with Epi-LASIK. No intraoperative or postoperative complication occurred, and all epithelial flaps were successfully repositioned in both groups.

Table 1 shows the patients' preoperative data.

Mean follow-up duration was 45.0 ± 7.7 months (range 28–56 mo) and 45.0 ± 7.1 months (range 30–58 mo) in the LASEK and Epi-LASIK groups, respectively ($p = 0.54$).

At the last visit, 95% of LASEK group and 95% of Epi-LASIK group achieved 20/25 or better UCVA ($p = 0.39$). Mean myopic regression was 0.68 D in both groups. The efficacy index was 0.94 in LASEK group and 0.96 in Epi-LASIK group ($p = 0.44$). The safety index was 1.01 in LASEK group and 1.02 in Epi-LASIK group ($p = 0.42$) (Table 2).

The details of visual outcome during follow-up course were shown in Table 3.

After 45.0 ± 7.7 months follow-up for LASEK group and 45.0 ± 7.1 months follow-up for Epi-LASIK group, no significant difference was noted for gray scale value (confocal microscopy, 58.09 ± 12.9 in LASEK group; 60.25 ± 9.1 in Epi-LASIK group ($p = 0.41$). Gray scale value changes during follow-up course were summarized in Table 4.

At 6 months no eye in either group developed more than +0.5 haze and maintained it until last follow-up visit. Also, at the end of the mean follow-up durations mean Schirmer test value was 14.8 ± 1.8 mm in LASEK group and 15.1 ± 1.2 mm in Epi-LASIK group ($p = 0.44$).