

Laser in Situ Keratomileusis versus Laser Assisted Subepithelial Keratectomy for the Correction of Low to Moderate Myopia and Astigmatism

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Abstract

Purpose: To compare the visual and refractive outcomes of laser in situ keratomileusis (LASIK) versus laser assisted subepithelial keratectomy (LASEK) in the treatment of low to moderate myopia and astigmatism

Methods: A retrospective comparative case series study comprised 2,474 eyes of patients with manifest refraction spherical component lower than -5.00 diopters (D) and cylinder components lower than -3.00 D were assigned to 2 groups: 1,238 eyes were treated with LASIK and 1,236 eyes with LASEK. Uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), remaining refractive error, and complications were evaluated at 1 week, 2, 6, 12, and 36 months postoperation.

Results: Preoperatively the mean refractive spherical equivalent (MRSE) was -3.42 D±1.01 (SD) in LASIK group and -3.36 D±1.01 (SD) in LASEK group, at 2 months it was -0.12 D±0.279 and -0.37 D±0.341, at 36 months postoperation in LASIK group it was -0.06 D±0.25 and in LASEK group it was -0.14±0.28 D, respectively. At 2 and 36 months, UCVA was ²⁰/₂₀ in 91.5% and 77.8% in LASIK group and, 94.7% and 90.9% in LASEK group, respectively. At 2 and 36 months, 95.4% and 78.7% in LASIK, 97.3% and 94.2% in LASEK group respectively were within ±0.5 D of emmetropia. Diffuse lamellar keratitis (DLK) in 5.9% and corneal ectasia in 1.05% of eyes (N=13) in the LASIK group and corneal haze in 10.6% (N=131) eyes in the LASEK group were seen.

Conclusion: Both LASIK and LASEK were safe and effectively treated eyes with low to moderate myopia and astigmatism. LASEK provided superior results in visual outcomes.

Keywords: LASIK, LASEK, Myopia, Astigmatism

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Introduction

Laser in situ keratomileusis (LASIK) has shown encouraging results in the treatment of myopia and astigmatism.¹⁻³ Despite the advantages of the procedure, complications related to the stromal flap include buttonhole,⁴ decentered flap, incomplete flap,⁵ free cap, striae,⁶ epithelial ingrowth,^{7,8} diffuse lamellar keratitis (DLK),⁹ late traumatic flap dislocation,¹⁰ and corneal ectasia.¹¹⁻¹⁴ Laser assisted subepithelial keratectomy (LASEK) is another approach to photorefractive keratectomy (PRK) which creates an epithelial flap that is replaced after photorefractive ablation.¹⁵ It is a surgical procedure to treat myopia and able to reduce intraoperative and postoperative LASIK complications.¹⁶ In 1999, Massimo Camellin, first described LASEK (M. Camellin, "LASEK May Offer the Advantages of both LASIK and PRK," Ocular Surgery News, March 1999, page 28). In this technique, the ablated corneal surface is covered by full-thickness epithelium.¹⁷ This epithelial coverage modifies the wound-healing response of cornea, effectively protects the bare surface of the stroma and prevents the influx of inflammatory cells from tears, reducing the initial inflammatory change to the corneal stroma.¹⁸ This may result in less postoperative haze and questionably less perioperative pain than PRK and more favorable visual outcomes.^{15,19,20} In addition, since no lamellar flap is created, LASEK may retain the biomechanical stability seen with PRK.¹⁵ In this study we retrospectively compare the visual and refractive outcomes, changes in best spectacle corrected visual acuity (BSCVA), and associated complications in patients who had LASIK or LASEK for the treatment of low to moderate myopia and myopic astigmatism. To our knowledge, there has been no comparison of the visual and refractive outcomes of LASIK and LASEK in the treatment of low to moderate myopia with this numbers of patients by a single surgeon.

Methods

A retrospective comparative case series study that included 2,474 eyes of patients with manifest refraction spherical component lower than -5.00 D and cylinder components lower than -3.00 D, between October 2001 and September 2004, in Negah Eye clinic. They

were assigned to 2 groups, 1,238 eyes were treated with LASIK and 1,236 eyes with LASEK.

All refractive surgeries were performed by a single surgeon (S.J.H) using the Nidek EC-5000 or Technolas 217z (Bausch & Lomb) excimer laser. The optical zone was 6.0 mm and the transition zone 7.0-8.0 mm. The preoperative ophthalmic examination included measurement of uncorrected visual acuity (UCVA), BSCVA, manifest and cycloplegic refractions, slit-lamp biomicroscopy, tonometry, indirect ophthalmoscopy, corneal topography and pachymetry (alternative orbscan II). Exclusion criteria were history of previous refractive procedures, keratoconus, cataract surgery, diabetes mellitus, glaucoma, connective tissue disorders, retinal disease, pregnancy or nursing period.

In LASIK group, A Moria, microkeratome was used to create a flap of 160 μm (routine flap thickness in time of our operations). The flap was raised using a spatula and the stromal bed exposed. The Nidek EC-5000 or Technolas 217z excimer laser was fired on the dried corneal surface with the ablation centered over the entrance pupil. The epithelial and stromal portions of the flap was replaced, and then irrigated with a cannula. At the end of operation, a drop of chloramphenicol and betamethasone 1% were instilled in the treated eye. The lid speculum was removed. Patients were instructed to apply 1 drop of betamethasone every 6 hours and chloramphenicol every 4 hours. One day postoperatively slit-lamp examination was done and betamethasone was administrated 4 times daily for 1 week, 2 times daily for 1 week and once a day for 1 week. Chloramphenicol every 6 hours for 1 week and artificial tear 4 times daily for 1 month.

LASEK was performed under topical anesthesia with tetracaine 0.5%. A rigid lid speculum was applied to the patient's eye. Irrigation of eyelid margin and fornixes was performed. A standard, round, corneal marker 8.0 mm was used. An alcohol solution cone (J2905, Janach) with an 8.5 mm diameter was placed on the eye. 20% alcohol solution was instilled inside the cone, left for about 20 seconds and then carefully absorbed using a dry sponge and washed off with a BSS. The epithelial flap was gently lifted with an

epithelial microhook and peeled back as a single sheet toward the 12 o'clock position. Excimer laser treatment was performed in the usual manner using the surface ablation nomogram. We didn't use mitomycin in any of our cases. The flap was washed with a balanced salt solution and then repositioned carefully with a spatula. A therapeutic soft contact lens was then placed on the eye. A drop of betamethasone and antibiotics were applied.

Postoperatively, the eyes were checked daily until the epithelial defect was completely closed (generally by day 3) and the bandage contact lens was removed. Postoperative medications included: Fluometholon QID for 1 month, TID for 1 month, BID for 1 month and once a day for 1 month. Artificial tear QID for 1 month and Chloramphenicol QID for 1 week were used. Routine postoperative examinations were scheduled at 1 week, 2 and 6 months, 1 and 3 years. The UCVA, manifest refraction, BSCVA, tonometry and slit-lamp biomicroscopy were performed at all examinations. Subepithelial corneal haze levels were checked at the slit-lamp at 2, 6 and 12 months and graded from 0 to 4 according to the method of Fantes et al. Postoperative complaints of pain or glare and halo were noted.

The study was approved by the Institutional Research Ethics Committee at the Eye Research Center, affiliated with the Tehran University of Medical Sciences. Informed consent was obtained from the all patients after explaining the risks and benefits of surgery including nonsurgical alternatives.

Statistical methods

All data were collected in an Excel database (Microsoft office 2007). Data analysis was done by SPSS for windows (version 16.0, SPSS Inc.). The unpaired student t and Pearson χ^2 test was used for statistical analysis as appropriate. A P-value less than 0.05 was considered statistically significant.

Results

The preoperative characteristics of the patients are shown in Table 1. At the preoperative examination, the between-group differences in the independent variables were not statistically significant. We excluded 20 patients in LASIK group because of ectasia

and retreatment and compare 1,218 patients in LASIK group with 1,236 patients in LASEK group. We excluded these patients, because of these complications may be due to incomplete corneal imaging evaluations (only topography and pachymetry) and didn't use of intraoperative pachymetry at that time. The mean age of patients was 28.77 ± 8.48 (range, 18-64 years) in LASIK group, and 28.49 ± 6.82 (range, 21-56 years) in LASEK group ($P=0.433$). The mean baseline spherical equivalent (SE) was -3.41 ± 1.01 diopters (D) in LASIK group and -3.36 ± 1.01 D in LASEK group ($P=0.193$). The mean follow-up time was 18.19 ± 14.47 (range, 2-36 months) in LASIK group and 16.48 ± 13.12 (range, 2-36 months) in LASEK group.

Predictability

At 2 months after the operations, in the LASIK eyes, the mean SE refraction was within ± 0.50 D of emmetropia in 95.40% eyes, at 6 months 93.54%, at 12 months 92.56% and at 36 months 78.7%. In the LASEK eyes, the mean SE refraction 2 months after operation was within ± 0.50 D of emmetropia in 97.30% eyes, at 6 months 98.05%, at 12 months 98.55% and at 36 months 94.2%. There are statistically significant differences in achieved SE between the 2 groups ($P=0.001$) (Figure 1).

At 2, 6, 12 and 36 months, in the LASIK eyes the mean SE refraction was within ± 1.00 D of emmetropia in 99.30%, 99.70%, 99.30%, 97.10%, respectively, and in LASEK eyes 99.90%, 99.60%, 99.50%, 99.30%, respectively, indicates the high predictability of both procedures in the treatment of low to moderate myopia (Table 2)(Figure 1).

In LASIK eyes, the mean postoperative astigmatism remained stable from, 2 to 36 months. At 2 months, in LASIK eyes the magnitude of cylinder was within ± 0.50 D of the intended correction in 89.80%, at 6 months 88.70% and at 12 months 87.10%. In LASEK eyes 91.10%, 92.80%, 93.10%, respectively. There are statistically significant differences between 2 groups ($P=0.003$) (Table 3)(Figure 2).

Efficacy

The between-group difference in UCVA was statistically significant from 1 week to 36 months postoperatively.

The efficacy index (ratio of postoperative UCVA and preoperative BSCVA) were 0.97 in LASIK and 0.99 in LASEK eyes ($P=0.001$) (Table 4).

At 12 months, the UCVA was $20/20$ or better in 89.6% LASIK eyes and 96.1% LASEK eyes and $20/40$ or better in 100% and 99.52%, respectively (Figure 3).

Safety

Thirty-six months after operation the BSCVA was the same in both groups (Table 5).

There were two-line loss of BSCVA in 3 LASIK eyes and one-line in 2 LASEK eyes, that was improved at 6 months postoperation. The main reasons to decreased BSCVA in LASIK eyes were stromal opacity, secondary to DLK, and in LASEK eyes due to corneal haze. Epithelial ingrowth, severe diffuse lamellar keratitis and corneal ectasia were excluded. Safety index (ratio of postoperative and preoperative BSCVAs) at 36 months was 1.007 in LASIK and 1.006 in LASEK eyes (Figure 4).

Stability

The change of mean SE between the 1 week and 36 months examinations was 0.35 D in LASIK and 0.09 D in LASEK eyes (Figure 5).

Retreatment

Three months after LASIK, 7 eyes needed retreatment due to overcorrection or under correction. These patients were excluded from the main collective. Two eyes were overcorrected (SE, 1.38 and 1.13 D), 5 eyes were under corrected (mean SE, -1.02 ± 0.31 D [range, -0.5 to -1.38]). Six months after retreatment, the overcorrected eyes had SEs of -0.88 and -0.5, respectively; the under corrected eyes had a mean SE of $-0.31 - 0.27$ D (range, 0 to -0.75). None of the eyes treated lost a line of BCVA.

Complications

No intraoperative complications occurred in the study population. Postoperatively, in LASIK group there were DLK in 3.96%, flap wrinkling in 0.7%, epithelial ingrowth in 0.3%, flap displacement in 0.16% and ectasia in 1.05% of the eyes. In LASEK group corneal haze grade 1 and 2 based on Fantes grading (0=No haze, completely clear cornea, 0.5=Trace haze seen with careful oblique illumination, 1=Haze not interfering with visibility of fine iris details, 2=Mild obscuration of iris details, 3=Moderate obscuration of the iris and lens, 4=complete opacification of the stroma in the area of the scar, anterior chamber is totally obscured) was appeared in 12.8% of eyes that improved 4 month postoperation.

Table 1. Preoperative independent variable

Variable		LASIK (N=1,218)	LASEK (N=1,236)	P
Age	Mean \pm SD	28.77 \pm 8.48	28.49 \pm 6.82	0.369*
	Range	18-64	21-56	
Sex	Female	873 (71.7%)	966 (78.2%)	0.000†
	Male	345 (28.3%)	270 (21.8%)	
Spherical Equivalent (D)	Mean \pm SD	-3.42 \pm 1.01	-3.36 \pm 1.01	0.193*
	Range	-1.00, -6.00	-1.00, -6.00	
Degree of cylinder (D)	Mean \pm SD	-0.74 \pm 0.94	-0.71 \pm 0.81	0.363*
	Range	0.0, -4.50	0.0, -4.50	
F/U time (Month)	Mean \pm SD	18.19 \pm 14.48	16.48 \pm 13.12	0.002*
	Range	2-36	2-36	

LASIK: Laser in situ keratomileusis, LASEK: Laser-assisted subepithelial keratectomy, NS: Not significant, *: Unpaired student t-test, †: χ^2 test

Table 2. Attempted and achieved spherical equivalent after LASIK and LASEK

Diopter	2 Month		6 Month		1 Year		3 Years	
	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK
n	1,201	1,236	867	980	736	726	407	308
≤±0.50	95.4	97.3	94.6	96.6	91.4	96.1	78.7	94.2
≤±1.00	99.3	99.9	99.7	99.6	99.3	99.5	97.0	99.4
≥±1.25	0.7	0.1	0.3	0.4	0.7	0.5	3.0	0.6
P	0.000		0.000		0.000		0.000	

Table 3. Magnitude of postoperative refractive cylinder

Diopter	2 Month		6 Month		1 Year		3 Years	
	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK
n	1,201	1,236	867	980	736	726	407	308
≤-0.50	89.8	91.1	88.7	92.8	87.1	93.1	78.5	86.9
≤-1.00	98.5	98.9	97.9	99.1	97.6	99.2	95.1	99.0
≥-1.25	1.5	1.1	2.1	0.9	2.4	0.8	4.9	1.0
P	0.514		0.514		0.001		0.007	

Table 4. Postoperative uncorrected visual acuity

UCVA	2 Months		6 Months		1 Year		3 Years	
	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK
n	1,201	1,236	867	980	736	726	407	308
≥20/20	91.5	94.7	91.8	94.7	89.7	93.9	77.9	90.9
P	0.002		0.013		0.003		0.000	
≥20/40	99.8	99.8	100	99.6	100	99.2	98.8	99.4
P	0.666		0.060		0.013		0.436	

UCVA: Uncorrected visual acuity

Table 5. Pre and postoperative best spectacle corrected visual acuity

BSCVA	Pre Op		2 Months		6 Months		1 Year		3 Years	
	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK	LASIK	LASEK
n	1,201	1,236	1,201	1,236	867	980	736	726	407	308
≥20/20	95.2	95.8	97.4	97.4	98.4	97.8	98.6	98.2	98.0	98.4
P	0.453		0.947		0.332		0.507		0.734	
≥20/40	100	100	100	99.9	100	100	100	100	100	100
P	1.000		0.321		1.000		1.000		1.000	

BSCVA: Best spectacle corrected visual acuity, Pre op: Preoperative

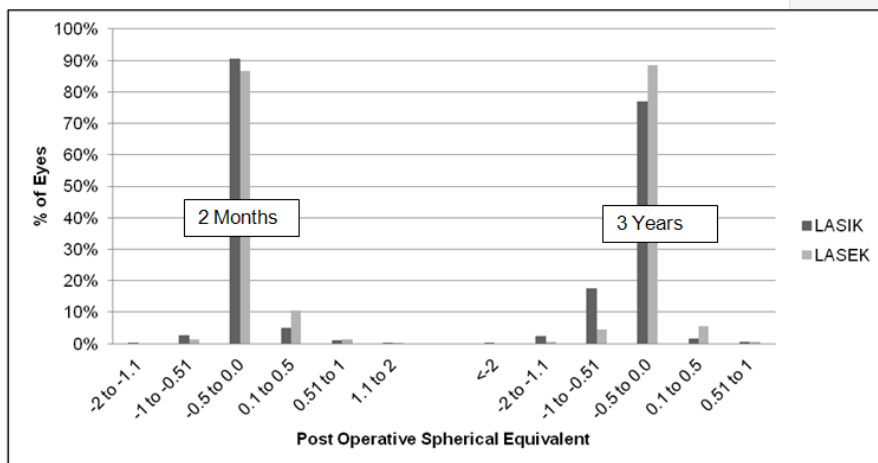


Figure 1. Achieved mean refractive spherical equivalent after LASIK and LASEK at 2 and 36 months postoperation

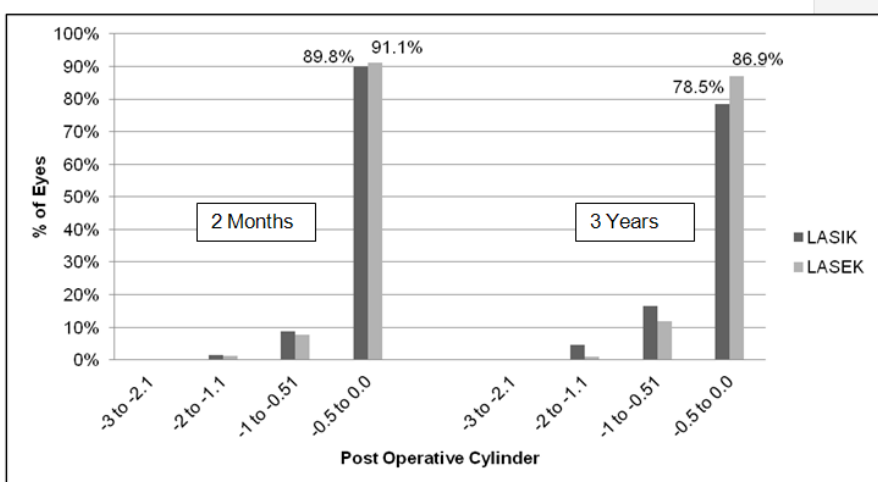


Figure 2. Comparison of postoperative refractive cylinder at 2 and 36 months postoperation

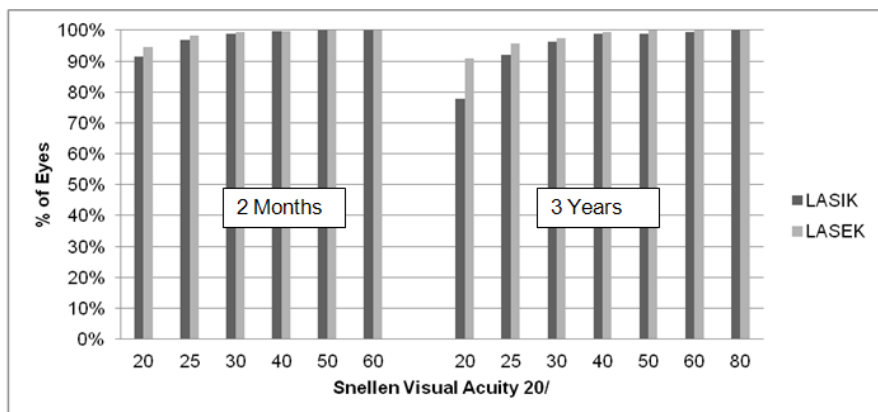


Figure 3. Cumulative Snellen 2 and 36 months postoperation uncorrected visual acuity

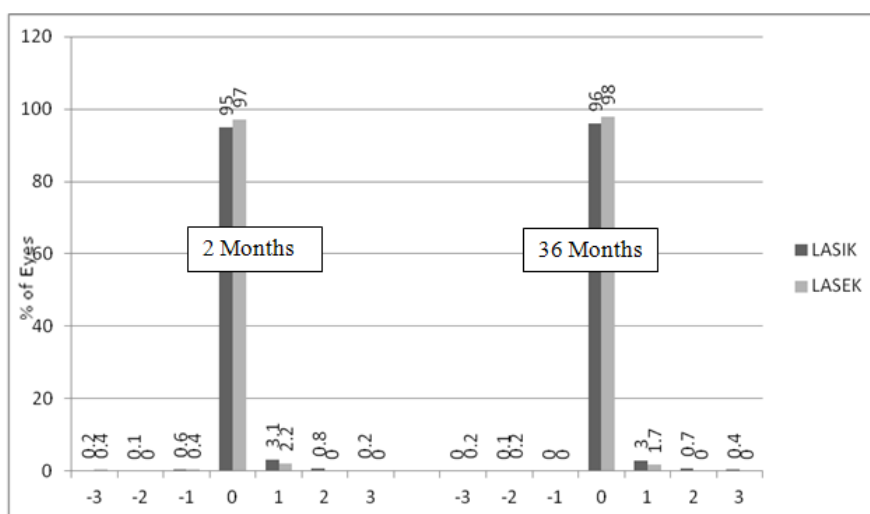


Figure 4. Changes in best spectacle corrected visual acuity from preoperatively to 2, and 36 months postoperatively

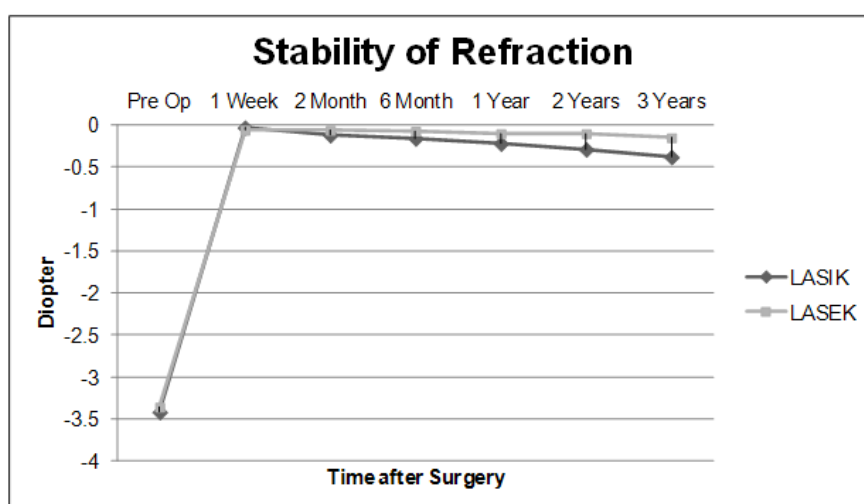


Figure 5. Stability of refraction

Discussion

Our data suggest that LASEK and LASIK in low to moderate myopic patients offer an excellent safety profile with predictable and stable refractive outcomes. However, the LASEK procedure was found to be a more favorable method for correcting low to moderate myopia than LASIK.

Analysis of the visual recovery and complications of LASEK and LASIK for the treatment of low to moderate myopia in this study resulted in several valid observations: No sight threatening complications were encountered in LASEK group; there were no cases of recurrent erosion syndrome; haze

associated with the loss of BSCVA occurred in 0.16% (2 eyes) after 8 weeks and long-term safety indices close to 1.0 were noted after 6 months.

In LASIK group there were DLK in 3.96%, flap wrinkling in 0.7%, and epithelial ingrowths in 0.3%, flap displacement in 0.16% and ectasia in 1.05% of eyes. The time required for the BSCVA to return to preoperative levels, which is an indicator of clinical wound healing, was 2 months for both groups. At this time the efficacy index also stabilized. A functional UCVA of $^{20}/_{40}$ or better was achieved in 99.5% of eyes at 1 week in LASEK and 99.2% in

LASIK group, but visual function stabilized as late as 8 weeks, based on safety and efficacy indices in eyes with an UCVA of $^{20}/_{20}$ or better.

One problem associated with the safety of LASEK is the formation of haze postoperatively. Haze peaking at 3-4 months has been reported in several studies with at least a 6-month follow-up.^{21,22} One hundred and thirty-six eyes in our study (12.8%) developed grade 1-2 haze, whereas higher percentages of visually significant haze were reported by Rouweyha et al (8%)²³ and Chalita and coauthors (8% to 10%).²⁴

In a prospective LASEK vs. LASIK comparative study at 6 months after surgery, Scerrati¹⁶ concluded that patients treated with LASEK showed better results in terms of corneal topography, UCVA, and sensitivity to contrast and refractive results, compared to patients with LASIK. Lee et al concluded PRK and LASIK to be similarly effective and predictive of correction in low to moderate myopia, because of less decentration of ablation PRK is more safer than LASIK, so they recommended PRK for low to moderate correction of myopia.²⁵ But Kim et al, in a study have been concluded both LASIK and LASEK safe and effectively treated eyes with high myopia, but LASIK provided superior results in visual predictability and corneal opacity.¹⁵ Shortt and Allan in their study showed LASIK has a faster visual recovery than PRK, but the effectiveness of these two procedure is comparable.²⁶ Yang concluded LASIK and PRK have similar effect for correction of myopia from -1.5 to -15.0 D.²⁷ de benito-Ilopis et al in comparison between

Femtosecond Laser-Assisted Sub-Bowman Keratomileusis vs. LASEK concluded both FSBK and LASEK are safe and effective for correction of myopia.²⁸ In a recent study, Na et al by a multicenter study in Korea showed that LASIK and surface ablation includings LASEK, Epi-LASIK, and PRK produced similar postoperative visual efficacy after corneal healing.²⁹ The epithelial flap remaining after LASEK may help stromal wound healing after excimer laser surgery.^{16,30,31} So, there are controversy about superiority of these two procedure to correct low to moderate myopia.

Limitations of our study: because of our limitations in time of study more patients in LASIK group were operated with Nidek EC-5000 machine, and this may had been had effect in our results, and we recommend a prospective study for comparison between these two procedure with a same excimer laser machine. Our study is a retrospective investigation, so we recommend a prospective, randomized, paired comparison of LASIK and LASEK for low to moderate myopia.

Conclusion

In conclusion, the results of this study indicate that both LASEK and LASIK for low to moderate myopia are effective, predictable and safe procedures. However, LASEK provided superior results in visual predictability and outcomes up to 3 years postoperatively. A long-term follow-up is needed.

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