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Original Article

LASER EPITHELIAL KERATOMILEUSIS (LASEK) FOR MYOPIA IN PATIENTS WITH THIN CORNEA

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Background – **We aimed to evaluate the effectiveness, safety, and patient satisfaction of laser epithelial keratomileusis (LASEK) for myopia in patients with thin cornea.**

Methods – **Seventy-one eyes of 56 patients with myopia of –1.50 to –8.75 diopters (D) and corneal thickness of 451 – 499 microns were enrolled in this prospective clinical study. Slit-lamp examination, manifest refraction, uncorrected and spectacle-corrected visual acuity, and videokeratography were done before surgery. Patients were visited in the first 7 days, and also at 1st and 3rd months after the surgery.**

Results – **All patients were examined in the first 7 days and at 1st month, while 48 eyes (71%) were examined 3 months after the surgery. At 3rd month, 46 eyes (95.8%) had an uncorrected visual acuity of 20/40 or better, 37 eyes (77.1%) had an uncorrected visual acuity of 20/20 or better, 36 eyes (75%) had a spherical equivalent (SE) within ± 0.50 D, and 46 eyes (96%) had a SE within ± 1.00 D. The mean corneal thickness was 409 ± 23 microns (SD) with a minimum of 372 microns. The epithelial healing time was 3.37 ± 1.05 days (SD). The mean subjective pain score in the scale of 0 to 3 (3 for severe) was 1.14 ± 0.75 (SD). One eye lost 2 lines of spectacle-corrected visual acuity, and no eye lost more than 2 lines. Thirty-four patients (82.9%) were very satisfied or satisfied with their operated eyes.**

Conclusion – **LASEK was shown to be effective and safe in correction of myopia in patients with thin cornea in a short period of time. LASEK can be considered as an alternative for treatment of myopic patients whose corneal thickness is inadequate for laser *in situ* keratomileusis (LASIK).**

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Introduction

Excimer laser refractive procedures modify the mechanical strength of cornea.[1] Adequate residual stromal bed thickness should be saved postoperatively to avoid a decrease in the corneal integrity and the subsequent complications.[1 – 4] Given the fast visual recovery and lower pain associated with it, laser *in situ* keratomileusis (LASIK) is preferred to photorefractive keratectomy (PRK). Nevertheless, PRK may be preferable to LASIK in patients with inadequate corneal thickness, especially in eyes with higher degrees of myopia. Major limitations of PRK are postoperative pain,[5 – 7] subepithelial haze,[8 – 17] and prolonged visual rehabilitation.[6, 18] Laser epithelial keratomileusis (LASEK), a recent modification of PRK introduced by Camellin[19] in 1999, has been suggested to have faster visual recovery and less potential for postoperative discomfort and haze as compared to PRK. On the other hand, LASEK, like PRK, offers the advantage of avoiding flap-related complications of LASIK, which makes it a reasonable alternative type of refractive surgery in myopic patients with thin corneas. In this work, we present the results of a prospective study of LASEK for myopia in patients who have inadequate corneal thickness for LASIK.

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Patients and Methods

Fifty-six patients with 71 myopic eyes were enrolled in a prospective clinical study between July and October 2001. Patients with at least 18 years of age, a baseline spectacle-corrected visual acuity of 20/40 or better, stable refraction during the past year, and a corneal thickness between 450 – 500 microns (not adequate for LASIK procedure) were included in the study. Exclusion criteria were: corneal or retinal disease, previous eye surgery, collagen vascular diseases, keratoconus, glaucoma, cataract, pregnancy, current systemic corticosteroid therapy, and inability to complete follow-up schedule in 3 months. Before surgery, the mean spherical equivalent (SE) refraction was –5.14 ± 1.66 diopters (D) (mean ± SD) and the mean corneal thickness was 484 ± 11 microns. Before the operation, the nature of the procedures, their results, and complications were thoroughly explained to all of the patients and then they were asked to read and sign a formal informed consent. A subjective questionnaire was used to assess patient satisfaction and quality of vision.

Clinical examinations

All of the patients received a complete preoperative ophthalmologic examination by an ophthalmologist. Preoperative ophthalmologic examination included slit-lamp microscopy, applanation tonometry, fundus examination, pachymetry, visual acuity, keratometry, and videokeratography. Uncorrected and spectacle-corrected visual acuities were tested using the Nidek SCP-660 chart projector (20/10 – 20/400; Nidek Co, Gamagori, Japan) with tumbling E letters; the smallest line in which the patient could read the four letters correctly was recorded as the final visual acuity. Refractive error was measured by optometrists using manifest refraction with fogging technique. Videokeratography was done using the corneal analysis system version 2.104 (EyeSys Laboratories, Houston, TX), according to the manufacturer's instructions.

All of the patients were examined every day for 7 days, followed by examination at 1st and 3rd postoperative months. During the visits in the first week, the eyes were evaluated specifically for epithelial healing. Patients were asked to grade the pain they experienced during and after the surgery according to a four-point scale from 0 to 3 for none, mild, moderate, or severe pain. Slit-lamp microscopy, manifest refraction, uncorrected and spectacle-corrected visual acuity, and videokeratography were done at 1st and 3rd months follow-up visits. Subepithelial stromal haze was evaluated with the slit-lamp microscope using broad tangential illumination and graded as follows: 0, no haze; 0.5^+, half trace-barely visible granularity; 1^+, trace-faint gray granularity; 2^+, mild-easily visible gray reticular pattern; 3^+, moderate-dense gray plaque; and 4^+, severe dense white corneal scare. Patient satisfaction and quality of vision were assessed at 1st and 3rd postoperative months visits, using a questionnaire previously validated in Noor Vision Correction Center.[20]

Surgical technique

All LASEK procedures were performed by a surgeon well experienced with PRK and refractive surgery. Patients received topical anesthesia without systemic sedation. Preincision of the corneal epithelium was made using a microtrephine with an 8-mm diameter and 70-µm deep calibrated blade (Janach, J 2900S). Twenty percent alcohol solution made with cold distilled water was instilled inside an 8.5-mm alcohol solution cone (Janach, J 2905). After 20 seconds, alcohol solution was absorbed by a small surgical sponge and the area was irrigated thoroughly with balanced salt solution. Then, the margin was lifted and epithelial debridement was carried out with an epithelial microhoe (Janach, J 2915A). The epithelial flap was gently detached, gathered, and folded at its hinge at the 12 o'clock position. On the next step laser ablation was performed using Nidek EC-5000 excimer laser (Nidek Co, Gamagori, Japan) or Technolas 217-C excimer laser (Bausch and Lomb, CA, USA) within a single 6-mm ablation zone. The epithelial flap was then repositioned using a repositioning spatula (Janach, J 2920A). Cornea was covered with a therapeutic soft contact lens after the procedure. Postoperative medications included 1 drop of both diclofenac 0.1% and ofloxacin 0.3%, 4 times a day, and artificial tears every 2 hours until the epithelium healed. Following complete regeneration of the epithelium, flourometholone 0.1% was prescribed 4 times daily for the first postoperative month, 3 times daily for the second month, twice daily for the third month, and once a day for the fourth month. Contact lenses were removed on the third or fourth day following the operation. Patients were instructed to use diclofenac-Na tablets 25 mg every 6 hours for 5 days after the surgery for pain

relief. Topical chloramphenicol was also prescribed for 5 days.

Statistical analysis

Statistical analysis aimed to determine predictability, changes over time, and safety of the procedure. All visual acuity measurements were converted from Snellen to logarithm of the minimum angle of resolution (LogMAR).[21] Repeated measures analysis of variance (ANOVA) was used to compare values over several periods of time. For all statistical tests 0.05 was considered as significant.

Results

LASEK procedure failed in three eyes because of epithelial flap abortion and surgical plan change to PRK. We present the postoperative results of 68 eyes. Of the 56 patients, 37 (66.2%) were females. Patients ranged in age from 18 to 50 years, with a mean of 29.04 ± 7.08 years. All 56 patients were examined at the first 7 postoperative days and at 1st month (mean, 32.39 ± 5.58 days), and 40 patients (48 eyes, or 70.6%) were examined at 3rd month (mean, 105.42 ± 16.47 days) after the operation.

The 16 patients who did not return for follow-up at 3rd month had similar age and sex distribution, compared to those who did return. The mean baseline and the 1st month postoperative spherical equivalent refraction of these patients were not statistically different from the rest of the study population.

Refractive outcome

The mean manifest SE refraction before and after the surgery as well as the number and percentage of eyes with SE within ± 0.50 D and ± 1.00 D are summarized in Table 1. Figure 1 illustrates the attempted vs achieved correction in the two groups. The mean SE changes over time were statistically significant ($p < 0.001$, repeated measures ANOVA). The postoperative change over time (1st month mean SE versus 3rd month mean SE) was statistically a borderline significance ($p = 0.058$, test of within-subject contrast in repeated measures ANOVA).

Visual outcome

The number and percentage of eyes with uncorrected visual acuity of 20/40 or better and 20/20 or better at 1st and 3rd months after the surgery are summarized in Table 1. None of the eyes lost more than two lines of spectacle-corrected visual acuity at 1st and 3rd months after the surgery. One eye lost 2 lines at one month after the surgery. No eye lost more than 1st line of spectacle-corrected visual acuity at 3rd month after the surgery.

Corneal thickness

The mean corneal thickness changed from 484 ± 11 microns (range, 451 – 499) at baseline to 409 ± microns (range, 372 – 460) at 3rd postoperative month.

Epithelium healing, pain, and haze

The epithelial defect was completely healed in all the eyes by the fifth day. The epithelial healing time was 3.37 ± 1.05 days. The mean subjective pain score was 1.14 ± 0.75 on the first day after the operation. All eyes became pain-free by the fifth day. Corneal haze grades at 1st and 3rd months after the operation are summarized in Tables 2 and 3.

Patient satisfaction and subjective assessment of vision

One month after the operation 45 (76.3%) of the patients were very satisfied or satisfied with their operated eyes. At 3rd month visit, this number

Table 1. Vision and refraction before and after laser epithelial keratomileusis for myopia with thin cornea.

Baseline	
SE mean (D) ± SD	–5.14 ± 1.66
SE range (D)	–1.50 – –8.75
1 week after surgery	
UCVA ≥ 20/40 [No. (%)]	56 (82.4)
UCVA ≥ 20/20 [No. (%)]	18 (26.5)
1st month after surgery	
SE mean ± SD	0.28 ± 0.60
SE range (D)	–1.50 – +2.13
UCVA ≥ 20/40 [No. (%)]	66 (97.1)
UCVA ≥ 20/20 [No. (%)]	46 (67.6)
SE within ± 0.50 D [No. (%)]	47 (69.1)
SE within ± 1.00 D [No. (%)]	62 (91.1)
3rd month after surgery	
SE Mean ± SD	0.06 ± 0.51
SE Range (D)	–1.13 – +1.63
UCVA ≥ 20/40 [No. (%)]	46 (95.8)
UCVA ≥ 20/20 [No. (%)]	37 (77.1)
SE within ± 0.50 D [No. (%)]	36 (75.0)
SE within ± 1.00 D [No. (%)]	46 (95.8)

UCVA= uncorrected visual acuity; SE= spherical equivalent refraction; SD= standard deviation; D= diopter.

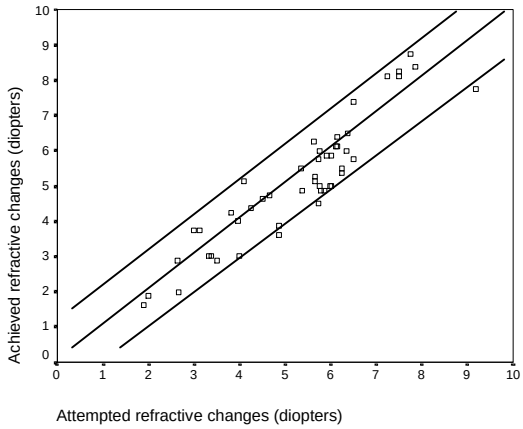

Figure 1. Scatter plots of the attempted refractive change versus the achieved refractive changes at 3rd month after LASEK.

reached 34 (82.9%) of the patients. Table 4 shows the mean of glare and halo scores at 1st and 3rd months after the surgery.

Discussion

In this prospective clinical study we assessed efficacy, predictability, safety, and patient satisfaction of LASEK for myopia of –1.50 to –8.75 D in patients who had inadequate corneal thickness for LASIK. LASEK, a recent modification of PRK, has been suggested to have faster visual recovery and less potential for postoperative discomfort and haze as compared to PRK, while it offers the advantage of avoiding flap-related complications of LASIK.

Although LASEK has been shown to be safe, effective, and predictable in many reports, [22 – 36] some comparative studies, although very few to this date, have been rather controversial. In a study of 27 patients (54 eyes) undergoing LASEK in one eye and PRK in the other, Lee et al [32] observed a lower incidence of postoperative pain in the LASEK group.

The mean glare scores, 1 and 3 months after laser epithelial keratomileusis for myopia with thin cornea were 2.20 ± 1.08 and 1.73 ± 1.07, respectively; likewise the mean halo scores 1 and 3 months after LASEK were 2.15 ± 1.32 and 2.20 ± 1.49.

Corneal haze score in this study was significantly lower in the LASEK patients compared to PRK patients one month after the procedure. Interestingly, this difference was not significant at 3rd postoperative month. Shah et al,[35] after a mean follow-up of 62.6 weeks of 72 eyes

Table 2. Corneal haze at 1st and 3rd months after laser epithelial keratomileusis for myopia with thin cornea.

Grade†	Time after surgery	
	1st month No. (%)	3rd months No. (%)
0	43 (63.2)	28 (58.3)
0.5+	15 (22.1)	11 (22.9)
1+	7 (10.3)	8 (16.7)
2+	3 (4.4)	1 (2.1)
Number of eyes	68	48

† Haze grade: 0= no haze; 0.5+= barely visible granularity; 1+= faint gray granularity; 2+= easily visible gray reticular pattern.

paired for PRK with flap (LASEK) and PRK with debridement (conventional PRK), reported faster visual recovery and reduced haze when an epithelial flap was made. Litwak and colleagues [31] in a similar, randomized, prospective, and comparative study of LASEK vs PRK in 25 patients (50 eyes) reported less discomfort and better visual acuity in PRK patients during the first month after the operation.

In our experience at Noor Vision Correction Center[36] a randomized, paired, and clinical study of 42 patients (84 eyes), LASEK was not found to have any advantage over PRK in terms of postoperative pain, epithelial healing time, or corneal haze. Apparently further studies with longer follow-ups are warranted to resolve the controversy. LASEK has been suggested to be an alternative treatment in patients who, for some reasons, are not proper candidates for LASIK, e.g., those with inadequate corneal thickness.[30, 31, 33] We studied safety and efficacy of this procedure in myopic patients with thin corneas in a prospective setting.

Our study had certain limitations: given the 3-month follow-up time, we could not investigate consistency of the results, nor was the long-term regression studied. Additionally, 16 patients (29.4%) did not return for the follow-up visit at the 3rd postoperative month. These patients did not

Table 3. Changes in the corneal haze between 1st – 3rd months after the LASEK.*

Corneal haze grade† at 1 month	Corneal haze grade† at 3 months				
	0	**0.5+**	**1+**	**2+**	**Total**
0	22	6	2	—	**30**
0.5+	5	3	2	—	**10**
1+	1	1	2	1	**5**
2+	—	1	2	—	**3**
Total	**28**	**11**	**8**	**1**	**48**

* Number of eyes (%); † Haze grade: 0= no haze; 0.5+= barely visible granularity; 1+= faint gray granularity; 2+= easily visible gray reticular pattern.

differ significantly with the ones who did return for the visit when compared for sex, age, and baseline spherical equivalent refraction. Also, when compared for spherical equivalent refraction and corneal haze at 1st month, these patients were not statistically different from those who returned for the 3rd-month visit.

At 3rd postoperative month, 36 eyes (75%) had a SE within ± 0.50 D and 46 eyes (96%) had a SE within ± 1.00 D. Forty-six eyes (96%) had an uncorrected visual acuity of 20/40 or better. One eye lost 2 lines of spectacle-corrected visual acuity, and no eye lost more than 2 lines. The minimum residual stromal thickness was 370 microns postoperatively. Thirty-four patients (82.9%) were very satisfied or satisfied with their operated eyes.

Adequate residual and stromal bed thickness should be saved postoperatively to avoid a decrease in the corneal integrity and subsequent complications.[1 – 4] Most surgeons have recommended that at least 250 to 300 µm of residual posterior stroma be left untouched to ensure adequate biomechanical corneal strength. [1 – 4, 22] In our study, at 3rd month after LASEK, the patients had a mean corneal thickness of 409 ± 23 µm, ranging from 372 to 460 µm, which is significantly more than the recommended thickness.

Considering the patients (48 eyes) who returned for both 1st and 3rd months visits, corneal haze improved in 10 (21%), and became worse or remained unchanged in 38 (79%). In Lee et al's study[32] improvement rates were 37% for the LASEK group and 74.1% for the PRK group.

While our study confirmed the results of previous studies for treatment of low to moderate myopia with LASEK, it also showed that this method is an effective, predictable, and safe technique for treating myopia in patients with thin cornea. LASEK might also be used in patients with narrow palpebral fissure, steep or flat corneas, large pupils, and many other cases in which LASIK is contraindicated. Additionally, LASEK seems to be a better choice than LASIK for wavefront-guided customized corneal ablation. We conclude that LASEK could be considered as a practical alternative for treatment of myopia in patients with inadequate corneal thickness for LASIK. However, further investigations are needed to address long-term results of LASEK in comparison to other techniques.

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