A Prospective, Randomized, Contralateral Eye Comparison of Epithelial Laser in situ Keratomileusis and Photorefractive Keratectomy in Eyes Prone to Haze

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ABSTRACT

PURPOSE: To compare refractive outcome, subepithelial haze, and pain after epithelial laser in situ keratomileusis (epi-LASIK) and photorefractive keratectomy (PRK).

METHODS: In this prospective, randomized study, 32 eyes of 16 patients were treated for myopia with epi-LASIK (epi-LASIK group) in one eye and PRK in the fellow eye (PRK group). All patients underwent ablation using the NIDEK EC-5000 CX II excimer laser platform. Mean patient age was 24.8 years (range: 19 to 35 years). Mean preoperative manifest refractive spherical equivalent (MRSE) was \(-2.76\) diopters (D) (range: \(-1.00\) to \(-4.88\) D). Refractive outcome, subepithelial haze, and pain out to 6 months postoperatively were compared between groups.

RESULTS: At 6 months postoperatively, the mean MRSE was \(-0.22\pm0.27\) D (range: \(0.25\) to \(-0.88\) D) in the epi-LASIK group and \(-0.23\pm0.29\) D (range: \(-0.50\) to \(-1.125\) D) in the PRK group. There was no statistically significant difference in the refractive outcomes between groups. By postoperative day 4, 18% of the epi-LASIK group and 7% of the PRK group achieved the final uncorrected visual acuity (UCVA). On day 1 postoperatively, 14% fewer patients in the PRK group experienced pain compared with the epi-LASIK group. On postoperative day 2, 36% fewer patients in the epi-LASIK group experienced pain. Seventy-one percent of patients in the epi-LASIK group and 36% of patients in the PRK group had no haze postoperatively.

CONCLUSIONS: Epi-LASIK and PRK produced similar refractive outcome. Patients who underwent epi-LASIK experienced faster recovery of vision, less haze, and less pain. [J Refract Surg. 2007;23:S1015-S1020.]

Photorefractive keratectomy is safe and effective for low to moderate myopia, although it has some disadvantages such as postoperative pain, slow visual recovery, prolonged steroid therapy, risk of haze, and myopic regression. Haze has been reported for treatments as low as 2.50 diopters (D) and may be more prevalent in certain populations with brown irides.

Laser epithelial keratomileusis was developed to reduce some of the complications associated with PRK, such as postoperative pain and haze. Laser epithelial keratomileusis is safe, efficacious, and predictable. However, there is no standardized procedure for this surgical technique, and concerns about the effect of alcohol on the epithelium remain.

Epi-LASIK is a surface procedure that automates the separation of the epithelium mechanically. Unlike with LASEK, alcohol is not required with epi-LASIK, and up to 85% of the epithelium remains viable.

This study assessed the safety, efficacy, stability, visual recovery, and patient satisfaction of epi-LASIK for the treatment of myopia with or without astigmatism using the Moria Epi-k (Moria SA, Antony, France) automated epithelial separ-
rator and the NIDEK EC-5000 CX II excimer laser platform (NIDEK Co Ltd, Gamagori, Japan).

**PATIENTS AND METHODS**

In this prospective, randomized, contralateral eye study, 32 eyes from 16 patients were treated with epi-LASIK in one eye (epi-LASIK group) and PRK in the fellow eye (PRK group). The 16 patients were undergoing treatment for myopia with or without astigmatism using the Moria Epi-K automated epithelium separator and the NIDEK EC-5000 CX II excimer laser platform. Mean patient age was 24.8 years (range: 19 to 35 years), and 69.7% of patients were male. Mean preoperative manifest refractive spherical equivalent (MRSE) was −2.76 D (range: −1.00 to −4.88 D).

**INCLUSION AND EXCLUSION CRITERIA**

To be included in the study, patients had to be at least 18 years of age, have a documented stable refraction for the past 12 months, and be poor candidates for LASIK because of thin corneas (less than 500 µm). Exclusion criteria included unstable refraction, keratoconus, suspected keratoconus, pellucid marginal degeneration, previous ocular surgery, and active ocular or systemic disease that could affect corneal wound healing.

Patients were randomized into one of two groups using a randomization schedule generated by a biostatistician.

All patients were informed of the risks and complications associated with the surgeries and alternatives to vision correction. All patients in the study signed an informed consent. The study protocol was approved by the Magrabi Hospital Human Research Committee.

**PREOPERATIVE AND FOLLOW-UP EVALUATION**

All patients underwent a baseline ophthalmic examination and postoperative examination daily at day 1 to day 7, followed by examinations at 2 weeks, 1 month, 3 months, and 6 months. Snellen uncorrected visual acuity (UCVA), Snellen best spectacle-corrected visual acuity (BSCVA), and manifest and cycloplegic refractions were measured. Slit-lamp examination, corneal topography and aberrometry using the NIDEK OPD-Scan (NIDEK Co Ltd), corneal pachymetry using the DGH pachymeter (DGH Technologies Inc, Exton, Pa), Goldmann tonometry, and a dilated fundus examination also were carried out. Postoperatively, all patients underwent the same preoperative evaluations with the exception of a dilated fundus examination, which was conducted only at month 6 or earlier if indicated. During the first week, patients were asked whether they experienced pain and which eye had more pain. All patients were masked to the procedure that each eye underwent.

**SURGICAL TECHNIQUES**

**Epi-LASIK.** Preoperatively, the eye undergoing surgery was anesthetized using topical anesthetic. A lid speculum was inserted to allow maximum exposure of the globe. Corneal thickness was measured using an ultrasound probe. Three gentian violet marks were placed on the peripheral cornea for better visualization of the epithelial flap. A suction ring with a 7.50-mm stop was placed on the eye, and forward movement was initiated with copious irrigation of balanced salt solution. Once the forward pass was completed, the reverse pass was initiated again with copious irrigation using balanced salt solution. The epithelial flap was reflected nasally, the cornea dried using a sterile surgical sponge, and the ablation delivered. Proper alignment of the eye with the laser was achieved with the laser-aiming diode centered on the first Purkinje image on the patient’s pupil. Patients fixated on a red fixation light, coaxial with the surgeon’s line of vision and the excimer laser beam, throughout the ablation. The flap was repositioned, and the interface was irrigated with balanced salt solution to remove any debris. The cornea was dried with a surgical sponge and a bandage contact lens was placed on the eye.

**Photorefractive Keratectomy.** Eyes of patients undergoing PRK were also anesthetized using topical anesthetic. A lid speculum was inserted to allow maximum exposure of the globe. Corneal thickness was measured using an ultrasound probe. The central 8.00 mm of the cornea was marked. Mechanical debridement of the epithelium of the central 8.00 mm was performed using a Beaver blade without damaging Bowman’s membrane. Excimer ablation was performed according to a customized nomogram internal to the NIDEK EC-5000 CX II excimer laser platform. Proper alignment of the eye with the laser was achieved with the laser-aiming diode centered on the first Purkinje image on the patient’s pupil. Patients fixated on a red fixation light, coaxial with the surgeon’s line of vision and the excimer laser beam, throughout the ablation. The surface of the cornea was irrigated with balanced salt solution to remove any debris. A bandage contact lens was placed on the eye. Postoperatively, patients were instructed to instill the topical antibiotic/topical nonsteroidal anti-inflammatory medication four times a day for 1 week and artificial tears four times a day for 1 month. The bandage contact lens was removed after the epithelium healed.
OUTCOMES ANALYSIS

Refractive outcomes for both epi-LASIK and PRK were compared. In addition, postoperative pain experienced with both procedures was compared, as was postoperative corneal haze. All outcomes are reported at 6 months postoperatively, with the exception of postoperative pain, bandage contact lens removal, visual recovery, and corneal haze.

RESULTS

No complications occurred during surgery in either group. Six months postoperatively, 75% (24/32) of patients were available for follow-up. All patients in the epi-LASIK group were within −1.00 D of the intended MRSE at 6 months postoperatively (Fig 1). The postoperative UCVA was similar in both the PRK and epi-LASIK groups (Fig 2). No eye in either group lost more than 1 line of BSCVA 6 months postoperatively (Fig 3). Stability was similar for both groups (Fig 4).

All patients in both groups were within −1.00 D of the intended MRSE at 6 months postoperatively. Twelve (68.75%) eyes were between plano and −0.50 D in the epi-LASIK group compared with 11 (62.50%) eyes in the PRK group. Two (12.50%) eyes were between +0.50 and +0.10 D in the epi-LASIK group compared with 3 (18.75%) eyes in the PRK group. Three (18.75%) eyes in both groups were between −0.51 and −1.00 D (see Fig 1). No patient had a >0.50-D change in MRSE between 3 and 6 months.
Figure 3. Safety at 6 months postoperatively (N=24 eyes).

Figure 4. Change in mean MRSE over time (N=24 eyes).

Figure 5. Visual recovery at 6 months. This graph shows the percent of eyes that achieved their final UCVA at each examination (N=24 eyes).
Uncorrected visual acuity was 20/20 or better in 12 (75%) eyes in the epi-LASIK group, whereas 11 (68.75%) eyes achieved the same level in the PRK group. Fifteen (93.75%) eyes had an UCVA of 20/25 or better in the epi-LASIK group, and 14 (87.50%) eyes reached this level in the PRK group. Fifteen (93.75%) eyes in both groups had an UCVA of 20/30 or better. All patients in both groups read 20/40 or better at distance without correction (see Fig 2).

In the early postoperative period (less than 1 week), visual recovery in the epi-LASIK group was faster than in the PRK group (Fig 5). Fewer eyes in the PRK group had no subepithelial haze (haze), and no eyes in the epi-LASIK group had grade 1 or higher haze 6 months postoperatively (Fig 6).

The results of a subjective patient questionnaire about postoperative pain in the first 4 postoperative days are plotted in Figure 7.

The average time of contact lens removal was 4 days (50% of patients) (Fig 8).

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DISCUSSION

Results of the eye study reported here show that there was less haze, faster visual recovery, and less pain in the eyes that underwent epi-LASIK compared with the fellow eyes that underwent PRK. However, MRSE, safety, and stability did not differ between groups. Both epi-LASIK and PRK were equally safe, effective, and predictable.

Patients who are not candidates for LASIK often undergo a surface ablation procedure such as PRK, LASEK, or, recently, epi-LASIK. However, haze is a possible unpredictable complication. Based on earlier studies of PRK, it appears that racial factors may play a role in the development of haze.\textsuperscript{5,6} Postoperative haze reduces visual quality.\textsuperscript{9} A number of concerns about the use of alcohol and mitomycin C (MMC) during LASEK and PRK remain. The devitalization of epithelial cells caused by alcohol and corneal edema, recurrent erosion, melting, perforation, and endothelial cell loss caused by MMC have been reported.\textsuperscript{3,7,10-13}
The significant absence of corneal haze in the epi-LASIK group makes this procedure a suitable alternative to both PRK and LASEK. The epithelial separation during the epi-LASIK procedure occurs just below the lamina densa and does not require alcohol for separating. Thus, the majority of epithelial cells remain vital postoperatively.\(^8\) The absence of haze in the majority of eyes that underwent epi-LASIK indicates that the use of MMC may not be warranted with this procedure.

Other advantages of epi-LASIK include the preservation of stromal stability and decreased severing of corneal nerves as well as the potential to decrease the future risk of ectasia due to the increased residual bed thickness. One disadvantage of epi-LASIK is the potential need for a full epithelial flap cut; however, such procedures can be converted to PRK. Another disadvantage is a deeper-than-intended separation at the level of the stroma. In our early cases (not included in this study), one such separation did occur, due to improper assembly of the epi-K epithelial separator. However, the cornea healed without adverse sequelae or loss of BSCVA by 1 month postoperatively.

Due to the friable nature of the epithelial sheet, meticulous handling is required.

One disadvantage of this study is the small sample size; however, we believe the randomized, contralateral eye study design increases the reliability of the results because it eliminates differences in individual wound-healing effects.

We found epi-LASIK and PRK similar in efficacy and predictability in reducing myopia with or without astigmatism. Epi-LASIK reduces the risk of corneal haze, is less painful, and provides faster visual recovery than PRK.

**REFERENCES**


**Figure 8.** Average days to removal of bandage contact lens (N=24 eyes).