

# Clinical Results after EPI-LASIK for Low to Moderate Myopic Eyes with Thin Corneas

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## Abstract

**Background:** Epi-LASIK is a surface ablation in which the epithelium is separated mechanically as a sheet with an automated device, epikeratome, and then repositioned on the photoablated corneal stroma.

**Aim:** to evaluate the safety and efficacy of Epi-LASIK (laser epithelial keratomileusis) for correction of low to moderate myopia and myopic astigmatism in eyes with thin corneas.

**Methods:** This is a prospective interventional non-comparative study that comprised 88 eyes of 44 patients with myopia who underwent epi-LASIK for correction of myopia, where the corneal epithelium was separated as a 9 mm flap with 2-4 mm nasal hinge using epikeratome (Lasatom, Geubor, Germany) and the corneal stromal ablation was performed using excimer laser (ML80, Carl Zeiss, Meditec, Germany). The epithelial flap was replaced after excimer laser ablation. The enrolled patients were followed-up daily until the epithelial healing was complete, then at 1 week, 1-, 3-, 6-, and 12-months postoperative intervals. During each visit, pre- and post-operative mean spherical equivalent (SE), uncorrected visual acuity (UCVA), and best spectacle corrected visual acuity (BSCVA) were recorded. Postoperative pain, time of epithelial healing, corneal haze and complications were also recorded.

**Results:** The subjective pain was experienced postoperatively by all patients. The mean epithelialization time was  $4.53 \pm 0.62$  days, range, 4 to 7 days. The UCVA was 20/20 or better in 81(92.1%) eyes after surgery. The mean preoperative spherical refractive equivalent(SE) was  $-3.9 \pm 2.05$  diopters (D), range, -8.25 to 1 D, and improved to  $-0.06 \pm 0.48$  D, range, -1.5 to +1 D, postoperatively with 79(89.9%) eyes were within 0.50 D of target refraction after surgery whereas 18(20.5%) eyes had 1 or more lines gain of preoperative BSCVA and no eye lost any line of preoperative BSCVA. 5 (5.7%) eyes had insignificant (trace) haze. No complication was encountered. **Conclusion:** The Epi-LASIK is safe and efficient technique for correction of low to moderate myopia and myopic astigmatism in eyes with thin corneas.

**Keywords:** Epi-LASIK, Myopic, Eyes, Cornea.

## Introduction:

Epi-LASIK was recently described by Pallikaris et al<sup>1,2</sup> as a surface ablation in which the epithelium is separated mechanically as a sheet with an automated device, epikeratome, and then repositioned on the photoablated corneal stroma. Unlike LASEK, in which the epithelial separation is achieved with the use of alcohol solution on the cornea, mechanical separation of the epithelial sheet, in Epi-LASIK, is not only prevents any potential toxic effects of alcohol<sup>3,4,5,6</sup> on the separated epithelial sheet,

but also provides a rather automated surgical procedure with a short learning curve for any experienced refractive surgeon<sup>7</sup>. The preserved epithelial sheet, which remains intact morphologically at least for the first 24 postoperative hours after its replacement<sup>8</sup>, theoretically may represent a barrier that protect the photoablated corneal stroma from postoperative cascade<sup>9</sup>. As LASIK is an invasive procedure and may be associated with any microkeratome related complications (in terms of corneal biomechanics)<sup>7</sup> and high risk for iatrogenic keratectasia<sup>10</sup>

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as well as LASIK is not suitable for thin corneas (less than 500  $\mu\text{m}$ )<sup>7</sup>, surface ablation represents the only alternative laser correction of refractive error in thin corneas. Lee et al<sup>11</sup> provided the first clinical evidence that patients treated with laser epithelial keratomileusis (LASEK) for low to moderate myopia had lower postoperative pain and haze than patients treated with photorefractive keratectomy (PRK). Thus, an increasing number of surgeons suggest that replacement of the epithelial flap onto the photoablated cornea may provide advantages over conventional PRK<sup>12,13,14,15</sup> and therefore, the number of laser surface ablation have risen recently<sup>16</sup>. Thus, the goal of Epi-LASIK is to overcome the limitations of conventional PRK such as slow visual recovery, and postoperative pain as well as the risk of corneal haze<sup>9</sup>.

In the current study, we evaluate the 1-year clinical results after Epi-LASIK for correction of low to moderate myopia and myopic astigmatism in eyes with thin corneas that are unsuitable for LASIK.

### Subjects and Methods

88 eyes of 44 patients, seeking laser treatment of their refractive error in Ophthalmic Center in Al-Thawra Modern General Teaching Hospital in Sana'a, Yemen, were included in this study. The enrolled patients fulfilled the general criteria for laser refractive surgery: age older than 18 years, myopic spherical equivalent less than 8 Diopters (D), stable refraction as documented by previous glass prescriptions, no ocular diseases, no previous refractive surgery or systemic diseases likely to affect the epithelial healing and had anatomic limitations to undergo LASIK surgery (estimated residual stromal thickness under the flap less than 280  $\mu\text{m}$ ). The preoperative examination include: measurement of UCVA, BSCVA, manifest and cycloplegic refraction, corneal videokeratography (Humphrey, Carl Zeiss, Meditec, Germany), biomicroscopy and dilated funduscopy. The patients were informed about the investigations, characters of the procedure, the technique and the alternative surgical

methods for the correction of their refractive error and they signed a consent form.

### Surgical Procedure

The operations were performed in the Ophthalmic Centre of Al-Thawra Modern Teaching General Hospital from May 2007 to May 2009. All patients underwent simultaneous bilateral epi-LASIK. An integrated corneal epithelial flap, with a diameter of 8 - 9-millimeter living a nasal hinge of 2 – 4 mm, was separated by using epikeratome (Lasatom, Geubor, Germany). The flap was reflected nasally to reveal the corneal stroma to allow laser ablation. As the patient focused on a fixation light, the excimer laser energy was delivered to the corneal stroma according to the coaxial sighted corneal reflex. All laser treatment were performed using excimer laser (ML-80 excimer laser, Carl Zeiss Meditec, Germany) at treatment zone of up to 6.5 millimeter according to the patient's mesopic pupil size attempting to achieve emmetropia. The ablated stroma was irrigated with physiological salt solution (BSS; Alcon Ltd., Fort Worth, TX) to remove debris of ablated stroma and the epithelial flap was then repositioned on the corneal stoma. A bandage contact lenses of -0.50 D (Acuvue 2; Johnson&Johnson Vision Care, Jacksonville, FL) were placed on both eyes at the end of the procedure and combined eye drops of tobramycin-dexamethasone (tobradex; Alcon Ltd., Fort Worth, TX) were instilled. The patients were examined with slit lamp biomicroscopy before dismissal.

### Postoperative Care

The bandage contact lens remained in place until complete reepithelialization was observed. A combined eye drops of tobramycin- dexamethasone (Tobradex; Alcon Ltd., Fort Worth, TX) were instilled four times daily until the completion of the corneal surface reepithelialization. Patients, who reported severe burning pain, received a single dose of oral diclofenac sodium enteric-coated 25 mg tablets on the operative days. After corneal surface healing was complete, all treated eyes received

fluorometholone eye drops four times daily (FML; Allergan, Irvine, CA) in a tapered dose for five weeks.

Also non-preserved artificial tears (Blink; Allergan, Irvine, CA) were described six times per day for 3 months.

#### Follow-up Examination

The patients were followed up daily until the epithelial healing was complete and the therapeutic lens was removed, then after one week, one month, 3 months, 6 months and 12 months post-operative intervals. During follow up visits, post-operative assessment included recording of subjective pain, epithelial healing time, UCVA, BSCVA, spherical equivalent (SE) refraction, subepithelial corneal haze, applanation tonometry, corneal topography, biomicroscopy and dilated fundoscopy. Pain scores within 4 days after surgery were evaluated according to a predetermined scale<sup>7</sup> ranging from 0 to 4 as follows: 0, no discomfort or pain; 1, mild discomfort; 2, moderate burning pain; 3, burning pain that require medication; and 4, severe, constant, or sharp pain. The follow up period was 12 months for each patient.

Data were entered and analyzed using SPSS software (version 13.0; SPSS Inc., Chicago, IL). Descriptive statistics was applied for data analysis using (frequency, percentage and Mean and standard deviation).

#### Results

This study included 88 eyes of 44 patients who underwent an uneventful Epi-LASIK surgery. The mean patients age ( $\pm$  standard deviation-SD) was  $19.51 \pm 6.77$  years (range, 19 - 50 years). Of the patients, 25(56.8%) were female. The mean ( $\pm$  SD) preoperative spherical equivalent(SE) refraction of the enrolled eyes was  $-3.91 \pm 2.05$  dioptries (D) (range, -1 to -8.25 D) with a mean ( $\pm$ SD) refractive cylinder of  $-0.76 \pm 0.74$  D (range, 0.0 to -3 D). The mean preoperative logarithm of the minimum angle of resolution (log MAR) BCVA was  $0.05 \pm 0.09$  (range, 0.00 – 0.4). The preoperative data was shown in table 1.

**Table 1: Preoperative data**

Variables	Outcomes
Mean age $\pm$ SD(years)	19.51 $\pm$ 6.77
Sex (no,%)	
Male	19(43%)
Female.	25(57%)
Mean log MAR BCVA $\pm$ SD	0.05 $\pm$ 0.09
Mean SE $\pm$ SD	-3.91 $\pm$ 2.05D
Mean keratometry $\pm$ SD	43.83 $\pm$ 1.72D
Mean pachymetry $\pm$ SD.	489.32 $\pm$ 27.32 $\mu$ m

#### PAIN SCORES

All eyes had experienced pain within the first 2 days after surgery. The mean pain scores on the post-operative days were at grade 2 (burning feeling) or less which occurred in 88.6 % (n=78) of eyes.. However, 11.4% (n=10) of eyes reported a burning pain (grade 3), during the first two post-operative days, that necessitating prescription of a single dose of oral diclofenac as sodium enteric-coated 25 milligram tablets. No postoperative pain of grade 4 occurred. On the third and fourth post-operative days, mild discomfort was reported in 5 eyes (5.7%) but it did not require any medication as shown in table 2.

**Table 2: Subjective pain scores of 0 through 4 during the first 4 postoperative days**

Pain score	Number (%) of eyes
Grade 0	0(0%)
Grade 1	26(29.5%)
Grade 2	52(59.1%)
Grade 3	10(11.4%)
Grade 4	0(0%)

#### CORNEAL EPITHELIAL HEALING TIME

The mean time of corneal epithelial healing was  $4.53 \pm 0.62$  days (range, 4 to 7 days). The bandage contact lenses were removed after complete epithelial healing on the fourth postoperative day in 45 eyes (51.1%), on the fifth postoperative day in 41(46.6%) eyes and on the seventh postoperative day in 2(2.3%) eyes. The vast majority (97.7%) of the eyes showed complete epithelial healing by the day 5 postoperatively. Table 3

Table 3: Time of corneal epithelial healing

Postoperative days	Number (%) of eyes
4 <sup>th</sup>	45(51.1%)
5 <sup>th</sup>	41(46.6%)
6 <sup>th</sup>	0(0%)
7 <sup>th</sup>	2(2.3%)
Group total	88(100%)

## VISUAL AND REFRACTIVE PERFORMANCE

### Efficacy

The mean( $\pm$ SD) post-operative log MAR UCVA was improved to  $0.01 \pm 0.06$  (range, -0.1 to 0.22) at the end of follow up period with 81 (92%) eyes had UCVA of 20/20 or better and 7 (8%) eyes achieved 20/40 or better at the end of follow up period.

### Safety

18 eyes (20.5%) gained one or more lines of preoperative BSCVA and there was no eye had lost any line of preoperative BCVA. The relation of preoperative BVCA and postoperative UCVA was shown in table 4.

Table 4: Relation of preoperative BCVA and postoperative UCVA of the operated eyes

		Postoperative UCVA		Group total
		$\geq 20/20$	$\geq 20/40$	
Preoperative BCVA	$\geq 20/20$	63(77.8%) eyes	0(0%) eyes	63(71.6%) eyes
	$\geq 20/40$	18(22.2%) eyes	7(100%) eyes	25(28.4%) eyes
Group total		81(100%) eyes	7(100%) eyes	88(100%) eyes

### Predictability

The mean ( $\pm$ SD) post-operative spherical equivalent refraction of the operated eyes was improved to  $-0.06 \pm 0.48$  D, ranging from -1.5 to 1 D, with 79 (89.8%) eyes were within 0.5D of the target refraction, 7 eyes (8%) were within 1D and 2 (2.2%) eyes were within more than 1 D of the target refraction.

## CORNEAL SUBEPITHELIAL HAZE

Mild haze was found in 5 (5.7%) eyes 1 month after surgery but this haze improved with time and become transient. There was no record of moderate haze. At the

end of follow-up all the enrolled eyes had either clear corneas or clinically insignificant trace corneal haze.

## COMPLICATIONS

Regarding the complications none was recorded as all procedures were performed uneventfully.

## Discussion

As compared with LASIK, Surface ablation procedures are less invasive (in terms of corneal biomechanics), prevent any microkeratome related - complications and provide the only alternative for laser vision correction for eyes with thin cornea<sup>7</sup>. These have driven an increased popularity for surface ablation. The Epi-LASIK was introduced as alternative to LASEK as the mechanically separated epithelium sheet which is replaced after ablation to potentially reduce the risk of haze by disturbing the time relations between epithelial migration and keratocytes activation after the photo refractive procedure<sup>17</sup>.

In this study the mean age of the patient was  $19.51 \pm 6.77$  years (range, 19 to 50 years). This is less than what was reported by Gamali et al<sup>18</sup> who reported the mean age of the patient was 24.8 years (range, 19 to 35 years). This may be explained by the increased acceptance of refractive surgery among people.

### Pain

This study showed that subjective pain was experienced postoperatively by all eyes, where 29.5%(n=26) reported mild discomfort(grade, 1), 59.1%(n=52) of eyes experienced burning sensation(grade,2) and 11.4%(n=10) of eyes reported burning pain that require medication(grade, 3) post-operatively after 24 hours. This is variable to what was reported by Katsanevaki et al<sup>7</sup> who found 16% (n=36) of patients reported a burning sensation (grade 2) or worse and 3% (n=7) of patients reported burning pain that required medication (grade 3). Also O'Doherty et al<sup>19</sup> found that all patients have the same pain level after four hours post-operatively which improved to minimum or no pain after 24 hours. In

addition, Hoang-Xuan et al<sup>20</sup> found post-operative pain was minimum or absent in 41.5% of treated eyes. Dai et al<sup>21</sup> reported mild discomfort in 150 patients (282 eyes, 93.4%) and moderated symptoms in 12 patients (20 eyes, 6.6%). This difference may be explained in this study as the patients were not given any analgesics tablets, steroid or non-steroids eye drops preoperatively.

#### Corneal Epithelial Healing Time

As regards the epithelial healing, this study showed that the mean healing time was  $4.53 \pm 0.62$  days and it was complete by day 5 in the vast majority (97.7%) of the eyes. This is similar to that noted by Katsanevaki et al<sup>7</sup> who found the mean epithelial healing time was  $4.7 \pm 0.87$  days (range, 3 to 7 days) and Hondur et al<sup>22</sup> noted a complete epithelial healing after epi-LASIK was  $4.86 \pm 0.64$  days. Also, Sharma et al<sup>23</sup> noted that the time for epithelial healing was  $4.13 \pm 0.64$  days. In addition, Kalyvianaki et al<sup>9</sup> reported the epithelial healing time was  $4.76 \pm 0.64$  days.

#### Visual and Refractive Results

Our results showed that epi-LASIK is efficient for correction of myopia and myopic astigmatism as the mean ( $\pm$  SD) post-operative log MAR UCVA was  $0.01 \pm 0.06$ . Postoperative UCVA was improved to 20/20 or better in 92.1 % (n=81) of treated eyes and to 20/40 or better in 100% (n=88) of treated eyes with no eye lost any line of preoperative BSCVA, whereas 20.5% (n=18) of the operated eyes gained one or more lines of preoperative BSCVA. This is similar to what was reported previously. Handur et al<sup>22</sup> found 92% of Epi-LASIK treated eyes achieved 20/20 or better UCVA. Katsanevaki et al<sup>7</sup> found 86% of treated eyes have UCVA of 20/20 or better after 1 year of treatment as well as there was no eye with loss of any line of BSCVA, whereas 60% of the operated eyes gained 1 or more lines of BSCVA. Also, Dai et al<sup>21</sup> found no eye lost any lines of BSCVA, whereas 12 (16.7%) of 72 eyes gained one or more lines of BSCVA.

This report found the mean ( $\pm$  SD) postoperative spherical equivalent refraction of the operated eyes was  $0.06 \pm 0.48$

D, with 89.9 % (n=79) of the operated eyes were within  $\pm 0.50$  D and 97.8 % (n=86) of the operated eyes were within 1.00 D of target refraction. These result correlate with what was reported by Hondur et al<sup>22</sup> who reported 92% of Epi-LASIK treated eyes were within  $\pm 0.50$  D of emmetropia. However, Dai et al<sup>21</sup> found, at 1 year postoperatively, the spherical equivalent refraction of 60 (83.3%) eyes was within  $\pm 1.0$  D. Also, Katsanevaki et al<sup>7</sup> found, 1 year after surgery, the mean spherical equivalent refraction of the operated eyes was  $-0.18 \pm 0.38$  D (range, -1 to 0.625 D) with 80% of the operated eyes were within 0.50 D and 97% within 1 D of target refraction. In addition, similar results were recorded with reports for matching attempted myopic correction using alternative ablation procedures<sup>15, 24,25,26</sup> Corneal Subepithelial Haze

In this study, mild corneal haze was noted in 5.7% (n=5) of operated eyes at 1 month after surgery, and all operated eyes had either clear cornea or clinically insignificant trace haze 1 year after surgery. Previous reports were variable. Dai et al<sup>21</sup> found corneal haze grade 0.5 in 2 eyes and all other eyes had no haze. Katsanevaki et al<sup>7</sup> reported 86% of the operated eyes had clear cornea and 14% had clinically insignificant (trace) haze. Hoang-Xuan et al<sup>20</sup> noted haze in 49.1% of the operated eyes at month 3 and it never exceeds grade 2.

#### Complications

No complications were reported in this study. This disagrees with other studies<sup>7</sup> which reported mild complications related to the epithelial separation and did not affect the visual results. This may be related to the use of the new generation of epithelial separators of the epikeratome in this study.

#### Conclusion

This study concluded that Epi-LASIK is a safe and efficient method for correction of low to moderate myopia and myopic astigmatism, with spherical equivalent up to -8 D, in eyes with thin corneas that are unsuitable for LASIK procedure as Epi-LASIK offers excellent



refractive and visual outcomes with clinically insignificant corneal haze, if any, for thin corneas.

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