



## EFFICACY, PREDICTABILITY AND SAFETY OF EPITHELIAL LASER IN-SITU KERATOMILEUSIS (EPI-LASIK) IN MYOPIA.

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**ABSTRACT** **AIM:** To study visual and refractive outcomes of Epi-LASIK in moderate myopia with Spherical Equivalent (SE) between -4.5 to -7.0 D (diopters).

**METHODS:** Retrospective, interventional study of 68 eyes of 39 patients, who had Epi-LASIK with Mitomycin C (MMC), in which primary outcome variables studied were uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), haze and regression.

**RESULTS:** Preoperatively, mean SE was  $-5.79 \pm 0.50$ . At 1 year final visit, mean SE was  $-0.03 \pm 0.10$ , 85.9% eyes achieved UCVA of 20/20, 7.6% achieved 20/25, 3.8% achieved 20/30, 2.7% achieved 20/40. BCVA of 2 eyes was 20/30 and 1 eye 20/40. 62 eyes were within  $\pm 0.75$  D of attempted correction. 4 eyes had trace haze, 2 had grade 1 haze and 1 grade 2 haze. 6 eyes had regression of myopia  $\geq -0.75$  D.

**CONCLUSION:** Epi-LASIK is safe, effective and predictable method for the treatment of moderate myopia.

**KEYWORDS :** Epi-LASIK, moderate myopia, efficacy, safety, predictability

### INTRODUCTION

Surface ablation has become the preferred corneal refractive surgery for many refractive surgeons. This is due to fewer complication rates compared to laser *in situ* keratomileusis (LASIK) specifically, no flap and flap-related complications, and very minimal risk of ectasia.<sup>1</sup> Epithelial laser *in situ* keratomileusis (Epi-LASIK) is the newer surface ablation procedure, which combines the advantages of both LASIK and older surface ablation method photorefractive keratectomy (PRK), while mitigating the complications of both procedures.<sup>2-6</sup> In myopes with refractive error up to -4.5 D (Diopters) spherical equivalent (SE), surface ablation is definitely, the procedure of choice for the advantages mentioned above.<sup>7</sup> But, in myopes with refractive error above -4.5 D spherical equivalent, LASIK is preferred over surface ablation in order to prevent haze and regression which may occur after surface ablation.<sup>8</sup> But, in moderate myopes ranging from -4.5 to -7.5 D spherical equivalent, who are not eligible for LASIK because of pachymetry between 470-500 microns, Epi-LASIK can be an option and this study is done with the purpose to determine efficacy, safety and predictability of Epi-LASIK in moderate myopes and to report visual and refractive outcomes of the same.

### MATERIALS AND METHODS

This was a retrospective, interventional case study done after Institutional Ethical Committee clearance in which medical records of 68 eyes of 39 patients who underwent Epi-LASIK from the period of October 2015 to April 2017 for moderate myopia with spherical equivalent ranging from -4.5 to -7.5 D were studied.

**Inclusion criteria:** Patients more than 18 years of age with stable manifest refractive error (myopia or myopic astigmatism) with spherical equivalent (SE) between -4.5 to -7.0 D (diopters)

**Exclusion criteria:** Patients with manifest refractive error – spherical equivalent  $< -4.5$  D or  $> -7.5$  D, hyperopes, astigmatism  $> \pm 3$  D and BSCVA  $\leq 20/40$

**Pre-operative evaluation:** All patients' uncorrected visual acuity (UCVA), Best Spectacle Corrected Visual Acuity (BSCVA), manifest and cycloplegic refraction, slit lamp examination, keratometry, applanation tonometry, ultrasound pachymetry, topography, tomography, aberrometry, scotopic pupillary diameter, Schirmer's test and dilated fundus examination were done and documented.

**Surgical procedure:** Epi-LASIK was done with standard aseptic protocol after taking informed consent from the patient. After application of topical anesthesia, wire speculum was applied. Epikeratome was used for cleaving of epithelium and epithelial flap was created which was removed with Merocel sponge. In standard procedure of Epi-LASIK, epithelial flap is preserved and repositioned back but we preferred to remove it because it anyways gets replaced by host epithelium in 4-5 days and presence of old epithelium may not

have any additional benefit. Standard laser ablation was done and at the end, 0.02% Mitomycin C (MMC) application done for 15-60 sec depending upon the amount of ablation. Antibiotic eye drops were applied and a bandage contact lens (BCL) was placed to reduce pain caused by mechanical friction of the blinking of eyelids.

Post-operatively, Loteprednol 0.5% eye drops were given 4 times/day tapering every 2 weeks, Moxifloxacin 0.5% eye drops 4 times/day for 1 week and lubricant eye drops Carboxymethylcellulose 0.5% 4 times/day for 6 months were given. BCL was usually removed on day 4 or 5 after epithelial defect was healed. Patient was called for follow up on 1<sup>st</sup> post-operative day, 5<sup>th</sup> post-operative day, 1 month post-operative follow up and a yearly review.

**Outcome measures:** Post-operative UCVA, BCVA, corneal haze and regression

**Data analysis:** All visual acuity measurements were reported as minus logarithm of minimum angle of resolution (LogMAR). Statistical analysis was performed using Microsoft Excel (Microsoft Office Professional Plus 2013; WA)

### RESULTS AND ANALYSIS

The study comprised 68 eyes of 38 patients who underwent Epi-LASIK. There were 19 males and 20 females. The mean age was  $25.41 \pm 3.22$  years (range 21 years to 36 years). Table 1 demonstrates that the mean preoperative spherical equivalent refraction was  $-5.79$  diopters (D)  $\pm 0.50$  D (range,  $-3.25$  D to  $-7.50$  D). The mean preoperative LogMAR BSCVA was  $-0.0038 \pm 0.0251$ .

#### Efficacy

The mean UCVA at the final visit was  $0.95 \pm 0.154$  decimal ( $0.028 \pm 0.101$  LogMAR). 85.9% (58 eyes) achieved UCVA of 20/20, 7.6% (5 eyes) achieved 20/25, 3.8% (3 eyes) achieved 20/30, 2.7% (2 eyes) achieved 20/40. The efficacy index was 0.96, which is the ratio of mean postoperative LogMAR UCVA converted to decimal to mean preoperative LogMAR BSCVA converted to decimal.

#### Predictability

The mean postoperative spherical equivalent was  $-0.03 \pm 0.10$  D. 62 eyes (91.18%) were within  $\pm 0.75$  D of attempted correction. Remaining 6 eyes (8.82%) were  $\geq \pm 0.75$  D of attempted correction. (Figure 1).

#### Safety

The mean postoperative BSCVA was  $0.98 \pm 0.099$  decimal ( $0.007 \pm 0.050$  LogMAR). Figure 2 depicts that at the final follow-up visit, 1 eye (1%) lost two lines, 2 eyes (3%) lost 1 line, remaining 65 eyes (96%) had no loss of lines of pre-operative BSCVA. BCVA of 65 eyes was  $> 20/30$ , 2 eyes was 20/30 and 1 eye 20/40. Overall, the safety index which is the ratio of mean postoperative BSCVA to mean preoperative

BSCVA at the final visit was 0.97.

**Haze**

4 eyes had trace haze, 2 had grade 1 haze and 1 grade 2 haze. This is shown in Figure 3.

**Regression**

6 eyes (8.82%) had regression of myopia  $\geq -0.75$  D.

**DISCUSSION**

A major advantage of surface ablation over LASIK is the avoidance of flap-related complications (buttonhole, free cap, incomplete microkeratome pass, epithelial ingrowth, deep lamellar keratitis, flap melt, interface debris, and traumatic flap dislocation). While iatrogenic keratectasia can occur after LASIK, it is unheard of after surface ablation.<sup>9</sup> PRK, LASEK and Epi-LASIK share the biomechanical advantage of surface ablation; however, EpiLASIK was introduced with a hope to overcome the main drawbacks of both PRK and LASEK, namely pain, haze and epithelial toxicity caused by alcohol. The epikeratome separates, rather than cuts, epithelium from Bowman's membrane with no toxicity from alcohol.<sup>10</sup> Mechanical corneal epithelial debridement results in keratocyte cell loss through programmed cell death (apoptosis) within hours of debridement.<sup>11-13</sup> The lost keratocytes are replaced through proliferation and migration of the peripheral keratocytes which change their phenotype to that of myofibroblast-like cells. This is accompanied with overproduction of collagen and glycosaminoglycans that may result in corneal haze.<sup>14</sup> The corneal epithelial sheet is essential in maintaining balanced epithelial stromal interaction and, if damaged, may lead to production of inflammatory cytokines and myofibroblast transformation.<sup>15</sup> Preserving the epithelial flap may prevent inflammatory cytokine production from the damaged epithelial cells that occurs during epithelial debridement in PRK and render the basement membrane in place to support the epithelial sheet. The epithelial flap may also serve as a mechanical barrier between the tear film and the bare stroma. Furthermore, the viable epithelial flap may speed healing and visual recovery, reduce discomfort, and reduce the incidence of haze.<sup>16</sup> However, in the current study, epithelial flap was removed after cleaving so partly, the benefits of flap might not have been useful to the patients.

In the present study, 85.9% of the patients gained UCVA of 20/20 or better and all the subjects had 20/40 or better at the end of 1 year - similar to Vandorselaer *et al.* who observed 96% eyes with UCVA of 20/40<sup>17</sup>

Reilly *et al.* had shown that Epi-LASIK has a slight advantage over PRK and LASEK in the early postoperative course with regard to pain and haze – similar to our study<sup>18</sup>

Some of the results of the present study differ from previous report. For example, in the present study, 96% of the eyes did not lose postoperative BSCVA and 1% eyes had corneal haze grade 2. These outcomes differ from previous study by Autrata *et al.* which reported that none of the eyes lost any line or had haze worse than grade 1.<sup>19</sup> This may be attributable to long follow up in their study.

**CONCLUSION**

Epi-LASIK is safe, effective and predictable method for the treatment of moderate myopia with no sight threatening complications.

**TABLES**

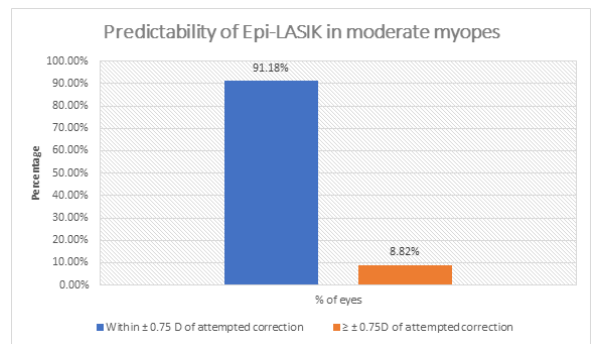
**Table 1: Pre-operative information**

	Range	Minimum	Maximum	Mean	SD*
LogMAR BCVA	0.2	0.1	-0.1	-0.0038	0.0251
Sphere	4.75	-2.25	-6.50	-5.75	0.7070
Cylinder	2.50	-0.50	-3.00	-0.50	0.00
Spherical Equivalent	4.25	-3.25	-7.50	-5.79	0.50

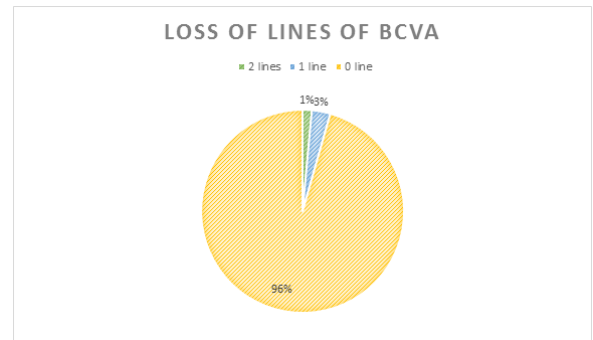
SD – Standard Deviation

**FIGURES**

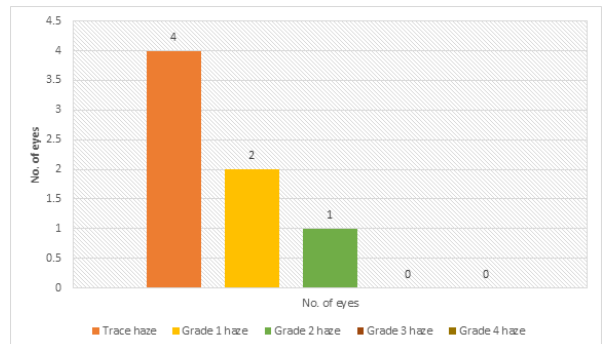
**Figure 1: Predictability of Epi-LASIK in moderate myopes**



**Figure 2: Loss of lines of BCVA post-operatively**



**Figure 3: Grades of corneal haze at final post-operative visit**



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