

# Comparison of the Short-Term Clinical Results of Epi-LASIK and Photorefractive Keratectomy with Mitomycin-C for Moderate to High Myopia

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## Abstract

**Purpose:** To compare the postoperative results of Epi-LASIK and photorefractive keratectomy-mitomycin (PRK-mitomycin) in patients with moderate to high myopia

**Methods:** For this double-blind clinical trial, samples were randomly selected among those subjects above 20 years of age who were visited for myopia correction and had a spherical equivalent between -4 to -8 D. We randomly performed PRK-mitomycin in one eye and Epi-LASIK in the other eye of the patients. Refraction examinations, visual acuity (VA) measurements, contrast sensitivity testing, and corneal examination were performed at 1, 3, and 6 months after surgery. In the current study, analysis was performed on 3- and 6-month data.

**Results:** Thirty-six eyes were studied. Six months after surgery, the mean spherical equivalent in PRK-mitomycin and Epi-LASIK groups was 0 and -0.1 D, respectively ( $p=0.994$ ). Six months after surgery, 13 eyes had a spherical equivalent of  $0\pm 0.5$  D in each group while one diopter of ametropia was seen in 16 and 15 eyes in the PRK-mitomycin and Epi-LASIK groups, respectively. Six months after surgery, one eye in the PRK-mitomycin group and two eyes in the Epi-LASIK group lost 1 line of best corrected visual acuity (BCVA). Six months after surgery, 12 eyes in the PRK-mitomycin group and nine eyes in the Epi-LASIK group had an uncorrected visual acuity (UCVA) of  $10/10$ . The safety index in the PRK-mitomycin and Epi-LASIK group was calculated to be 1.25 and 1.19, respectively ( $p=0.480$ ). No haze was seen in the PRK-mitomycin group 6 months after surgery while 2 cases in the Epi-LASIK group had haze grade 0.5. There was no significant difference in contrast sensitivity between the two groups ( $p>0.05$ ).

**Conclusion:** The two methods were similar in postoperative VA and refractive results. Since the chance of haze formation in Epi-LASIK surgery without the application of mitomycin-C (MMC) is similar to PRK with mitomycin, Epi-LASIK can be considered as an alternative to PRK with MMC for the treatment of moderate to high myopia.

**Keywords:** Photorefractive Keratectomy, Mitomycin, Epi-LASIK, Corneal Haze, Safety Index

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*Iranian Journal of Ophthalmology 2013;25(1):19-26 © 2013 by the Iranian Society of Ophthalmology*

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Received: September 27, 2012

Accepted: April 10, 2013

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## Introduction

Nowadays, the use of superficial laser for correcting refractive errors, specially in those with myopia  $> 4$  or  $5$  D, is a common practice worldwide.<sup>1,2</sup> According to some reports on photorefractive keratectomy (PRK), due to some disorders in collagen and corneal stroma, the activity of corneal fibroblasts could lead to the corneal haze formation.<sup>3</sup> Mitomycin is an antibiotic with antimetabolic properties and several studies have shown its effectiveness in the prevention of corneal fibroblasts activity and keratocyte proliferation as a preventive measure against corneal haze.<sup>4,5</sup>

The role of mitomycin in prevention of corneal haze after PRK has been showed by Porges et al<sup>6</sup> and Xu et al<sup>5</sup> in their studies on experimental models. Moreover, a report by Majmudar et al<sup>7</sup> showed that mitomycin could even heal postoperative corneal haze after PRK. However, in addition to its effect on the prevention of corneal haze formation, mitomycin may also have some long-term adverse effects due to its chemical formulation.

Some studies have reported a decrease in the number of corneal endothelial cells after MMC application although some other studies have reported no changes in the postapplication number of corneal endothelial cells.<sup>8,9</sup> On the other hand, long-term effects of MMC on limbal stem cells are not still known.

Gambato et al have reported that topical 0.02% MMC does not induce long-term change in cornea.<sup>10</sup> Shojaei et al have also reported that in their study the grade of postoperative haze was lower in MMC group, whereas significant difference was not observed in endothelial cell density comparing with control group.<sup>11</sup>

Epi-LASIK is another alternative to PRK-mitomycin method for the treatment of patients with high myopia. It has been claimed that in this method, which does not involve mitomycin application, the outcome is quite satisfactory and corneal haze is minimal.<sup>12,13</sup> Moreover, the epithelium and basal membrane, along with the epithelial flap, act as barriers and prevent stromal stimulation by cytokinins and other stimulating factors, resulting in the prevention of haze formation in corneal stroma. The current study was

designed and conducted to compare PRK-mitomycin and Epi-LASIK in individuals with high myopia in order to suggest Epi-LASIK as an alternative to PRK-mitomycin if there are no differences between the two methods due to probable adverse effects of mitomycin.

## Methods

The current study was a double-blind clinical trial study. The subjects were selected from patients visited at Noor Eye Hospital for the correction of their refractive error. Inclusion criteria were: age above 20 years, no changes in the refraction of both eyes for at least a year, a spherical equivalent of  $-4$  to  $-8$  D, and a corneal thickness of at least  $480 \mu$  in a way that the thickness of remaining corneal stroma was not less than  $380 \mu$ .

Patients with any sort of ophthalmologic or systemic diseases like diabetes, anisometropia  $> 1$  D, collagen vascular diseases, medications affecting cornea or hindering corneal healing, and subjects who were hard to follow like those who resided in other provinces or countries were excluded from the study.

Random allocation was done using balanced block method. Each eye was selected randomly to undergo Epi-LASIK or MMC-PRK. In this study, six blocks was designed containing six samples; in every block samples were allocated to Epi-LASIK or MMC-PRK groups randomly using the random digit table.

In addition, the right eyes of patients were considered as cases, and if one patient's right eye has undergone Epi-LASIK, then the other has had MMC-PRK, and vice versa.

Randomization was performed by someone other than the surgeon. After final selection of the patients and signing a written informed consent, the surgical method for each eye was determined by taking out a piece of paper from a box with the name of the surgical method written on it.

Preoperative examinations for all participants included UCVA and BCVA measurements, manifest refraction, contrast sensitivity with and without glare, topography and pachymetry. Preoperative examinations for those patients with soft and RGP contact

lenses were performed at least 3 days and 3 weeks after removal of their lens, respectively.

Topographic evaluation was done every two weeks for patient who had warpage. These patients underwent surgery after that in topography warpage had not observed anymore.

### **Surgical method**

Each eye randomly underwent either Epi-LASIK or PRK-mitomycin surgery. Both groups were operated with a similar nomogram using Bausch & Lomb Z100 excimer laser. In this study, optical zone was considered 6 mm for all of surgeries.

In Epi-LASIK method using Epikeratom, the corneal epithelium is detached from its underlying stroma at Bowman's membrane in the form of a multilayer epithelial plate and is kept as a flap on one side of cornea (the nasal side). In all eyes, flap was lifted completely.

After ablation, using excimer laser the flap is returned to its original place. Then, the contact lens is placed on the eye.

In PRK with mitomycin, after epithelial removal with hockey knife and disposal of the separated epithelium, ablation is performed on the underneath stroma. Then, a mitomycin-soaked sponge (0.02%) is placed in place for 20 to 60 seconds depending on the ablation depth. After that, the surface of the cornea is washed with 30 cc physiological serum and the contact lens is placed on the eye.

### **Postoperative examinations**

Postoperative examinations included UCVA and BCVA measurements, manifest refraction, and contrast sensitivity test with and without glare using a VectorVision CSV-1000 unit. The examinations were done for all patients within the first seven days and then 1, 3, and 6 months after surgery.

In addition to the mentioned examinations, the anterior segment was evaluated for redness, eyelid swelling, epithelial defects, corneal infection, contact lens status, and subconjunctival hemorrhage only within the first seven days.

Also, postoperative corneal haze was studied 1, 3, and 6 months after surgery. Postoperative follow-ups were performed by an ophthalmologist who was blinded to the type of performed surgery.

Postoperative drug regimen for both eyes was similar in both groups. The application time of mitomycin for each spherical equivalent was also fixed (20-60 seconds).

Postoperative drug regimen included chloramphenicol drops every 4 hours for 1 week, betamethasone drops every 4 hours for 2 weeks, one drop of fluorometholone every 6 hours for the first 2 weeks, every 8 hours for the next 2 weeks, every 12 hours for the following 2 weeks, and every 24 hours for last 2 weeks. Oral analgesics PRN and UV protecting glasses were also prescribed for 3 months.

In our study, we defined different grades for corneal haze, considering what Fantès et al<sup>14</sup> have done in their study: grade 0.5 for trace haze recognized by slit-microscopy through careful oblique illumination; grade 1.0 for more prominent haze without any interference with visibility of fine iris details; grade 2.0 for mild obscuration of iris details; grade 3.0 for moderate obscuration of the iris and lens, and grade 4.0, completely opaque stroma in the area of ablation.

### **Ethical considerations**

The study was approved by the Ethics Committee in Medical Research, Noor Eye Research Center. The aim of the study and its procedures were first explained to the patients and if they were willing to participate, they were asked to sign an informed written consent. The participants had the right to withdraw from the study at any time.

### **Statistical analysis**

In this study, we used the Statistical Package for the Social Sciences (SPSS) software version 11.5 for data analyses. Quantitative variables are summarized as their mean and standard deviation before and after surgery. Comparison of pre and postoperative values was done using the Paired *t* tests, and surgical outcomes in two groups were compared using the analysis of covariance (ANCOVA). In this analysis, we considered the postoperative variable as the dependant variable, and the preoperative variable as the covariate. Safety was defined as the ratio of postoperative to preoperative corrected vision and demonstrated in terms of lost or gained lines of BCVA after surgery compared to

before surgery. Loss or gain of vision was expressed as lines.

## Results

In this study, 36 eyes of 18 subjects were evaluated. Of the mentioned number, 13 were female and 5 were male. The mean age of the participants was  $27.2 \pm 6.8$  years (20-48 years). The response rate was 79% and 89.5% at 3 and 6 months, respectively.

Mean and standard deviation of refraction spherical equivalent before and after surgery in the PRK-mitomycin and Epi-LASIK group was  $-5.4 \pm 0.9$  and  $-5.4 \pm 1.1$  D, respectively. Paired *t* test did not show any significant differences between the two groups ( $p=0.608$ ). Preoperative corneal thickness in the PRK-mitomycin and Epi-LASIK group was  $514.7 \pm 14.5$  and  $513 \pm 13.1$   $\mu\text{m}$ , respectively ( $p=0.413$ ). Preoperative corrected vision of all the patients was  $10/10$ .

Figure 1 shows spherical equivalent results of the patients in both groups at 1, 3, 6 months after surgery. Based on the results of this study, spherical equivalent improved with time and as it is shown in figure 1, six months after surgery, spherical equivalents of  $0.0 \pm 0.37$  and  $-0.10 \pm 0.69$  D were seen in PRK-mitomycin and Epi-LASIK groups, respectively. Repeated measures analysis of variances showed no significant postoperative difference in spherical equivalent between the two groups ( $p=0.994$ ).

Table 1 shows the spherical equivalent of the subjects by 0.5 and 1 D of ametropia during the study period. As shown in the table, 13 eyes in both groups had a spherical equivalent of 0.5 D of ametropia. The mentioned number for 1 D of ametropia in PRK-mitomycin and Epi-LASIK group was 16 and 15 eyes, respectively. McNemar's test did not show any significant differences between the two groups after six months.

## Visual acuity

The mean visual acuity (VA) based on logMAR did not show a significant difference between the two groups. Also as shown in figure 2, VA between the two groups did not show a significant difference during the study period ( $p=0.293$ ).

The findings of our study showed that 6 months after surgery, one eye in the PRK-mitomycin group and two eyes in the Epi-LASIK group lost 1 line of BCVA. Twelve eyes in the PRK-mitomycin group and nine eyes in the Epi-LASIK group had an UCVA of  $10/10$  six months after surgery but the difference was not significant ( $p>0.05$ ). Safety index was 1.25 and 1.19 in the PRK-mitomycin and Epi-LASIK group, respectively ( $p=0.480$ ).

## Corneal haze

Three months after surgery, two eyes (13.3%) in the PRK-mitomycin group and four eyes (26.6%) in the Epi-LASIK group had a corneal haze grade 0.5 ( $p=0.390$ ). Evaluation at the 6<sup>th</sup> month showed that there was no haze formation in any eyes in the PRK-mitomycin group while two patients in the Epi-LASIK group had a haze grade 0.5.

## Contrast Sensitivity

Based on the results of the study, mean contrast sensitivity with glare in the first month in Epi-LASIK and PRK-mitomycin groups was  $2.36 \pm 1.1$  and  $2.52 \pm 1.43$ , respectively ( $p>0.05$ ). Mean contrast sensitivity with glare in the 3<sup>rd</sup> and the 6<sup>th</sup> month was  $2.02 \pm 1.2$  and  $1.90 \pm 1.4$  in the Epi-LASIK group and  $2.14 \pm 1.17$  and  $1.9 \pm 1.43$  in PRK-mitomycin group, respectively. No significant difference was found in contrast sensitivity with glare between the two groups after 3 and 6 months ( $p>0.05$ ).

**Table 1.** The distribution of the spherical equivalent by 0.5 and 1 D of ametropia in the two groups

	$\pm 0.5$ D		$\pm 1$ D	
	PRK-mitomycin	Epi-LASIK	PRK-mitomycin	Epi-LASIK
	Number	Number	Number	Number
1 month	1	4	2	9
3 months	8	10	10	13
6 months	13	13	16	15

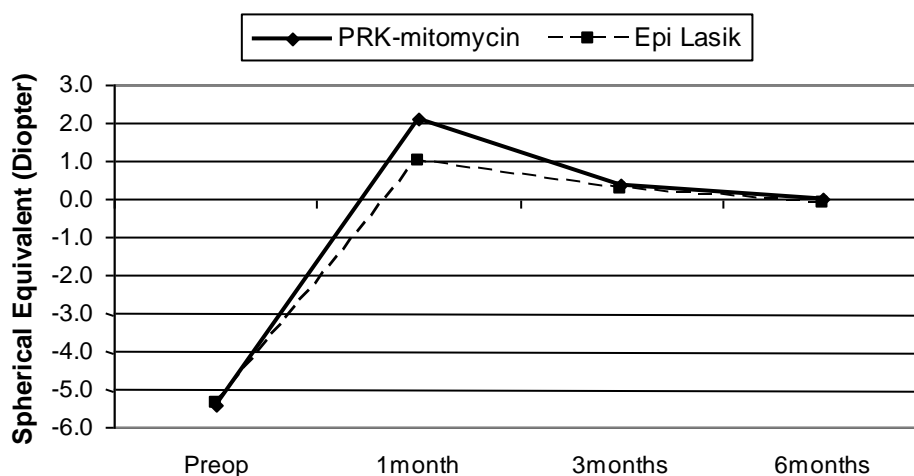


Figure 1. Comparison of the spherical equivalent of the patients during the study period

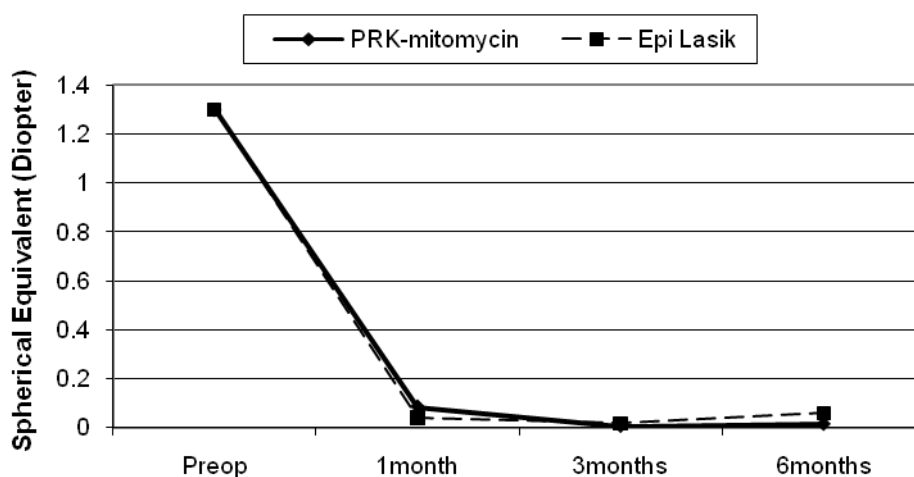


Figure 2. Uncorrected visual acuity of the patients during study period

## Discussion

A review of the previous studies, specially those on the first generation Excimer Laser systems, shows a moderate to severe increase in corneal haze after PRK surgery. There is a direct relationship between the chance of haze formation and increasing the depth of ablation. The reason for haze formation is the disorganized deposition of the alpha 3 chain of type IV collagen alpha in stroma and cellular hyper-proliferation.<sup>3</sup>

It has been shown in the recent years that the use of MMC 0.02%, an antimetabolite

agent, after laser application on the corneal surface for 12 seconds to 2 minutes can successfully decrease corneal haze acting through inhibiting the proliferation of keratocytes.<sup>5</sup>

MMC has no effect on corneal epithelial wound healing. However, there is concern over its long-term effects on endothelium or even limbal stem cells but there is no common agreement among different studies on the effects of MMC on corneal endothelium as some have reported a decrease in the number

of these cells while some have not mentioned any abnormal effects.<sup>8</sup> Hence, if the corneal haze could be decreased through alternative methods, they could substitute for the application of MMC.

One of these methods is Epi-LASIK in which a layer of corneal epithelium is mechanically separated from the stroma by the use of an epikeratom. This epithelial sheet is replaced after performing laser. Primary studies have reported a decrease in haze in this method although the decrease in haze after Epi-LASIK can be a result of low attempted correction or better smoothness of the laser-applied cornea in newer lasers. There are some other studies that have compared Epi-LASIK with off-flap Epi-LASIK and reported an even lower chance of haze formation in off-flap Epi-LASIK.<sup>15,16</sup>

The mentioned difference was reported when no MMC was applied and Wang reported that even when MMC was applied, the chance of haze formation in the off-flap group was lower. In the current study, although haze grade 0.5 was seen in 2 patients in the Epi-LASIK group, no haze was seen in the PRK-mitomycin group 6 months after surgery. No statistical difference was seen between the two groups, suggesting that the chance of haze formation in moderate to severe myopia is insignificant in Epi-LASIK, similar to MMC application. However, it was not possible to study the role of the better smoothness of newer lasers in decreasing haze.<sup>17,18</sup>

Regarding the refractive results, no significant difference was seen between the two groups after 6 months as more than 80% of eyes in both methods were in the range of 1 D of ametropia 6 months after surgery. Although no study has ever compared these two methods in a comprehensive investigation like ours before, the results of the previous reports on these two methods, with regard to the preoperative range of the refractive error in our patients, suggests that the regression was low in these two methods and they were similar in refractive results.

Like this study, the majority of studies on PRK-mitomycin and Epi-LASIK showed that 6 months after surgery with these two methods, more than 30% of the patients were within 0.5 D range of ametropia and 40% to 75% were within 1 D range of ametropia. In

summary, a review of other reports shows that the results of these two methods in correcting high refractive errors are relatively acceptable.

Vision is one of the most common outcomes of refractive surgery. Using this index, the efficacy of the refractive error surgery is evaluated. Previous studies on PRK showed that some patients had a postoperative decrease in their corrected vision which could be attributed to the higher chance of haze formation. Although we had a patient with decreased postoperative corrected vision in the PRK-mitomycin group, the safety index of the method was 1.25, indicating the favorable outcome of this method.

Previous studies have also reported the safety index of PRK-mitomycin to be between 1.15 and 1.3.<sup>18,19</sup> As mentioned, although Epi-LASIK did not have any significant differences with PRK-mitomycin in vision, loss of line was observed in the corrected vision of 2 patients in this group. Besides, the safety index of Epi-LASIK was 1.19 and about 60% of the individuals in this group had an uncorrected vision of  $10/10$ , 6 months after surgery.

Generally, a review of previous studies shows that the safety index of Epi-LASIK is lower than PRK-mitomycin method.<sup>18,20-22</sup> However, the difference is insignificant and does not have a noticeable clinical value. As mentioned, this difference was 0.6 in the current study. Considering the fact that evaluating corneal haze and its comparison between the two methods was one of our main goals, another alternative was PRK-mitomycin in which mitomycin was added as a supplement to prevent postoperative haze.

Because mitomycin inhibits DNA synthesis and has cytotoxic effects, it inhibits the subepithelial fibrosis through the inhibition of the growth of stromal keratocytes. No corneal haze was observed in any eyes treated with the PRK-mitomycin method six months after surgery, but 2 eyes in the Epi-LASIK group had haze grade 0.5.

The difference was not statistically significant. In a report by Gamaly<sup>23</sup> comparing Epi-LASIK and PRK methods, it was reported that haze formation in the Epi-LASIK method was less than PRK which shows that the application of mitomycin with PRK can

produce results similar to Epi-LASIK. In summary, in the Epi-LASIK method, the existence of the epithelial layer during the first few days after surgery is responsible for the prevention of inflammation mediators from entering the cornea resulting in a controlled epithelial healing and a lower risk of haze formation.

This study has had weak and strong points. The most important strong point is its performing in an Iranian population. Moreover, the high response and low fail rate in follow-ups are other significant advantages which reduce the selection bias of current study. Nevertheless, there are some weaknesses; 1 year seems a better follow-up time due to possibility of incidence of haze

and complications 6 months after surgeries in cases with high myopia. In addition, it seems that the absence of a statistical relation between some indexes can be attributed to small sample size and low power.

### Conclusion

Postoperative refraction results of PRK-mitomycin and Epi-LASIK methods did not have any differences. Also, corrected vision and corneal haze did not clinically differ between the two methods. Epi-LASIK is a suitable alternative for the correction of moderate myopia when it is preferred to avoid mitomycin.

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