

Original Article

A control-matched comparison of flap off and flap on laser-assisted subepithelial keratectomy (LASEK) for the treatment of myopia and myopic astigmatism



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Abstract

Purpose: To compare the visual and refractive outcomes of flap off and flap on, Laser Assisted Subepithelial Keratectomy (LASEK) for low to moderate myopia.

Methods: A prospective non-randomized control-matched study was conducted in which 53 patients underwent LASEK for the treatment of low to moderate myopia and myopic astigmatism. Right eye of each patient had the flap removed (flap off) while in the left eye the flap was recapped (flap on). Equal number ($N = 53$) of flap on was matched with flap off having preoperative manifest refraction spherical equivalent within ± 0.75 Diopters (D). Primary outcome variables included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA) and manifest refraction.

Results: Preoperatively, the mean spherical equivalent (SE) was -3.59 ± 1.46 D for flap off and -3.67 ± 1.51 D for flap on ($p = 0.779$). The mean preoperative sphere was -3.32 ± 1.58 D for flap off group and -3.36 ± 1.61 D for flap on group ($p = 0.338$) whereas, the mean preoperative cylinder was -0.55 ± 0.70 D and -0.63 ± 0.68 D for flap removal and flap preservation groups respectively ($p = 0.576$). Postoperatively, the mean LogMAR UCVA was -0.035 ± 0.079 for flap off and -0.043 ± 0.085 for flap on. The percentages of eyes that had UCVA of 20/40 or better were 98.1% for flap off group and 100% for flap on group ($p = 0.317$). Mean postoperative SE was 0.00 ± 0.19 D for flap off group and -0.03 ± 0.43 D for flap on group. In flap removal group, 100% eyes were within ± 0.50 D of the intended correction while in flap preservation group, 92.5% and 100% eyes were within ± 0.50 D and ± 1.00 D of the intended correction, respectively. Mean postoperative LogMAR BSCVA was -0.013 ± 0.044 for flap removal group and -0.016 ± 0.049 for flap preservation group ($p = 0.727$).

Conclusions: The differences in the visual and refractive results between flap preservation and flap removal groups were not clinically significant. Both procedures seemed safe and effective for the treatment of myopia and myopic astigmatism.

Keywords: LASEK, Flap on, Flap off, Subepithelial keratectomy, Refractive surgery

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Introduction

Laser-assisted subepithelial keratectomy (LASEK) was developed by Massimo Camellin¹ and recently it has emerged as a procedure for treating myopia that may blend the

positive aspects of photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) while eliminating some of the complications seen with both.² The conceptual advantages attributed to LASEK were less postoperative pain, faster visual recovery and less haze when compared to PRK.³

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LASEK can be described as a corneal surface ablative refractive procedure similar to PRK combined with the creation of an epithelial sheet to cover the ablated area similar to the flap in LASIK.⁴ The basic difference between the conventional LASEK and PRK is that instead of completely removing the epithelium as with PRK, epithelial adhesion is released from the corneal stroma in LASEK. The loosened epithelium is then moved aside from the treatment zone as a hinged sheet. Laser ablation of the subepithelial stroma is performed before the epithelial sheet is returned to its original position, as with the LASIK flap.⁵

However, during the recent times there have been many concerns from several surgeons on the significance of preserving flap as few believe that replacing the epithelium hinders the formation of a new epithelial sheet, thereby prolonging surface healing.^{6,7}

Though, there exists literature comparing the efficacy of flap preservation and flap removal LASEK surgeries, none of the results were conclusive.^{6,7} Hence, the present study is initiated to compare the visual and refractive outcomes of flap off and flap on LASEK for low to moderate myopia.

Methods

Study design

Approval from the Institutional Review Board of Magrabi hospitals was obtained for the study and appropriate consents were taken from the patients. The charts of 106 eyes that underwent flap off and flap on LASEK were reviewed. All eyes were operated by the same surgeon (FMT) between November 2008 and February 2011. Our database was obtained by excluding all eyes that had preoperative manifest spheres greater than -7.50 Diopters (D), hyperopic spheres, cylinders of more than -3.00 D, preoperative best corrected visual acuities (BSCVA) of 20/24 or worse, as well as eyes that were aimed for near correction. Fifty-three eyes had flap off and 53 eyes had flap on LASEK. Each flap off treated eye was matched to a flap on LASEK-treated eye of the same patient.

Patients

One hundred and six eyes of fifty-three patients were considered for inclusion. In the right eye of each patient, the flap was removed after epithelial separation (flap off), and the flap was recapped in the left eye (flap on). Thus, 53 flap off eyes were matched with 53 flap on eyes having preoperative manifest refraction spherical equivalent within ± 0.75 D.

Examination

The preoperative evaluation included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, ocular dominance, slit lamp examination, keratometry, tonometry, pachymetry, computerized videokeratography (Orbscan II), mesopic pupil size measurement using a pupillometer, and dilated fundus examination.

Surgical procedure

We used our standard LASEK technique as described previously.⁸ In brief, after topical anesthesia and lid speculum application, a semisharp circular well was used for administration of 18% alcohol for 25–35 s on the corneal epithelial surface. Prior to alcohol exposure, positioning marks were used to mark the corneal surface. The margins of the delineated area were freed using jewelers forceps or Vannas scissors leaving two to three clock-hour of intact margins for the hinge. The loosened epithelium was then peeled back using a Merocel sponge. After standard laser ablation, the epithelial sheet was gently repositioned using intermittent irrigation. The epithelium was carefully realigned using the preplaced positioning marks and allowed to dry for 3–5 min in the flap on group and was cut in the flap off group.

A combination of antibiotics, and fluorometholone eye-drops was applied, followed by placing a bandage contact lens to reduce the mechanical friction by the eyelid and to reduce postoperative pain. EC-5000 CXIII excimer laser (Nidek Co. Ltd.) was used for laser ablation. Prophylactic antimetabolite mitomycin-C (MMC) 0.05% was applied for 15–60 s in eyes that will have more than 70 microns of ablation, to reduce the risk of haze formation.

The postoperative regimen varied according to the depth of ablation. If the depth of ablation was more than 70 microns, topical antibiotics and prednisolone acetate 1% eye-drops four times per day for two weeks, followed by fluorometholone for 2–3 months on tapered dose were given. If less than 70 μm of ablation, topical antibiotics and prednisolone acetate 1% eye-drops four times per day for one week, followed by fluorometholone for one month on tapered dose were provided. Lubrication was prescribed as required. Patients were reviewed everyday or every other day until corneal epithelial healing was complete. After complete re-epithelization, patients were followed up at 1 and 3 months.

Data acquisition and analysis

All visual acuity measurements were reported as minus logarithm of minimum angle of resolution (LogMAR). Descriptive data and frequency graphs were made; data have been presented according to the guidelines of Holladay.⁹

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, 15.0) software. Paired *t* test was performed in order to assess the significance of difference between the flap off and flap on eyes for various preoperative and postoperative variables. Chi square test was executed in order to test the significance of association between the comparative groups and spherical equivalent within ± 0.5 D or ± 1.0 D.

Results

Preoperative descriptive data

Preoperatively, the mean spherical equivalent in flap off eyes group was -3.59 ± 1.46 D and in the flap on eyes group was -3.67 ± 1.51 D ($p = 0.779$); the mean preoperative sphere was -3.32 ± 1.58 D for flap off eyes group and -3.36 ± 1.61 D for flap on LASEK ($p = 0.338$). Moreover,

the mean preoperative cylinder was -0.55 ± 0.70 D and -0.63 ± 0.68 D for flap removal and flap preservation groups respectively ($p = 0.576$). There was no significant difference between the flap off and flap on eyes groups for sphere, cylinder and spherical equivalent (Table 1).

Postoperative descriptive data

Postoperatively, the mean LogMAR UCVA was -0.035 ± 0.079 for flap off LASEK and -0.043 ± 0.085 for flap on LASEK. The mean postoperative LogMAR BSCVA was -0.013 ± 0.044 for flap removal group and -0.016 ± 0.049 for flap preservation group ($p = 0.727$). The percentages of eyes that had UCVA of 20/40 or better were 98.1% for flap off group and 100% for flap on group ($p = 0.317$). Though insignificant, the mean post-op log Mar UCVA, mean post-op log Mar BSCVA and the mean epithelialization time were slightly greater in eyes that underwent flap on surgery than the flap off eyes group (Table 2).

The mean postoperative spherical equivalent was 0.00 ± 0.19 D for flap off eyes and -0.03 ± 0.43 D in the comparative group. In flap removal group, 100% eyes were within ± 0.50 D of the intended correction while in flap preservation group, 92.5% and 100% eyes were within ± 0.50 D and ± 1.00 D of the intended correction respectively.

Efficacy

Table 2 demonstrates that the mean postoperative LogMAR UCVA for flap off and flap on was -0.035 and -0.043 respectively and there was no significant difference between the procedures. In addition, the efficacy index (ratio of mean post-operative UCVA to preoperative BSCVA) for flap off and flap on groups was 1.0011 and 0.979 respectively.

Predictability

Though insignificant, mean post-operative spherical equivalent of flap off eyes was 0 ± 0.19 in comparison with 0.03 ± 0.43 in flap on eyes. All the eyes that underwent flap off surgery were within ± 0.5 D SE while in flap on group 92.5% eyes were within ± 0.5 D and this difference was

significant ($p = 0.042$). As illustrated in Table 3 all the eyes were within ± 1.0 D.

Safety

Fig. 1 presents the line loss or gain of flap off eyes matched with flap on eyes. None of the eyes lost more than two lines and 15 flap off eyes gained lines in comparison with 10 flap on eyes. The safety index which is the ratio of mean post-operative BSCVA to mean preoperative BSCVA was 1.053 and 1.042 for flap off and flap on eyes respectively.

Postoperative complications

There were no significant differences between the flap off and flap on groups for post-operative complications Table 4. A haze of 1 was observed among 3.8% eyes in both the groups. All the eyes that underwent surgery had postoperative pain which was reported to be mild. Severe pain was reported in 3.8% eyes in flap off and 5.7% eyes in flap on groups.

Discussion

It is presumed that LASEK combines the advantages of PRK and LASIK avoiding the disadvantages of both the procedures. It reduces the risk of keratectasia associated with LASIK and also has faster recovery period than PRK with less pain and haze.^{8,10} However, there have been conflicting reports on advantages of Epi-LASIK over LASEK. Reilly et al.,¹¹ found Epi-LASIK to have a slight advantage than LASEK in the post-operative course with regard to pain and haze.

In contrary, a study found that the grade of haze was similar in epi-LASIK and LASEK treated eyes throughout a post-operative period of one year; in addition, the mean time to epithelial healing was slightly longer after Epi-LASIK.¹²

There have always been conflicting opinions on preserving or removal of epithelial flaps, and it has been proposed that presence of the flap reduces postoperative pain and development of corneal haze. In contrast, the other school of thought is to discard the epithelial flap as presence of epithelial cells in the flap might hinder the migratory phase of epithelial regeneration and thus delay the visual recovery.¹³

Table 1. Pre-operative data of 53 matched eyes that underwent flap off and flap on LASEK surgeries.

Procedure	Sphere Mean \pm SD	Significance	Cylinder Mean \pm SD	Significance	Spherical equivalent Mean \pm SD	Significance
Flap off	-3.32 ± 1.58	0.338 (NS)	-0.55 ± 0.70	0.576 (NS)	-3.59 ± 1.46	0.779 (NS)
Flap on	-3.36 ± 1.61		-0.63 ± 0.68		-3.67 ± 1.51	

SD – standard deviation, NS – non significant, and p value was calculated using paired 't' test.

Table 2. Post-operative visual results of 53 matched eyes that underwent flap off and flap on LASEK surgeries.

Procedure	Flap off	Flap on	p -Value
Mean post-op LogMar UCVA	-0.035 ± 0.079	-0.043 ± 0.085	0.561 (NS)*
Mean post-op LogMar BSCVA	-0.013 ± 0.044	-0.016 ± 0.049	0.727 (NS)*
UCVA 20/20 or better	75.5	66	0.286 (NS)
UCVA 20/40 or better	98.1	100	1.00 (NS)**
Epithelialization time	4.23 ± 2.12	4.28 ± 1.87	0.615 (NS)**

SD – standard deviation and NS – non significant.

* p value was calculated using paired 't' test.

** p value was calculated using Fisher exact test.

Table 3. Postoperative refractive results of the study population in relation to the flap off and flap on procedure.

Procedure	Sphere Mean ± SD		Spherical equivalent Mean ± SD		Spherical equivalent within ±0.5 D (% of eyes)		Spherical equivalent within ±1.0 D (% of eyes)	
Flap off	0.05 ± 0.25	0.709	0.00 ± 0.19	0.532	100	0.041**	100	NS**
Flap on	0.08 ± 0.45	(NS)*	-0.03 ± 0.43	(NS)	92.5		100	

SD – standard deviation and NS – non significant.

* p value was calculated using paired 't' test.

** p value was calculated using Fisher exact test.

Table 4. Post-operative complications observed in the operated eyes.

Procedure	Corneal Haze (% of eyes)			Pai (% of eyes)		
	0	1		Mild	Severe	
Flap off	96.2	3.8	1.00 (NS)	96.2	3.8	0.646 (NS)
Flap on	96.2	3.8		94.3	5.7	

NS – non significant, and p value was calculated using Fisher exact test.

Hence, the present study intended to compare the visual and refractive outcomes of flap off and flap on LASEK for low to moderate myopia. Though insignificant, the mean epithelialization time was slightly greater in eyes that underwent flap off LASEK surgery than the flap off eyes group. In addition, the efficacy index in flap off groups was greater than that of flap on group.

In accordance with previous studies, the presence of epithelial flap failed to significantly improve the rate of epithelial healing. Although the difference between the comparative groups for epithelialization was insignificant, it was surprising to note that flap off eyes (4.23 ± 2.12) had a faster epithelial healing than the flap on eyes (4.28 ± 1.87).^{13,14} One of the strengths of the present study is that the same patient

underwent flap off LASEK surgery in one eye and the flap on technique in the contralateral eye. Thus, the subjective bias that is usually encountered while assessing pain has been eliminated in this study. Eyes that were reported to have post-operative pain were slightly fewer in flap off group than in the flap on group but the difference was statistically insignificant. It was noted that the pain was less in flap off Epi-LASIK eyes when compared to flap on eyes during the early postoperative period.^{7,13,15}

It can be extrapolated from the recent literature that during the initial post-operative period, flap removal is advantageous over flap preservation by causing less pain; however, there exists no difference later.^{16,17} The post-op spherical equivalent was almost similar between the groups and the only significant finding in the study was, all the flap off eyes were within ±0.5 D while in flap on group 92.5% eyes were within ±0.5 D. Though, the present evidence suggests that visual results and refractive outcomes are comparable between flap off and flap on procedures Na et al., found flap removal Epi-LASIK surgery to be more predictable and less painful than epi-LASIK surgery.¹⁸

Conclusions

Despite the differences in the visual and refractive results between flap preservation and flap removal groups, these differences were not clinically significant. Both procedures seemed safe, effective and predictable for the treatment of myopia and myopic astigmatism. Thus, it seems from the present study findings that preservation of epithelium in LASEK provides no added advantage over flap removal as both the techniques had comparable predictability and safety. In fact, the flap off groups have greater efficacy than the flap on groups. However, future studies on larger samples would provide a better picture on this aspect.

Conflict of interest

The author declares no conflict of interest.

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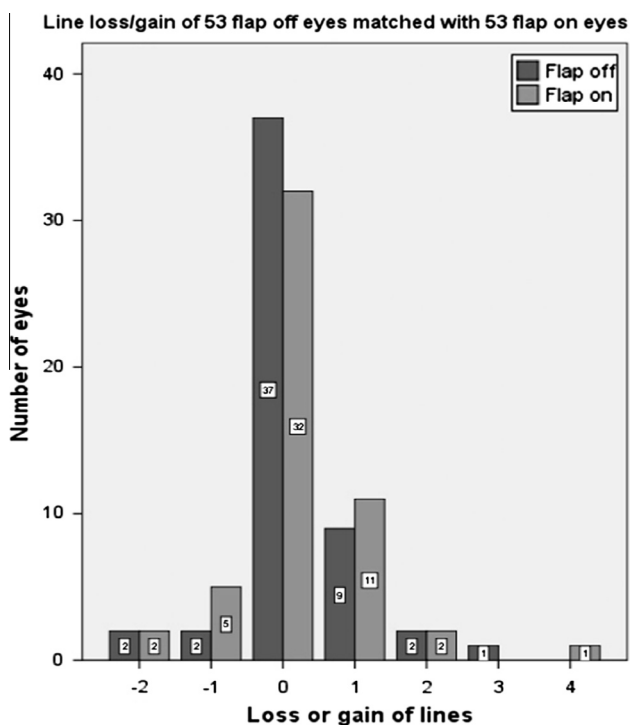


Figure 1. Line loss/gain in 53 flap off eyes matched with 53 flap on eyes.

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