

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,

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