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Usefulness of bandage contact lenses in the immediate postoperative period after uneventful myopic LASIK

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ABSTRACT

Purpose: To determine the usefulness of a silicone-hydrogel bandage contact lens (BCL) in the immediate postoperative period after uneventful myopic laser in-situ keratomileusis (LASIK).
Methods: The study design was randomized but not masked and data collection was prospective. This study comprised 51 consecutive myopic eyes intervened by means of the LASIK technique to compensate their refractive error. Patients were randomly assigned to two different groups. The experimental group included 24 eyes of 12 patients that were fitted with a BCL immediately after the flap replacement. The control group included 27 eyes of 14 patients with no BCL. Patients were examined 24 h after the surgery; the experimental group was analyzed immediately after the extraction of the BCL. Postoperative uncorrected distance visual acuity (UDVA) and postoperative topographic indexes were compared to baseline in both groups.
Results: The experimental group achieved worse results in the majority of the studied variables. Postoperative UDVA was worse in experimental group ($p < 0.01$). Likewise, corneal asphericity (Q) was significantly higher in experimental group ($p = 0.024$). Topographic indexes showed higher asymmetry in the corneal maps pertaining to experimental group. Specifically, the index of surface variance (ISV) ($p = 0.017$) and index of vertical asymmetry (IVA) ($p = 0.031$) were higher in experimental group. Also, the postoperative central corneal thickness (CCT) resulted in higher values for eyes pertaining to experimental group.
Conclusions: The fitting of a silicone-hydrogel BCL after uneventful LASIK provokes morphological changes in the ocular structures that may lead to a worse UDVA secondary to a higher postoperative CCT and corneal edema.

1. Introduction

During the past decades there has been an increasing interest about the correction of refractive errors through laser refractive surgery as an alternative to traditional compensatory methods like spectacles or contact lenses. Proof of this has been the development of different techniques like photorefractive keractectomy (PRK), laser-assisted subepithelial keratectomy (LASEK), laser in-situ keratectomy (LASIK), or the more recent hopeful alternatives using femtosecond energy [1]. Although PRK was the preferred procedure during the 90's [2], LASIK is still the most widespread option because it is less painful and facilitates a faster recovery of the epithelial corneal layer and visual function [3,4]. However, all of these techniques induce alterations on the corneal surface and the use of bandage contact lenses (BCL) in the postoperative period has been proposed to reduce the pain secondary to the mechanical traction of the lids over the cornea or to diminish the dependence on oral or topical analgesic treatments [5]. Also, it has been suggested that BCL are useful to achieve a better and faster epithelial healing [6]. It is well-known that BCL fitting play a major role after the PRK and LASEK procedures because there is no flap and an epithelial flap respectively, and thus both techniques are painful [7,8]. However, there is still controversy on its usefulness after LASIK. The use of BCL is not standardized after LASIK as there is no agreement in the medical community [9–12]. There is a lack of research and the benefits are

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unclear as the flap replacement after the stromal ablation is recognized as a natural bandage. While some studies conclude that BCL are useful to reduce discomfort in the management of recurrent epithelial loosening following LASIK [9], in cases of excessive hydration of the flap and to prevent epithelial ingrowth [10], other studies point out that there is not benefit on this practice that potentially may lead to corneal edema or infection [11,12].

Some of these studies have chosen Likert-type [13] or normalized scales (as the Cornea and Contact Lens Research Unit Grading Scale) in order to evaluate corneal integrity [14]; both provide subjective results as are conditioned by the examiner criteria and thus, the accuracy may be compromised. In the recent years some devices based on Scheimpflug imaging technology have been used to objectively evaluate the corneal changes induced after refractive surgery [15]. However, it has not been yet applied to the study of the influence of BCL in the immediate postoperative period after LASIK. Regarding the materials employed in BCL, some studies after PRK or LASEK, concluded that silicone-hydrogel achieved better epithelial healing and significantly reduce discomfort compared to conventional hydrogel [16]. After LASIK there are no comparative studies available among different materials.

The present study aims to evaluate the usefulness of BCL fitting in the immediate postoperative period after LASIK by determining visual and topographic changes in each of both considered groups.

2. Methods

This prospective clinical study included 51 eyes of 26 patients intervened of myopic LASIK. The study was randomized but not masked. Experimental group comprised 24 eyes of 12 patients fitted with a BCL immediately after the surgery while control group included 27 eyes of 14 patients with no BCL. Patients were randomly assigned to one group or another. All patients were informed about the study and provided a specific informed consent focused on the fitting of BCL to accept or regret the full research (whether they belong to the control group or not) in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). The study received the approval of the local Ethics Committee.

Inclusion criteria included ages from 18 years and older and low to moderate myopia in both eyes, demonstrated refractive stability and best spectacle-corrected distance visual acuity (BCVA) better than 20/25 in both eyes. Exclusion criteria were postoperative central keratometry less than 36.0 diopters (D), estimated stromal residual bed thickness below 300 mm after the laser ablation was programmed, significant corneal topographic asymmetry, cataract, glaucoma, previous ocular surgery, keratoconus, nonrealistic expectations, pregnancy or breastfeeding, autoimmune disease, and active ocular disease. Patients discontinued contact lens wear before the preoperative examination at least 2 weeks before in case of hydrophilyc material (conventional and silicone hydrogel lenses) or 1 month in case of hard or gas-permeable material.

2.1. Preoperative examination

The preoperative ophthalmologic examination included uncorrected (UDVA) and best spectacle-corrected (BCVA) distance visual acuities using a 6 m logMAR acuity charts under photopic conditions (85 cd/m^2), refraction (objective, manifest, and cycloplegic), slit lamp biomicroscopy, Goldmann applanation tonometry, pupil size measurement under scotopic conditions (0 cd/m^2) with Colvard Pupillometer® (Oasis Medical), corneal tomography with Pentacam® (Oculus Optikgeräte GmbH), ultrasound pachymetry (DGH 5100, DGH Technology, Inc.), optical biometry with IOLMaster® (Carl Zeiss Meditec AG), ocular wavefront aberrometry with iTrace system® (Tracey Technologies), binocularity evaluation, and fundoscopy. All the analyzed corneal topographic parameters were obtained by means of the Pentacam® device and included: 1) Anterior corneal surface asphericity (Q): Q-values are negative ($-1 < Q < 0$) for prolate corneas, and positive ($Q > 0$) for oblate corneas. 2) The index of surface variance (ISV), which describes the deviation of the individual corneal radii from the mean value. 3) The index of vertical asymmetry (IVA), which gives the degree of symmetry of the corneal radii with respect to the 180° meridian as axis of reflection. 4) The index of height asymmetry (IHA), which gives the degree of symmetry of height data with respect to the horizontal meridian as axis of reflection. 5) The index of height decentration (IHD), which is calculated from first harmonic of Fourier analysis of height and is a measure for vertical decentration. 6) The central corneal thickness (CCT). Table 1 shows the normal, abnormal and pathological values of the corneal topographic parameters measured by means of Pentacam® in recent studies [17–19].

Table 1
Values for the corneal topographic parameters measured by means of Pentacam®.

Parameter	Normal (mean ± sd)	Abnormal[§]	Pathological[§]
ISV	19.000 ± 7.000[*]	≥37	≥41
IVA	0.100 ± 0.000[*]	≥0.28	≥0.032
IHA	3.390 ± 2.800[*]	≥19	≥21
IHD	0.006 ± 0.003[*]	≥0.014	≥0.016
CCT	542.000 ± 29.300[†]	–	–

ISV = index of surface variance; IVA = index of vertical asymmetry; IHA = index of height asymmetry; IHD = index of height decentration; CCT = central corneal thickness.
[*] Hashemi et al. [17].
[†] Lackner et al. [18].
[§] From topography device user's manual [19].

2.2. Refraction notation

The preoperative spherocylindrical refractions were converted to vectorial notation using the power vector method described by Thibos and Horner [20]. In this method, any spherocylindrical refractive error can be expressed by 3 dioptric powers: M, J_0, and J_{45}, where M is a spherical lens equal to the spherical equivalent of the given refractive error and J_0 and J_{45} are the 2 Jackson crossed cylinders equivalent to the conventional cylinder. These numbers are the coordinates of a point in a 3-dimensional dioptric space (M, J_0, J_{45}). The length of this vector is a measure of the overall blurring strength (B) of a spherocylindrical refractive error.

2.3. Surgical technique

Preoperatively, the eyes undergoing surgery were prepared by cleansing the periocular zone and two drops of a topical anesthetic were instilled. The flap was performed using a mechanical microkeratome (M2, Moria) that creates a flap with 110 µm of thickness, a total diameter between 9.0 and 9.5 mm and superior hinge. After lifting the corneal lenticule, the ablation was perfomed using a solid-state laser platform (Pulzar Z1, CV Laser Pty, formerly CustomVis Laser Pty Ltd.). Aspheric profiles were programmed in order to minimize the induced primary spherical aberration. The flap was then repositioned and the stromal bed was gently washed to eliminate epithelial cells and Meibomian glands detritus. At the end of the procedure, the experimental group was fitted with a BCL. Table 2 shows the specifications of the lens. Topical postoperative treatment was administered to all patients consisting of a combination of dexamethasone and tobramycine four times a day during one week, according to the practice protocol used. Likewise, patients were instructed to use an artificial tear solution preservative free at least every two hours the day after the surgery and at least four times a day during one month. In all cases, the target postoperative refraction was emmetropia.