

Visual acuity and macular sensitivity in myopic eyes before and after laser *in situ* keratomileusis

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PURPOSE. To evaluate the changes in visual acuity (VA) and in macular sensitivity in myopic eyes subjected to laser *in situ* keratomileusis (LASIK) refractive surgery.

METHODS. In 38 myopic eyes, VA by Snellen's table and macular sensitivity by scanning laser ophthalmoscope (SLO) microperimetry were assessed before and after 24 weeks after LASIK surgery. The myopic eyes were divided into three age-matched groups: Group A = from -5 diopters (D) to -7 D and normal SLO-macular sensitivity (15 eyes); Group B = from -8 D to -16 D and normal SLO-macular sensitivity (9 eyes); and Group C = from -8 D to -16 D and abnormal SLO-macular sensitivity.

RESULTS. In Group A and B eyes, at the first week after LASIK surgery, we observed a significant (analysis of variance, $p < 0.01$) reduction in VA and SLO-macular sensitivity with respect to baseline values, while after 12 and 24 weeks no differences ($p > 0.01$) were found when compared to baseline. In Group C patients, at 1 and 4 weeks after surgical treatment, we observed a significant ($p < 0.01$) reduction in VA and SLO-macular sensitivity with respect to baseline values. At 12 and 24 weeks the values of VA were reduced, but not significantly ($p > 0.01$), while values of SLO-macular sensitivity were still significantly ($p < 0.01$) reduced.

CONCLUSIONS. LASIK could induce a reduction in VA and SLO-macular sensitivity in all myopic eyes during the 4 weeks following the surgery. This reduction is still present after 24 weeks only in eyes with the highest preoperative degree of myopia combined with the greatest reduction in macular sensitivity. (*Eur J Ophthalmol* 2005; 15: 695-701)

KEY WORDS. Laser *in situ* keratomileusis (LASIK), Myopia, Retinal sensitivity, Scanning laser ophthalmoscope (SLO)

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INTRODUCTION

Laser *in situ* keratomileusis (LASIK) is today the most widely used method in refractive surgery for the treatment of medium to high myopia (1, 2). The inclusion criteria for LASIK procedure are based essentially on refractive and corneal parameters of patients, but at present the evaluation of functional parameters such as macular sensitivity has not been included (3).

Macular sensitivity can be evaluated by scanning laser ophthalmoscope (SLO) microperimetry (Rodenstock,

Dusseldorf, Germany), which allows us to perform manual static microperimetry with assessment of retinal threshold sensitivity on 30 to 40 points in the macular area under ophthalmoscopic monitoring. SLO microperimetry permits an exact, point-to-point correspondence between fundus image, derived by the direct visualization of the macular area, and perimetric results. This psychophysical test has proven to be a more accurate indicator of the anatomic and functional state of the macula compared to visual acuity (VA) (4).

In myopic eyes, in which the presence of a macu-

lar dystrophy at slit lamp biomicroscopy fundus examination was detected, the SLO microperimetry revealed a reduction in retinal sensitivity with respect to normal eyes (5).

The aim of our study was to assess changes in VA and in macular sensitivity in patients with myopia ranging from 5 to 16 negative diopters, subjected to LASIK refractive surgery.

MATERIALS AND METHODS

Patients

Sixty patients (32 men and 28 women, mean age 31.2 ± 7.4 years) with myopia ranging between 5 and 16 negative diopters were examined for enrollment in the study.

A complete ophthalmic evaluation was performed in all patients, including best-corrected VA measurement, Goldmann tonometry, slit lamp biomicroscopy, 90-diopter Volk noncontact lens fundus examination, and SLO.

Because several pathologies may influence SLO microperimetry and VA, we excluded patients with presence of moderate to dense lens opacities, implanted intraocular lens, glaucoma or ocular hypertension, previous history of intraocular inflammation such as anterior or posterior uveitis, multifocal choroiditis, previous history of retinal detachment or laser treatment for peripheral retinal diseases, diabetes, systemic hypertension in medical treatment, connective tissue diseases, previous history of ocular trauma or optic neuropathy, or other systemic or neurologic diseases. We also excluded patients with myopic macular juxta- or subfoveal choroidal neovascularization (CNV) and patients presenting corneal opacities as cause of incomplete visual recovery after the first month of follow-up and in the following months of observation.

On the basis of the inclusion criteria, we enrolled 38 eyes from 20 myopic patients (10 male, 10 female, mean age 29.3 ± 8.2 years).

Myopic eyes were compared to 20 eyes from 20 age-matched control subjects. The same exclusion criteria used for myopic patients were applied to control subjects. In control eyes, the refractive error was within ± 0.50 spherical diopters.

In both myopic and control eyes, we evaluated best-

corrected VA and SLO microperimetry, according to the following methods.

Best-corrected VA was performed at 3 meters using a standard Snellen chart with a presentation of 10 lines from 20/200 (0.1) to 20/20 (1.0) of VA.

Macular sensitivity was evaluated by SLO microperimetry (Rodestock, Dusseldorf, Germany). SLO microperimetry permits an exact, point-to-point correspondence between fundus image, with a direct visualization of the macular area under ophthalmoscopic monitoring, and perimetric results (4). SLO obtains retinal images continuously with a near-infrared laser (780 nm) and scans graphics on the retina with a modulated visible helium-neon laser (633 nm). Any pattern produced by the SLO computer and projected onto the patient's retina is displayed simultaneously on the retinal image in real time. Thus, confocal SLO with graphic capabilities allows the investigator to determine the retinal location of visual stimuli directly on the retinal image in real time. The stimuli are observed by the patient while the images of the stimuli are seen directly on the patient's retina by the observer.

The central fixation aim is a cross directly projected onto the foveal area, visualized on the monitor display. The search for threshold value by static manual perimetry is performed by testing 25 to 30 points in the macular area, starting from a supraliminal stimulus. Microperimetry is performed with a different-sized point stimulus, ranging from Goldmann I to Goldmann IV (4). The area of perimetric examination comprises 33×21 degrees, consisting of 512×512 pixels.

The digital fundus image is stored on the hard disk when microperimetry is performed. When the macular area is sufficiently tested, the digital fundus image is frozen and saved on the hard disk.

The intensity of the stimuli is inversely corresponding to the tested retinal sensitivity, expressed in an alphabetic representation by letters from A (0 dB) to Z (25dB). Not viewed stimuli are represented by a dark square.

We studied macular sensitivity of 30 points on the macula to evaluate the mean value, expressed in dB. We considered the lowest normal limit to be 17.45 dB, obtained by calculating mean values (21.8 dB) observed in control eyes, minus 3 standard deviations (one standard deviation = 1.45 dB).

On the basis of the degree of myopia and mean mac-

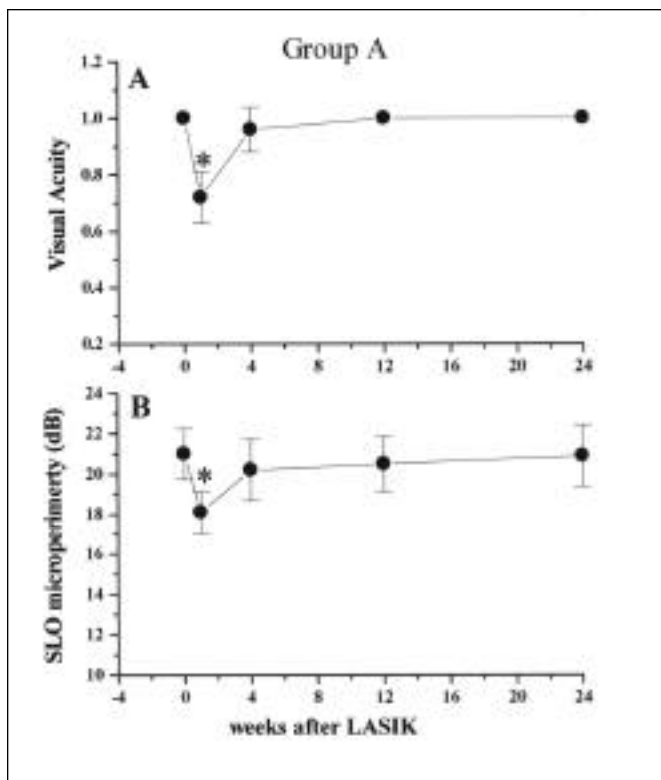


Fig. 1 - Graphic representation of mean values \pm one standard deviation (vertical lines) of visual acuity (A) and macular sensitivity (scanning laser ophthalmoscope microperimetry) and expressed in dB (B) observed in Group A eyes in baseline (preoperative) conditions (O) and at 1, 4, 12, and 24 weeks after laser in situ keratomileusis. * $p < 0.01$, Analysis of variance with respect to baseline conditions.

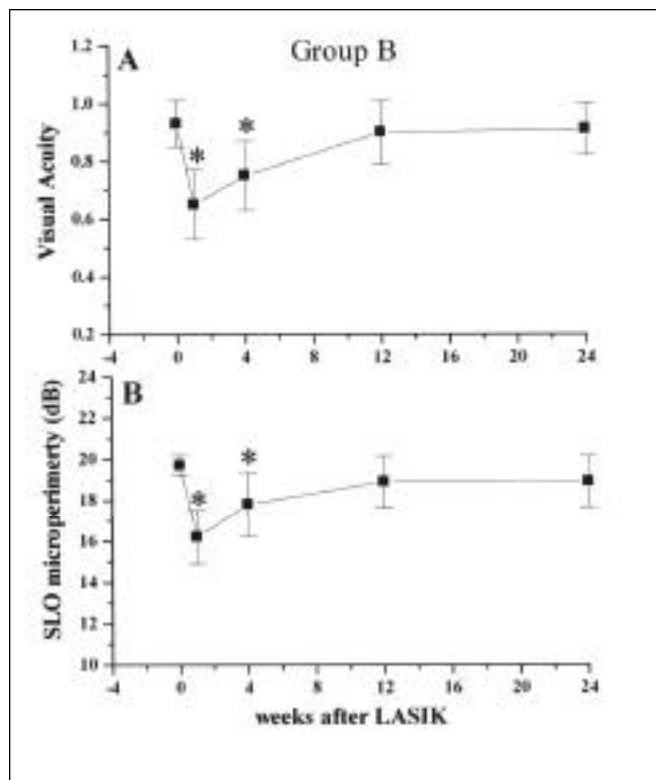


Fig. 2 - Graphic representation of mean values \pm one standard deviation (vertical lines) of visual acuity (A) and macular sensitivity expressed in dB (B) observed in Group B eyes in baseline (preoperative) conditions (O) and at 1, 4, 12, and 24 weeks after laser in situ keratomileusis. * $p < 0.01$, Analysis of variance with respect to baseline conditions.

ular sensitivity, the 38 myopic eyes were divided into three age-matched groups.

The first group (Group A, mean age 27.8 ± 5.3 years) included 15 eyes from 8 patients with myopia ranging between 5 and 7 negative diopters and with mean macular sensitivity within the lowest normal limit.

The second group (Group B, mean age 28.4 ± 6.7 years) included 9 eyes from 6 patients with myopia ranging from 8 to 16 negative diopters and mean macular sensitivity within the lowest normal limit.

The third group (Group C, mean age 30.3 ± 7.3 years) included 14 eyes from 8 patients with myopia ranging from 8 to 16 diopters, showing macular sensitivity below the lowest normal limit.

We found that in Group A and B eyes, no alterations of the macular area were observed, while all eyes of Group C showed a macular dystrophy, represented by choroidal and retinal thinning with slight Bruch's cracks.

LASIK procedure

All myopic eyes underwent refractive surgery, performed with LASIK procedure using Bausch & Lomb C-217 excimer laser, according to a common protocol applied by the same surgeon (P.D.).

Before surgery, corneal topography, pupillometry, and central corneal thickness were evaluated with ultrasonic pachymetry to assess safe limits of corneal stromal removal with the laser ablation.

The first step of the surgery, after marking the epithelium, was to create the corneal flap, 160 μ m thick and with an estimated diameter of 9.5 mm, using the Bausch & Lomb Hansatome microkeratome to make a flap with superior hinge (Down Up LASIK) (6, 7).

This phase, in current opinion, is the most delicate, because a pneumatic suction ring is placed onto the eye to create a vacuum so to obtain globe fixation and a perfect adherence of the microkeratome to the

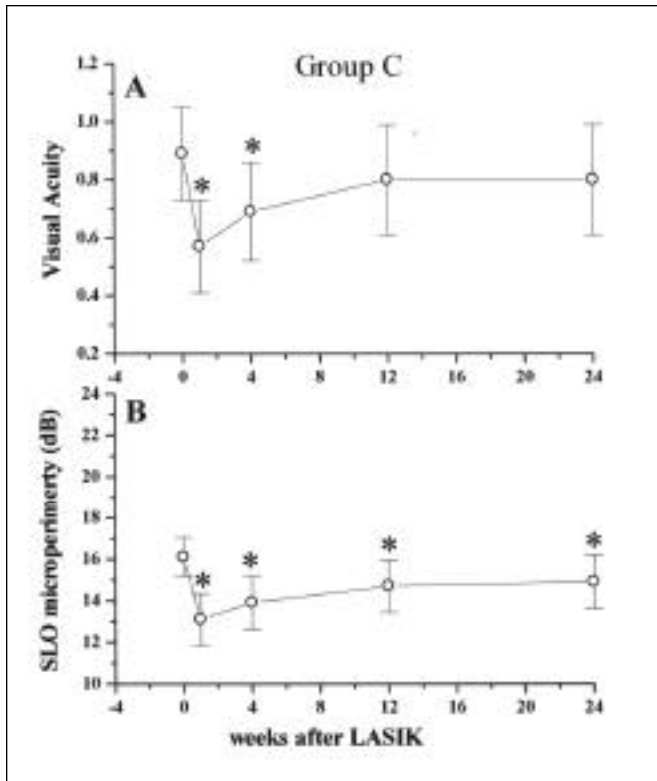


Fig. 3 - Graphic representation of mean values \pm one standard deviation (vertical lines) of visual acuity (A) and macular sensitivity expressed in dB (B) observed in Group C eyes in baseline (preoperative) conditions (O) and at 1, 4, 12, and 24 weeks after laser in situ keratomileusis. * $p < 0.01$, Analysis of variance with respect to baseline conditions.

ocular surface. A few seconds after the vacuum has been activated the intraocular pressure rises to values greater than 65 mmHg, evaluated with the Barraqer tonometer: suction time for all the patients treated was lower than 33 seconds. It is well known that a high intraocular pressure is dangerous for optic nerve and it is likely to be involved in alteration of the Bruch layer (8, 9).

After the flap was done the procedure continued as usual: the flap was lifted and folded out of the ablation field; the eye-tracker system was fixed to the center of the pupil; the ablation was performed with an optical zone of 6 mm; the backside of the flap and the stromal bed were irrigated with BSS; the flap was then replaced onto the stromal bed and, after another irrigation of the interface, inspected to ensure proper position.

Immediately postoperatively all eyes received one drop each of fluorometholone 0.1% and ciprofloxacin 0.3% and a shield was placed over the orbit, without

pressure patch.

The postoperative treatment was as follows: for the first week, fluorometholone 0.1% drops tid, ciprofloxacin 0.3% drops tid, and a lacrimal substitute tid; for the second week, fluorometholone 0.1% drops bid and a lacrimal substitute tid; for the third week, fluorometholone 0.1% drops once a day and a lacrimal substitute tid; then the patient was instructed to use only lacrimal substitutes when needed.

In all myopic eyes VA and SLO microperimetry were assessed 1, 4, 12, and 24 weeks after LASIK procedure.

Statistics

The differences of macular sensitivity and VA observed at baseline conditions between myopic and control eyes have been evaluated by one-way analysis of variance (ANOVA); the differences observed in each group of myopic eyes after 1, 4, 12, and 24 weeks with respect to the baseline condition have been evaluated by one-way ANOVA for repeated measures. A p value less than 0.01 was considered significant.

RESULTS

Mean values of VA and macular sensitivity observed in Groups A, B, and C are shown in Figures 1-3.

Examples of SLO microperimetry are shown in Figures 4-6.

In baseline conditions, Group A eyes showed macular sensitivity ranging from 19 to 23 dB. Group A eyes presented mean macular sensitivity similar to that of control eyes (Group A: 21.0 ± 1.25 dB, controls: 21.8 ± 1.45 dB, $p = 0.096$). Group B eyes showed macular sensitivity ranging from 19 to 20 dB. Nevertheless, a reduction in macular sensitivity was observed when comparing this group with the group of control eyes (Group B: 19.7 ± 0.5 dB, controls: 21.8 ± 1.45 dB, $p < 0.001$). Group C eyes presented macular sensitivity ranging from 14 to 17 dB, with a significant reduction in mean macular sensitivity when compared to controls (Group C: 16.1 ± 0.94 dB, controls: 21.8 ± 1.45 dB, $p < 0.001$).

In Group A eyes, at 1 week after surgical treatment, we observed a significant (ANOVA, $p < 0.01$) reduction in VA and mean macular sensitivity with respect to

baseline values. At 4, 12, and 24 weeks after surgical treatment, no differences in VA or in macular sensitivity ($p > 0.01$) were found when compared to baseline values.

In Group B eyes at 1 and 4 weeks after surgical treatment, we observed a significant (ANOVA, $p < 0.01$) reduction in VA and mean macular sensitivity with respect to baseline values. At 12 and 24 weeks after surgical treatment, no differences in VA or in macular sensitivity ($p > 0.01$) were found when compared to baseline.

In Group C eyes, at 1 and 4 weeks after surgical treatment, we observed a significant ($p < 0.01$) reduction in VA and mean macular sensitivity with respect to baseline values. After 12 and 24 weeks the mean values of VA were reduced, but not significantly ($p > 0.01$), with respect to those observed before surgical treatment, while values of mean macular sensitivity were still significantly ($p < 0.01$) reduced.

During the first 4 weeks of follow-up a typical alteration of the interfaces in the corneal flap was observed, together with incomplete VA and a reduction of retinal sensitivity.

During the following weeks of observation, no significant alterations of corneal interfaces or edema were observed in all patients.

DISCUSSION

This work aims to evaluate the changes in visual function by VA and macular sensitivity assessment after LASIK procedure in myopic eyes.

We observed a reduction in VA and in macular sensitivity in all myopic eyes 1 week after the LASIK procedure. This impairment was still present after 4 weeks from the surgical procedure in eyes with myopia ranging from 8 to 16 negative diopters, while in the same period of follow-up eyes with myopia ranging from 5 to 7 negative diopters showed a recovery of VA and macular sensitivity.

The results obtained in all eyes, independently to the degree of myopia, at 1 and 4 weeks after LASIK are in agreement with those observed in several studies in which the visual function was assessed by visual contrast sensitivity. In these studies a reduction in contrast sensitivity was observed between 1 and 4 weeks after LASIK (10-12).

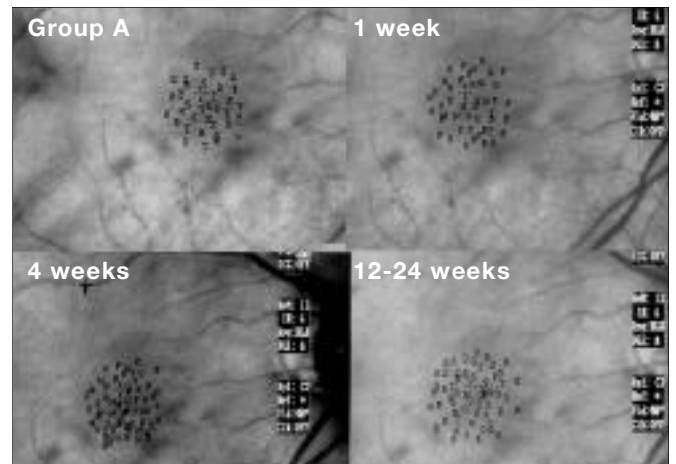


Fig. 4 - Scanning laser ophthalmoscope microperimetry in a Group A eye at baseline conditions and at 1, 4, and 12 weeks after laser in situ keratomileusis. The evaluation at 24 weeks gave the same results as the examination performed after 12 weeks.

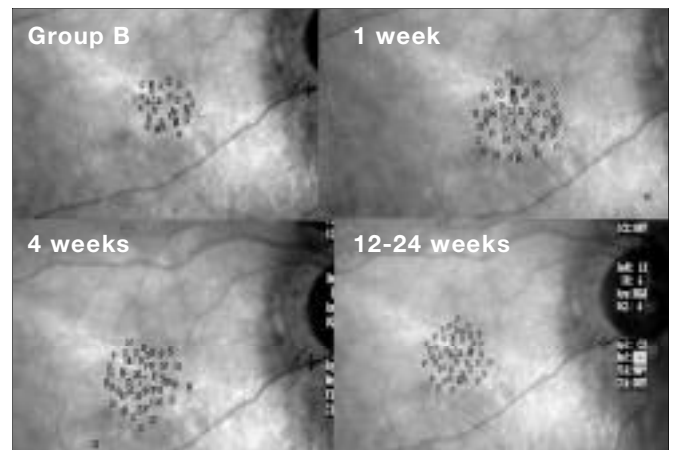


Fig. 5 - Scanning laser ophthalmoscope microperimetry in a Group B eye at baseline conditions and at 1, 4, and 12 weeks after laser in situ keratomileusis. The evaluation at 24 weeks gave the same results as the examination performed after 12 weeks.

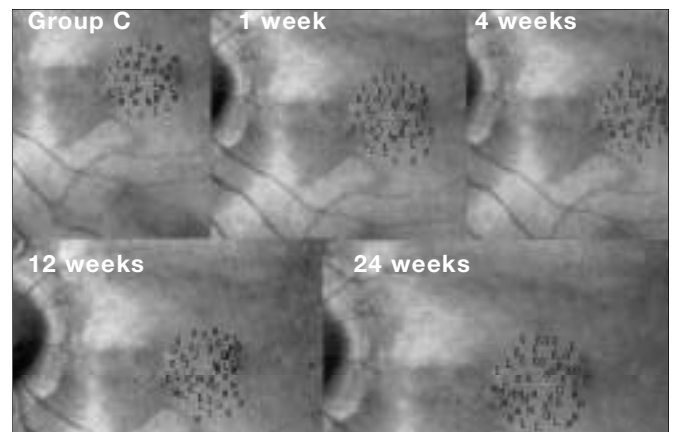


Fig. 6 - Scanning laser ophthalmoscope microperimetry in a Group C eye at baseline conditions and at 1, 4, 12, and 24 weeks after laser in situ keratomileusis.

According to studies performed by contrast sensitivity evaluation (10-16), it is likely that the observed changes in VA and macular sensitivity should be ascribed to optical factors but, as suggested by Chan et al (10), a contribution of a retinal dysfunction related to a sharp increase of the intraocular pressure during the flap opening in LASIK cannot be excluded.

At 12 and 24 weeks after LASIK procedure, we found a recovery in VA in all eyes, while a reduction in macular sensitivity was still present in Group C eyes, which had both high myopia and abnormal preoperative macular sensitivity.

At fundus examination all the Group C eyes showed the characteristic aspect of myopic macular dystrophy, with a thinning both of the chorioretina and the sclera associated with chorioretinal atrophy.

All that was observed in Group C eyes could be ascribed to corneal or retinal dysfunction or both.

Our study tends to exclude the role of the cornea as being the predominant factor in visual function decrease, because the same corneal flap with a thickness of 160 microns and an optic zone less than or equal to the pupil diameter (5 to 6 mm) were carried out in all examined eyes.

Moreover, the typical alterations of corneal interfaces were detected only in the first 4 weeks of observation but no significant alterations of corneal interfaces or edema were observed during the following 20-week follow-up.

These observations seem to suggest that the condition of the cornea, minimally modified during the surgical maneuvers, does not play an essential role in the postoperative reduction of VA and macular sensitivity observed in these eyes in the last period (12 and 24 months) of follow-up.

On the contrary, we suppose a possible role of retinal factors in the reduction of macular sensitivity. In fact, it is likely that eyes with the highest degree of myopia with myopic macular dystrophy and dysfunction (the latter revealed by baseline reduced macular sensitivity) may be more vulnerable to a possible hemodynamic and/or mechanical shock induced by the LASIK procedure (9, 17-21).

Suction time, causing a temporary increase of intraocular pressure, is considered to be the critical phase during LASIK surgery (22).

The choroid has a very elevated hypo-oxygenation threshold with specific autoregulatory mechanisms that

respond differently in different individuals because of differences in the morphology, elasticity, and anatomy of the retina, especially in the macular area (23, 24).

In high myopia, anatomic changes such as retinal and choroidal thinning due to the lengthening of the eye have been demonstrated (25). We hypothesize that both intraoperative suction time and characteristic anatomic and physiologic predispositions may play critical roles in the reduction of macular sensitivity in highly myopic eyes subjected to LASIK, as shown in our patients with myopia ranging from 8 to 16 negative diopters and baseline impaired macular sensitivity.

The final reduction in macular sensitivity probably results from hypo-oxygenation due to the mechanical shock on the choroid and on the retina during the suction phase of the LASIK procedure. These considerations could explain the observations present in literature about the possible development of choroidal neovascularization after LASIK surgery (19).

In conclusion, in this open study, performed in a selected series of patients, we observed that myopic eyes subjected to LASIK procedure may present a reduction in macular sensitivity during the 4 weeks following surgical treatment.

This functional impairment could be related to optical or retinal factors, or both.

Myopic eyes with the highest degree of myopia (between -8 D and -16 D) and concomitant preoperative conditions of reduced macular sensitivity may present an incomplete visual function recovery.

This led us to believe that the evaluation of macular sensitivity could be considered in the preoperative evaluation, in order to obtain more selective parameters for inclusion or exclusion criteria in the LASIK procedure, and for the functional prognosis of highly myopic eyes.

The authors have no proprietary interest in the development or marketing of the instrument used.

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