Femtosecond Laser versus Mechanical Keratome LASIK for Myopia

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Objective: To assess efficacy, safety, predictability, stability, and changes in corneal higher-order aberrations (CHOAs) and contrast sensitivity (CS) after a femtosecond laser for LASIK and standard LASIK for myopia.

Design: Prospective, randomized, comparative clinical study.

Participants: Two hundred eyes of 100 consecutive patients who underwent LASIK treatment using the VISX S2 laser system. A femtosecond laser for flap creation was used in 100 eyes (50 patients; spherical equivalent [SE], -2.85 ± 1.79 diopters [D]), and a mechanical microkeratome was used in 100 eyes (50 patients; SE, -2.90 ± 1.63 D).

Methods: Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, CS by means of the Functional Acuity Contrast Test, and CHOAs by means of custom software linked to topography were evaluated preoperatively and 6 months after treatment.

Main Outcome Measures: Efficacy, safety, predictability, stability, CHOAs, and CS were evaluated before and after surgery at 6 months' follow-up.

Results: At 6 months postoperatively, UCVA was 1.0 or better in 100% of the eyes. Efficacy indexes were 1.07 for the femtosecond laser for LASIK patients and 1.00 for LASIK patients. No eye lost $\geq$1 lines of BCVA; for the femtosecond laser for LASIK group, 24 eyes gained 1 line, and 18 eyes gained $\geq$2 lines; for the LASIK group, 18 eyes gained 1 line. The femtosecond laser for LASIK group showed a percentage of eyes (98%) within the 0.5-D range in SE higher than that of the LASIK group (92%). For a 3.5-mm pupil, CHOAs' root-mean-square (RMS) increased for both the femtosecond laser for LASIK (2.21-fold) and LASIK (2.81-fold) groups. For a 6-mm pupil, CHOA RMSs were increased significantly after femtosecond laser for LASIK (4.18-fold) and LASIK (5.07-fold) surgeries ($P<0.01$). Contrast sensitivity improved only in the femtosecond laser for LASIK group at the highest spatial frequency (18 cycles/degree; $P<0.01$) after surgery.

Conclusions: A femtosecond laser for LASIK surgery is an effective and, in this series, safe procedure for treatment of myopia. The improvements in UCVA and CS after the femtosecond laser for LASIK are related to the differences in postoperative CHOAs found with femtosecond and microkeratome flap creation. *Ophthalmology 2007;114:62–68 © 2007 by the American Academy of Ophthalmology.*

One of the most interesting technical developments in laser refractive surgery during the last few years has been the emergence of the new ultrashort-pulse lasers (picosecond and femtosecond).[1,2] Current clinical applications of femtosecond lasers have been developed to create flaps for LASIK.[3,4] The femtosecond laser is a focusable infrared (1053 nm) laser that uses ultrafast pulses in the 100-femtosecond (100×10^{-15}-second) duration range. The laser delivers closely spaced spots that can be focused at a preset depth to photodisrupt tissue within the corneal stroma with minimal inflammation and collateral tissue damage. During treatment, the cornea is flattened with a suction-applanating lens to immobilize the eye and to allow treatment of a geometrically simpler planar cornea.

Several recent studies have addressed preliminary outcomes of a femtosecond laser for LASIK (IntraLase, IntraLase Corp., Irvine, CA) using small samples of patients at a few months after surgery.[5–8] The femtosecond laser demonstrated more predictable flap thickness, an insignificant increase in higher-order aberrations after flap creation, better uncorrected visual acuity (UCVA), and decreased epithelial injury relative to mechanical microkeratomes. However, no studies have been performed to assess the optical and visual impact of this new surgery in a large population over a follow-up period.

The purpose of this study was to assess efficacy, safety, predictability, stability, and changes in corneal optical aberrations (CHOAs) and contrast sensitivity (CS) after the femtosecond laser for LASIK and to compare it with standard microkeratome LASIK surgery for the correction of myopia.

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Patients and Methods

Study Design

A randomized, observational, prospective study was carried out on 200 consecutive eyes of 100 patients who had undergone LASIK treatment. The femtosecond laser for flap creation was used in 100 eyes (50 patients), and a mechanical microkeratome was used in 100 eyes (50 patients). Excimer laser ablation was performed with the VISX S2 laser system (Visx USA, Inc., Santa Clara, CA) with a target of full correction in all eyes. Antibiotic prophylaxis before surgery consisted of topical ciprofloxacin (Oftacilox, Alcon Cusí, S.A., Barcelona, Spain) every 8 hours for 3 days. Antiseptic prophylaxis was performed by applying 1 drop of povidone–iodine 5% solution to the conjunctiva immediately before surgery. After surgery, topical tobramycin and dexamethasone eyedrops (TobraDex, Alcon Laboratories, Inc., Fort Worth, TX) were used every 8 hours for 1 week in the LASIK group and every 2 hours for 3 days and every 8 hours for 4 days in the femtosecond laser for LASIK group. Before the LASIK procedure, patients had a complete ophthalmologic examination, including manifest and cycloplegic refraction; determination of UCVA, best spectacle-corrected visual acuity (BSCVA), and contrast sensitivity; elevation computerized videokeratography, slit-lamp biomicroscopy, Goldmann applanation tonometry, binocular indirect ophthalmoscopy through dilated pupils, and ultrasonic pachymetry. Postoperative examinations were routinely performed at 1, 3, and 6 months after surgery. All patients completed a 6-month follow-up.

Femtosecond Laser

The IntraLase femtosecond laser was used to create the flap. The laser software creates a circular cleavage plane starting at one side of the cornea and progressing across the cornea using a raster pattern. After the horizontal cleavage plane is created, the pattern changes to a vertical one, continuing through Bowman's layer and the epithelium. It then creates a flap edge with a programmable angle using a circumferential pattern of shallower pulses. An arc along the edge is left uncut to create the hinge. The software controls the planned flap diameter and thickness, angle of the side cut, hinge size and location, and all energy settings to create the flap.

Femtosecond laser flaps were programmed with the following settings: 120-μm thickness, 9.0-mm diameter, 45° superior hinge angle to achieve equivalent corneal stromal surface exposure, 70° side-cut angle, laser raster patterns spot/line separation of 12/10 μm, and stromal energy of 1.8 microjoules with a side-cut energy of 2.4 microjoules.

Mechanical Microkeratome

The Carriazo-Barraquer mechanical microkeratome (Moria, Antony, France) was used to create the flap (superior hinge). With this microkeratome, the selected plate thickness was 130 μm and the suction ring selected was −1, 0, or +1 as a function of the corneal curvature to achieve a 9.5-mm diameter.

Corneal Higher-Order Aberrations and Contrast Sensitivity

Topographic data were obtained with a TMS-2N instrument (Tomey Corp., Nagoya, Japan). During the initial setup, measurements in each eye were repeated until a well-focused and aligned image was obtained. Following the procedure used in earlier studies,[9–12] corneal videokeratographic data were downloaded onto floppy disks in ASCII files, which contained information about corneal elevation, curvature, power, and position of the pupil. The videokeratographic data were fitted with Zernike polynomials up to the sixth order to determine aberration coefficients. The calculation of CHOAs was performed using CT-View 6.32 software (Sarver & Associates, Inc., Merritt Island, FL) for 2 pupil diameters, 3.5 and 6 mm. The Zernike coefficients were used to calculate the total higher-order monochromatic aberration, and the aberration contributed by spherical aberration (Z_4^0) and comalike aberrations (Z_3^1 and Z_5^1). Wavefront aberrations were calculated relative to the pupil center instead of the normal vertex (videokeratoscope axis) because the pupil center is more relevant to visual acuity (VA). Aberration analysis was performed by an independent masked observer.

Contrast sensitivity was measured using the Functional Acuity Contrast Test (Stereo Optical, Chicago, IL), which has been used by the authors in several research studies to test visual performance after refractive surgery.[13–17] All examinations were performed by one masked ophthalmic technician.

Data Analysis

Data analysis was performed using SPSS for Windows (version 12.0, SPSS Inc., Chicago, IL). Normality was checked by the Shapiro–Wilk test, and a *t* test was performed to compare both groups. Differences were considered to be statistically significant when $P<0.01$. To explore the statistical significance of any intergroup differences, a *t* test was performed on the data of the 2 groups (absolute log CS values) at each frequency and before and after surgery.

Results

Table 1 shows patient baseline characteristics for both groups. There were no statistically significant differences between the femtosecond laser for LASIK and LASIK groups with respect to age, spherical equivalent (SE), keratometry, and pachymetry.

Efficacy

In the femtosecond laser for LASIK group, UCVA (Snellen decimal VA) improved in 100% of the patients from 0.55±0.15 preoperatively to 1.10±0.09 at 6-month follow-up (Fig 1), with an efficacy index (ratio of postoperative UCVA and preoperative BCVA) of 1.07. In the LASIK group, UCVA improved in 100% of the patients from 0.54±0.17 preoperatively to 1.03±0.10 at 6-month follow-up (Fig 1), with an efficacy index of 1.00.

Table 1. Patient Characteristics

	Femtosecond Laser for LASIK (n = 100) (Mean ± SD)	LASIK (n = 100) (Mean ± SD)	*P* Value
Spherical equivalent (D)	−2.85±1.79	−2.90±1.63	0.314
Age (yrs)	30.1±5.71	31.8±4.22	0.421
Preoperative keratometry (D)	43.44±1.25	43.59±1.56	0.530
Preoperative pachymetry (μm)	554±35	559±26	0.511

D = diopters; n = no. of eyes; SD = standard deviation.

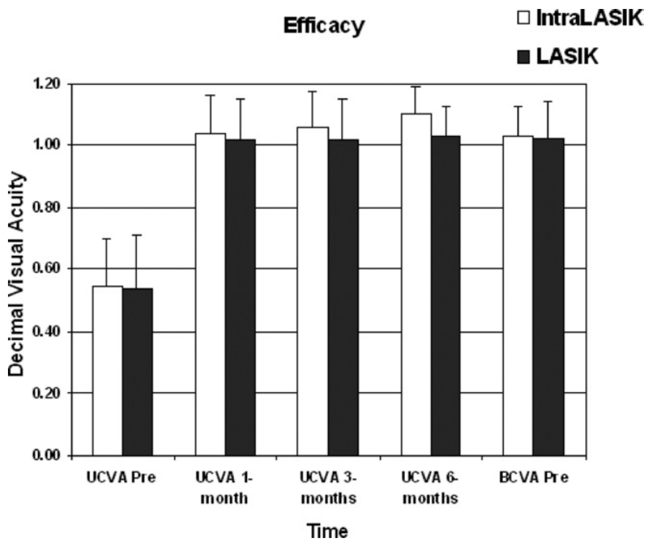

Figure 1. Uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BCVA) in both groups before (pre) LASIK surgery and UCVA after LASIK surgery (efficacy). IntraLASIK = femtosecond laser for LASIK.

Safety

In the femtosecond laser for LASIK group, 6 months after surgery none of the examined eyes had lost ≥1 lines of BCVA (Fig 2). Fifty-eight eyes did not change after surgery, 24 gained 1 line, 12 gained 2 lines, and 6 gained >2 lines of VA. The safety index (ratio of postoperative and preoperative BCVA) at 6 months was 1.07. For the LASIK group, BCVA after surgery remained unchanged in 82 eyes, and 18 eyes gained 1 line of VA at 6 months. The safety index at 6 months was 1.01.

Predictability

The mean postoperative SE for the femtosecond laser for LASIK group was +0.04±0.16 diopters (D) (range, −0.25 to +0.50) at 6 months. For the LASIK group, the mean postoperative SE was −0.14± 0.32 D (range, −0.75 to +0.50) at 6 months. At 6 months, all eyes in both groups were within 1 D of the aimed-for

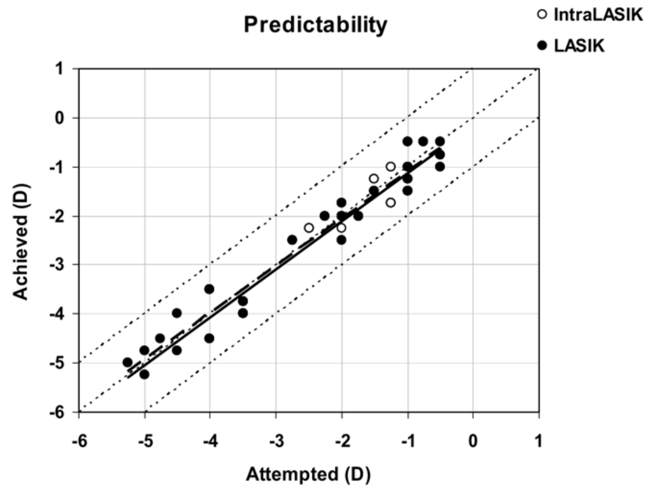

Figure 3. Attempted versus achieved correction of spherical equivalent (predictability) 6 months after femtosecond laser for LASIK (IntraLASIK; dotted line, R = 0.98) and LASIK (solid line, R = 0.97). Correlation coefficients (Rs) were similar in both groups (P>0.05). D = diopters.

refractive change (Fig 3). Ninety-eight eyes for the femtosecond laser for LASIK group and 92 eyes for the LASIK group were within 0.5 D of the target refractive change.

Stability

For the femtosecond laser for LASIK group, the change of mean SE between 1 and 3 months was −0.07 D, that between 3 and 6 months was −0.01 D, and the overall regression was 0.08 D. For the LASIK group, the change between 1 and 3 months was −0.25 D, that between 3 and 6 months was −0.19 D, and the overall regression was −0.44 D. Figure 4 shows the results found in both groups.

Corneal Higher-Order Aberrations

Corneal higher-order aberrations before and 6 months after surgery for both groups are summarized in Table 2. For a 3.5-mm pupil, both femtosecond laser for LASIK and LASIK significantly in-

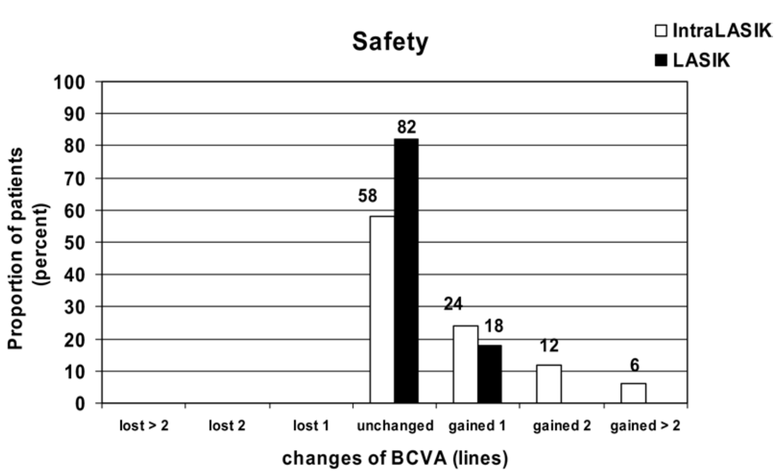

Figure 2. Changes in best spectacle-corrected visual acuity (BCVA) 6 months after LASIK surgery in both groups (safety). IntraLASIK = femtosecond laser for LASIK.

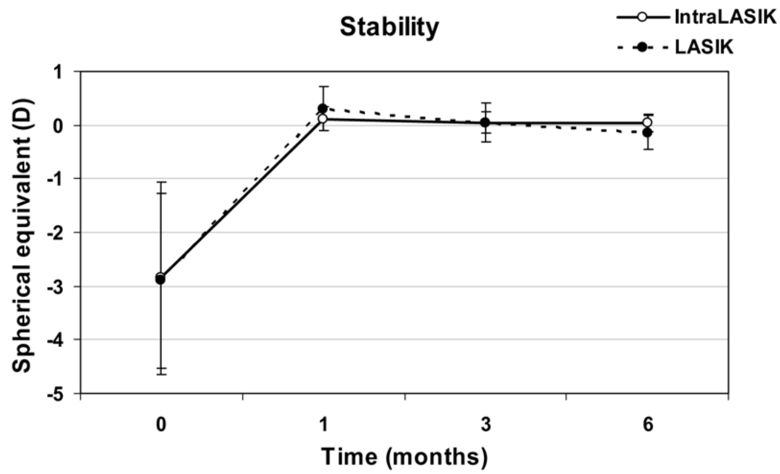

Figure 4. Time course of the spherical equivalent and standard deviation after LASIK surgery for both groups (stability). D = diopters; IntraLASIK = femtosecond laser for LASIK.

creased total, spherical, and comalike aberrations (between 1.66-fold and 2.83-fold). Larger increments were found for a 6-mm pupil after both types of surgeries (between 4.18-fold and 5.20-fold). The increase in comalike aberrations was more pronounced than that in spherical aberration for a 3.5-mm pupil, whereas for a 6-mm pupil the increase factor was higher for spherical aberration than for comalike aberrations. A similar pattern was found for femtosecond laser for LASIK and LASIK surgeries. However, LASIK surgery always showed a larger increase than femtosecond laser for LASIK.

Contrast Sensitivity

Logarithmic CS values were used for statistical analysis, and normalized values were used for graphical representation. Figure 5 shows changes in the mean of the normalized CS values in femtosecond laser for LASIK and LASIK groups for each spatial frequency. Data are shown separately before and after surgery through a series of 2 graphs. Standard mean measurement of postmyopic LASIK, as found by Montés-Micó et al[13,16] using the Functional Acuity Contrast Test, is included for comparison.

No statistically significant differences in CS values at any spatial frequency were found between groups before surgery ($P>0.01$). A similar performance was found after surgery at low and medium spatial frequencies (1.5, 3, 6, and 12 cycles/degree). This behavior corresponds almost exactly to data found for postmyopic LASIK eyes under similar testing conditions by Montés-Micó et al[13,16] (Fig 5). However, a statistically significant improvement in CS for the postsurgery femtosecond laser for LASIK group was obtained at the high spatial frequency (18 cycles/degree; $P<0.01$). This value was better (about 8%) than that for our LASIK group and that found by Montés-Micó et al[13,16] (Fig 5; $P<0.01$).

Discussion

Clinical Outcomes

Our study shows an improvement in UCVA after surgery for both groups, with 100% of eyes having UCVAs of 20/20 or better at 6 months (Fig 1). Both efficacy indexes were good, although the femtosecond laser for LASIK group (1.07) showed better results than the LASIK group (1.00). We have observed satisfactory visual outcomes in relation to the safety index for both groups, with most eyes maintaining their BCVA and some gaining multiple lines of BCVA. No patients lost ≥1 lines of BCVA during the follow-up. However, considering our sample size we can detect adverse events that happen with a ≥3% frequency reliably, bearing in mind that it is necessary to increase the sample size to 300 to detect a rate of 1% severe adverse events. LASIK outcomes showed values similar to those found in the literature.[18] Femtosecond laser for LASIK patients gained more lines of BCVA than LASIK patients (Fig 2). This result disagrees with Kezirian and Stonecipher's[6]: similar results with IntraLase and the Carriazo-Barraquer microkeratome based on the change in BCVA at 3 months after surgery. Differences between studies may arise from differences in the time of postsurgery examinations and degree of myopia corrected (about −4.00 D). Predictability was also good, with 100% of eyes within the 1-D range in SE (Fig 3). The femtosecond laser for LASIK group showed a higher percentage of eyes (98%) within the 0.5-D range in SE than did the LASIK group (92%). Kezirian and Stonecipher[6] found similar results at 3 months (linear regressions of 0.96 and 0.94 for femtosecond laser for LASIK and LASIK groups, respectively). These authors argued that the reason for this improvement may be the decrease in use of irrigation with IntraLase. Considering that laser ablation rates vary with tissue hydration,[19,20] by avoiding the need for irrigation tissue hydration may be more standarized with IntraLase than with mechanical keratomes. This would correlate with the better results found in improved BCVA using IntraLase versus LASIK (Fig 2). In terms of stability, our study shows a small regression between the first month and 6 months of follow-up in both groups, being larger for the LASIK group (Fig 4). The stability index at the 6-month period was excellent for the femtosecond laser for LASIK group (0.08-D change of SE). No comparison with previous studies is possible because this is the first study that evaluates stability for a period of 6 months after femtosecond laser for LASIK surgery.

Table 2. Corneal Higher-Order Aberrations for Femtosecond Laser for

	Corneal Higher-Order Aberrations* RMS			
	3.5 mm		6 mm	
	Femtosecond Laser for LASIK	*LASIK*	*Femtosecond Laser for LASIK*	*LASIK*
Preoperatively	0.11±0.04	0.10±0.03	0.49±0.14	0.51±0.13
6 mos postoperatively	0.24±0.08§	0.28±0.09§	2.05±0.74§	2.59±0.85§
Increasing factor	2.21	2.81	4.18	5.07

RMS = root-mean-square.
Mean ± standard deviation (μm).
*$Z_3^i+Z_4^i+Z_5^i$.
†Z_4^0.
‡$Z_3^i+Z_5^i$.
§$P<0.01$; significantly higher than the preoperative value.

Corneal Higher-Order Aberrations

The results found in our study indicate that LASIK surgery was associated with higher values of CHOAs after surgery than femtosecond laser for LASIK for both small and large pupil diameters (Table 2). For both groups, spherical aberration increased significantly, showing a high increase factor for LASIK compared with femtosecond laser for LASIK ($P<0.01$). This coincides with previous literature on the change in spherical aberration after LASIK surgery.[21,22] Marcos et al[21] found an increase factor of 3.93 for a 6.5-mm pupil ($P<0.001$), and Oshika et al[22] had values of 1.8 and 9.4 for 3- and 6-mm pupils, respectively ($P<0.001$). Differences between studies could arise from the different laser systems used and degree of myopia corrected (up to −13 D of correction): Marcos et al[21] used a narrow-beam (flying spot) laser system, and Oshika et al[22] used a broad-beam laser system (VISX STAR S2, non–eye tracker). The use of eye trackers improves optical outcomes after laser surgery, reducing the increase of spherical aberration.[23] Our increase factors in spherical aberration for LASIK were 1.89 and 5.20 for 3.5- and 6-mm pupils, respectively. Our results are more comparable to Oshika et al's,[22] considering the use of the same laser system and despite the use of a different mechanical microkeratome (MK-2000, Nidek Ltd., Tokyo, Japan). The femtosecond laser for LASIK group showed values of the increase factor after surgery lower than those of the LASIK group for both pupil diameters (Table 2). Porter et al[24] concluded that the majority of the increase in spherical aberration after LASIK was due to the laser ablation and not the microkeratome incision. They measured the change for a 6-mm pupil, and considering our results for the same pupil, this explanation seems plausible. However, taking into account the results found for a small pupil (3.5 mm), the differences between the groups may be due to the use of a femtosecond laser instead of a mechanical keratome. The geometric differences created on the stromal bed between the femtosecond laser and mechanical keratome may play a role in the differences found between the 2 groups.

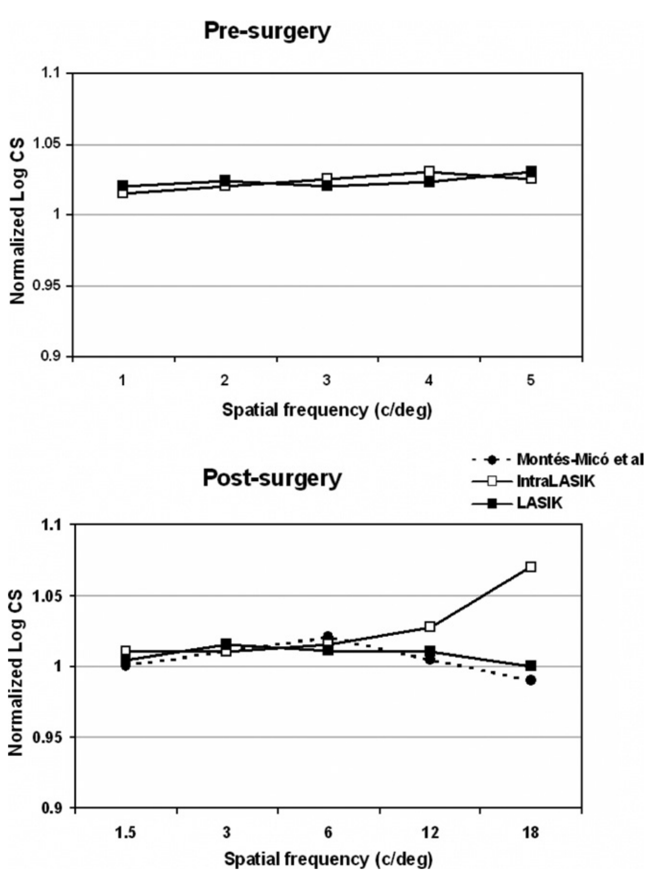

Figure 5. Normalized monocular best-corrected $\log_{10}$ contrast sensitivity function (log CS) before and after LASIK surgery. Standard deviation (SD) error bars have been omitted for clarity. Typical values of the SD varied from 0.02 to 0.05. c/deg = cycles/degree. □, femtosecond laser for LASIK (IntraLASIK) group; ■, LASIK group; ●, previous data on contrast sensitivity found by Montés-Micó et al[13,16] after 6 months of standard LASIK surgery.

Comalike aberrations increased after surgery for both groups (Table 2). Increase factors found with LASIK were similar to those found by Oshika et al[22] (2.4 and 4.4 for 3- and 6-mm pupil diameters, respectively [$P<0.001$]). The femtosecond laser for LASIK group showed lower increase factor values. This result coincides with that found by Tran et al,[7] who compared the induced aberrations with IntraLase

LASIK and Standard LASIK Groups before and after Surgery

Spherical Aberration† RMS				Comalike Aberrations‡ RMS			
3.5 mm		*6 mm*		*3.5 mm*		*6 mm*	
Femtosecond Laser for LASIK	*LASIK*	*Femtosecond Laser for LASIK*	*LASIK*	*Femtosecond Laser for LASIK*	*LASIK*	*Femtosecond Laser for LASIK*	*LASIK*
0.06±0.02	0.06±0.02	0.25±0.12	0.24±0.11	0.07±0.02	0.06±0.02	0.45±0.19	0.44±0.22
0.10±0.02§	0.12±0.03§	1.12±0.71§	1.25±0.82§	0.15±0.03§	0.17±0.02§	1.61±0.82§	1.79±0.89§
1.66	1.89	4.48	5.20	2.14	2.83	3.57	4.06

and Hansatome (Bausch & Lomb, Rochester, NY) flap creation. The increase in comalike aberrations in the mechanical microkeratome group may be related to the difference in the hinge angle between both flaps. The flap in the microkeratome depends on the corneal diameter and corneal curvature, and the variation in the hinge angle between patients is beyond the surgeon's control. In contrast, the hinge angle in the femtosecond laser for LASIK group is always constant (45° in our study). In both groups, the increase of comalike aberrations after surgery is expected, due to the effect of the flap hinge on the aberrations. Pallikaris et al[25] suggested that the position of the flap hinge may influence the type of aberrations induced after the incision. In this way, Porter et al[24] reported that superior hinges contribute to shifts in the trefoil mode.

Contrast Sensitivity

No statistically significant differences in CS were found before and after surgery for either group for low and medium spatial frequencies ($P>0.01$; Fig 5). After surgery, CSs were very similar in both groups and were close to that found by Montés-Micó et al[13,16] for postmyopic LASIK eyes. However, a statistically significant improvement in CS for the postsurgery femtosecond laser for LASIK group was obtained at the high spatial frequency (18 cycles/degree; $P<0.01$). This value was better (about 8%) than those of our LASIK group and Montés-Micó et al[13,16] (Fig 5; $P<0.01$). Yamane et al[26] reported that standard LASIK increases higher-order aberrations, and these can contribute to the loss of CS. An increase of CHOAs would show poor CS at the high–spatial frequency pattern followed by the LASIK group (Fig 5, bottom). This finding corroborates the relationship between CHOAs and CS at high spatial frequencies reported by Montés-Micó and Charman.[13] If we are able to reduce the increase in CHOAs after laser surgery—using the femtosecond laser, for example—better results in CS will be achieved.

Wavefront-Guided Laser Surgery

The visual benefit of correcting higher-order aberrations of the eye has been reported.[27] However, some discrepancy still exists as to the outcomes of wavefront-guided versus standard LASIK to correct higher-order aberrations (see Kohnen et al[28] for a review). Factors such as preoperative refractive error, microkeratome, laser system, and ablation algorithm used to perform the surgery may influence the results achieved, and we should include the possibility of creating the flap using a femtosecond laser among these factors. It is suggested that wavefront-guided customized ablation reduces the increase of higher-order aberrations compared with standard LASIK. For instance, to control residual primary spherical aberration with a tolerance of one-quarter wavelength, the precision of the ablation must range from 0.2 to 0.3 μm (over a 6-mm-diameter optical zone). In theory, this precision should be achievable because the ablation depth per pulse can be lower than 0.1 μm per pulse. However, in practice this precision will be difficult to achieve because of variations in energy per pulse, inhomogeneities of the optical and mechanical properties of the cornea, wound healing, stromal remodeling, hydration changes, and biomechanical effects, among others.[29] We should take into consideration the differences between femtosecond and microkeratome flap creation—for example, the uniform flap thickness and the stromal bed (which receives the ablation laser pattern). To achieve the best results possible with wavefront-guided ablation, it is crucial to understand the relative contributions of creating a femtosecond or a microkeratome flap to the overall optical quality of an eye undergoing laser surgery. Further investigations of femtosecond- or microkeratome flap–induced aberrations relative to those induced after customized ablation will be required.

In summary, our study demonstrates that femtosecond laser for LASIK seems to be better, considering the improvement in CS and to avoid the negative effect on visual performance found after standard LASIK (e.g., increase in higher-order aberrations). Femtosecond laser for LASIK surgery may be a better choice for wavefront-guided LASIK. Further studies involving groups of patients with different degrees of myopia and hyperopia are needed to evaluate the advantages and disadvantages of femtosecond laser for LASIK for laser refractive surgery.

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