Comparison of Corneal Aberration Changes After Laser In Situ Keratomileusis Performed With Mechanical Microkeratome and IntraLase Femtosecond Laser: 1-Year Follow-up

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**Purpose:** To compare corneal aberration changes 1 year after myopic laser in situ keratomileusis (LASIK) performed with a mechanical microkeratome and IntraLase femtosecond laser.

**Methods:** Twenty-four eyes of 15 patients underwent LASIK with the Hansatome mechanical microkeratome, and 23 eyes of 13 patients underwent LASIK with the IntraLase femtosecond laser. A standard ablation was performed with the Bausch & Lomb Technolas 217 excimer laser. Topography data were used to calculate corneal aberrations with a 3.0 mm and 5.0 mm pupil, before and 12 months after surgery. The increasing factor (IF), defined as the ratio between the postoperative and preoperative mean value of the optical aberration, was calculated. The method of Mulhern et al was used to evaluate the centration of ablation. The corneal aberration was correlated with the decentration of ablation. The Student’s t test was used for the statistical analysis.

**Results:** The postoperative mean decentration of ablation was <0.5 mm. The corneal aberration appeared to be positively correlated with the decentration of ablation in both groups with a 5.0-mm pupil \( (P < 0.05) \). With a 3.0-mm pupil, the corneal aberration changed in the Hansatome group, whereas with a 5.0-mm pupil, all aberrations statistically significantly changed in both groups \( (P < 0.05) \). The IF similarly increased in 2 groups for spherical-like aberration, whereas IF greatly increased for total and corneal aberrations in the Hansatome group.

**Conclusions:** Wavefront corneal aberrations change significantly 1 year after myopic LASIK performed with the Hansatome microkeratome as well as with IntraLase femtosecond lasers. Both of the procedures induce higher-order aberrations in the anterior corneal surface, but the amount of corneal aberration increases more with the Hansatome mechanical microkeratome.

**Key Words:** LASIK, mechanical microkeratome, IntraLase femtosecond laser

Las in situ keratomileusis (LASIK) has become a widespread and effective surgical treatment to correct low-to-moderate myopia. In this technique, a stromal flap is created with a mechanical microkeratome, folded back, and after laser photoablation repositioned. The flap creation is the main surgical step of this procedure and may produce several complications.

Recently, the femtosecond solid-state laser has been introduced as a new and alternative technology for creating flaps in LASIK surgery.

The IntraLase femtosecond laser is a solid-state laser used to create corneal lamellar flaps producing a circular cleavage plane starting at 1 side of the cornea and progressing across the cornea in a back-and-forth pattern. It creates a flap edge of a programmable angle by using a circumferential pattern of progressively shallower pulses. A predefined arc along the edge is left uncut to create the hinge. The entire process takes place through a glass appplanation plate that is fixed to the eye with a low-pressure suction ring.

The IntraLase generally creates flaps with good predictability of thickness.

In this study, we compared corneal wavefront aberration changes induced by the mechanical microkeratome and IntraLase femtosecond laser flap creation at 1-year follow-up after myopic LASIK performed with standard ablation, in an attempt to evaluate whether these 2 procedures could differently induce optical changes in the anterior corneal surface.

**MATERIALS AND METHODS**

Forty-seven eyes of 28 myopic patients were enrolled in this comparative randomized interventional study. Any experimental study reported herein was performed with informed consent and followed all the guidelines for experimental investigation with human subjects as required by the institution with which all the authors are affiliated. The following enrollment criteria were used: surgery performed...
between June 2004 and November 2005, bilateral LASIK treatments for spherical and spherocylindrical myopia, and preoperative astigmatism value <2.00 D. The study cohort was composed of 24 eyes of 15 myopic patients (mean age, 38.7 ± 9.8 [SD] years; mean spherical equivalent defect, −5.2 ± 3.3 D) that underwent LASIK with a Hansatome microkeratome (Bausch & Lomb, Rochester, NY) and 23 eyes of 13 patients (mean age, 39 ± 10.08 years; mean spherical equivalent defect, −6.25 ± 3.6 D) that underwent LASIK with the IntraLase femtosecond laser. The surgeon (L.B.) changed from mechanical microkeratome (Hansatome) to the IntraLase at the end of March 2004, allowing for an appropriate learning curve interval before patient enrollment in the study. Patients were randomly assigned to either the mechanical microkeratome or IntraLase and were masked to the surgeon before the surgical procedure.

A non–wavefront-guided excimer laser treatment was performed with the Bausch & Lomb Technolas 217 excimer laser, without complications or retreatments. The laser parameters (6.0-mm optical zone) were constant for all treatments, and all procedures were assisted by an eye tracker. A mechanical flap, superiorly hinged, was created by using a 160-micron head and a 9.0-mm ring. The femtosecond laser flap was programmed to deliver equivalent geometric dimensions (120-μm thickness, 9.0-mm diameter, and 50-degree superior hinge angle).

The CSO EyeMap (version 6.2; Costruzione Strumenti Oftalmici) Placido disk corneal topography system applies an effective Zernike analysis to the corneal height numerical data. After measuring the corneal surface, the system applies normal values to the surface and then, applying the Snell law to each point, calculates wavefront (A. Calossi, unpublished data, 2001). Corneal aberrations were calculated relative to the videokeratoscope axis, which is centered on and perpendicular to the corneal vertex (whereas in wavefront analysis systems, optical aberrations are centered relative to the pupil center). The CSO topography system represents the corneal wavefront with the seventh-order Zernike polynomial expansion, where tilts and defocus are not considered. The root mean square (RMS) metric of the wavefront was used as a measure of the optical quality. The topographic software tool used to acquire information on the corneal aberrations was in accordance with a previously described system.6 The CSO topography system convention conforms to the Optical Society of America standards for Zernike format. Corneal topography was measured without pupil dilatation.

Patients were evaluated preoperatively, 1 day, and 12 months after surgery. Although routine visits were performed at 1 week and 1 and 3 months after surgery, only the results from the preoperative and 3- and 12-month postoperative visits are reported here. Preoperative and 3- and 12-month postoperative outcome measures included the amount of total, comalike, and spherical-like corneal aberrations.

With the function of the topography software options, corneal aberrations were estimated with pupil diameters of 3.0 and 5.0 mm.

The increasing factor (IF), defined as the ratio between the postoperative and preoperative mean value of the optical aberration, was calculated.

The method of Mulhern et al7 was used to evaluate the centration of ablation.

The comalike aberration was correlated with the decentration of ablation.

Sample size estimates of patients for this study were from a preliminary study, in which the between-subject and within-subject variability (expressed as data SD) of aberration values was determined. Given the expected difference between the mean aberration values of 20% and the expected SD from the mean value for each group of 20%, the sample size considered in this study (n = 24 eyes in the Hansatome group and n = 23 eyes in IntraLase group) provided a power of 85% at an α level of 0.02. Preoperative data approximated a normal distribution; therefore, a Student t test was used. A paired Student t test was used to compare the preoperative and postoperative RMS error value for each aberration, and an independent Student t test was used to compare each aberration between the 2 groups. P < 0.05 was considered significant.

RESULTS

The postoperative mean spherical equivalent defect was −0.18 ± 0.5 D in the microkeratome group and −0.3 ± 0.8 D in the IntraLase group. The postoperative mean uncorrected visual acuity was 9.3 ± 1.6 in the Hansatome group and 8.6 ± 2.3 in the IntraLase group, whereas the mean best-corrected visual acuity was 9.5 ± 0.9 and 9.1 ± 1.1, respectively.

The postoperative mean decentration of ablation was <0.5 mm, without a significant difference between the 2 groups (P > 0.05, independent t test). The comalike aberration appeared to be positively correlated with the decentration of ablation in both groups with a 5.0-mm pupil (Hansatome group: P < 0.05, r = 0.7; IntraLase group: P < 0.05, r = 0.6).

The postoperative mean value of each corneal aberration was not statistically different between the 2 groups (P > 0.05, independent t test), whereas the postoperative mean value showed a significant difference for each aberration (P < 0.05, independent t test).

The 3.0-mm pupil statistically significantly changed the amount of comalike aberrations in the Hansatome group (P < 0.05, paired t test).

In contrast, with the 5.0-mm pupil, the amount of total and higher-order corneal wavefront aberrations significantly changed in both groups (P < 0.05, paired t test).

With the 3.0-mm pupil, the preoperative RMS (Table 1) of total corneal aberration was 0.2 ± 0.4 μm in the microkeratome group and 0.15 ± 0.08 μm in the IntraLase group; at 3 months postoperatively, total aberration mean value was 0.32 ± 0.2 μm in the microkeratome group and 0.19 ± 0.01 μm in the IntraLase group; and at 1 year postoperatively, total aberration mean value was 0.4 ± 0.8 μm in the microkeratome group and 0.19 ± 0.03 μm in the IntraLase group. The preoperative RMS of spherical-like aberration was 0.07 ± 0.1 μm in the microkeratome group and 0.04 ± 0.03 μm in the IntraLase group; at 3 months postoperatively, the spherical-like mean value was 0.09 ± 0.08 μm in the microkeratome group and 0.06 ± 0.01 μm in the IntraLase group.
group; and at 1 year postoperatively, the spherical-like mean value was 0.09 ± 0.09 μm in the microkeratome group and 0.05 ± 0.03 μm in the IntraLase group. The preoperative RMS of comalike aberration was 0.06 ± 0.08 μm in the microkeratome group and 0.04 ± 0.02 μm in the IntraLase group; at 3 months postoperatively, the comalike mean value was 0.13 ± 0.07 μm in the microkeratome group and 0.07 ± 0.02 μm in the IntraLase group; and at 1 year postoperatively, the comalike mean value was 0.20 ± 0.1 and 0.06 ± 0.05 μm, respectively (Fig. 1).

With the 5.0-mm pupil, the preoperative RMS (Table 2) of total corneal aberration was 1.2 ± 0.4 μm in the microkeratome group and 1.1 ± 0.5 μm in the IntraLase group; at 3 months postoperatively, the total aberration mean value was 4.08 ± 1.2 μm in the microkeratome group and 2.01 ± 1.2 μm in the IntraLase group; and at 1 year postoperatively, the total aberration mean value was 4.0 ± 0.8 μm in the microkeratome group and 1.9 ± 0.8 μm in the IntraLase group (Fig. 2). The preoperative RMS of spherical-like aberration was 1.0 ± 0.4 μm in the microkeratome group and 0.7 ± 0.5 μm in the IntraLase group; at 3 months postoperatively, the spherical-like mean value was 3.18 ± 1.31 μm in the microkeratome group and 1.45 ± 1.4 μm in the IntraLase group; and at 1 year postoperatively, the spherical-like mean value was 2.9 ± 1.4 μm in the microkeratome group and 1.7 ± 1.0 μm in the IntraLase group (Fig. 3). The

**TABLE 1.** Preoperative and Postoperative Total, Spherical-like, and Comalike Aberration Mean Values With a 3.0-mm Pupil 1 Year After LASIK Performed With the Hansatome Microkeratome and IntraLase Femtosecond Laser

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hansatome</th>
<th>IntraLase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total aberration RMS mean value</td>
<td>0.2 ± 0.4</td>
<td>0.15 ± 0.08</td>
</tr>
<tr>
<td>Preoperative</td>
<td>0.2 ± 0.4</td>
<td>0.15 ± 0.08</td>
</tr>
<tr>
<td>Postoperative</td>
<td>0.4 ± 0.8</td>
<td>0.19 ± 0.03</td>
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</table>

**TABLE 2.** Preoperative and Postoperative Total, Spherical-like, and Comalike Aberration Mean Value With a 5.0-mm Pupil 1 Year After LASIK Performed With the Hansatome Microkeratome and IntraLase Femtosecond Laser

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Total aberration RMS mean value</td>
<td>1.2 ± 0.4</td>
<td>1.1 ± 0.5</td>
</tr>
<tr>
<td>Preoperative</td>
<td>1.2 ± 0.4</td>
<td>1.1 ± 0.5</td>
</tr>
<tr>
<td>Postoperative</td>
<td>4.0 ± 0.8</td>
<td>1.9 ± 0.8</td>
</tr>
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</table>

**FIGURE 1.** With a 3.0-mm pupil, preoperative and postoperative comalike aberration mean values (± SEM) are plotted for the Hansatome microkeratome and IntraLase femtosecond laser groups. A statistically significant change in comalike aberration was seen after LASIK (P < 0.05, paired t test) in the Hansatome group.

**FIGURE 2.** With a 5.0-mm pupil, preoperative and postoperative total aberration mean values (± SEM) are plotted for the Hansatome microkeratome and IntraLase femtosecond laser groups. A statistically significant change in total aberration was seen after LASIK (P < 0.05, paired t test) in both groups.
With a 5.0-mm pupil, preoperative and postoperative spherical-like aberration mean values were 0.9 ± 0.2 μm in the microkeratome group and 0.4 ± 1.9 μm in the IntraLase group; at 3 months postoperatively, the spherical-like mean value was 1.66 ± 0.72 μm in the microkeratome group and 1.03 ± 0.8 μm in the IntraLase group; and at 1 year postoperatively, the spherical-like mean value was 1.9 ± 0.2 and 0.7 ± 0.2 μm, respectively (Fig. 4).

Three months postoperatively with the 3.0-mm pupil, the IF was 1.1 for total aberration, 1.8 for spherical-like aberration, and 1.4 for comalike aberration in the Hansatome group and 1.3 for total aberration, 2.0 for spherical-like aberration, and 1.7 for comalike aberration in the IntraLase group. One year postoperatively, it was 2.0 for total aberration, 1.2 for spherical-like aberration, and 2.1 for comalike aberration in the Hansatome group and 1.3 for total aberration, 1.2 for spherical-like aberration, and 1.5 for comalike aberration in the IntraLase group (Table 3).

Three months postoperatively with the 5.0-mm pupil, the IF was 1.7 for total aberration, 3.18 for spherical-like aberration, and 1.7 for comalike aberration in the Hansatome group and 1.8 for total aberration, 2.6 for spherical-like aberration, and 2.8 for comalike aberration in the IntraLase group. One year postoperatively, it was 3.3 for total aberration, 2.9 for spherical-like aberration, and 2.7 for comalike aberration in the Hansatome group and 1.7 for total aberration, 2.4 for spherical-like aberration, and 1.7 for comalike aberration in the IntraLase group (Table 4).

**DISCUSSION**

Some authors examined the effect of lamellar corneal flap creation on the optical aberrations in LASIK performed with a mechanical microkeratome: Pallikaris et al. observed that a lamellar cut increased corneal higher-order aberrations (especially spherical and comalike aberrations normal to the axis of the flap’s hinge), whereas Zadok et al. documented that corneal flap creation with the microkeratome did not induce changes of higher-order optical aberrations. Porter et al. observed a statistically significant increase in higher-order aberrations after isolated, flap-only procedures with a mechanical microkeratome.

Few reports compared changes occurring after creating the flap with the mechanical microkeratome and the IntraLase. Tran et al. observed significant changes in defocus after Hansatome and IntraLase flap creation, whereas total higher-order aberrations changed only with the mechanical microkeratome.

Several studies compared the wavefront aberrations induced by the mechanical microkeratome and IntraLase femtosecond laser flap creation, calculated after excimer laser treatment.

Tran et al. by using a Hartmann–Shack device for a pupil of 6.0 mm, measured and compared the changes in objective wavefront aberration after LASIK flap creation with the Hansatome microkeratome and the IntraLase, 3 months after a non–wavefront-guided excimer laser treatment. The authors observed a non–statistically significant increase of spherical aberration secondary to the excimer ablation in both groups and a statistically significant increase in coma in the mechanical microkeratome group related to the variation beyond the surgeon’s control in the achieved hinge angle of the flap and to the decentration specially recorded with larger optical zone algorithms and blending zones. They reported that the IntraLase produced a more symmetrical flap geometry because the software checks the flap centration over the pupil and creates a constant hinge of the angle outside of the bed of stromal dissection allowing a regular ablation for 360 degrees.

Lim et al. measured higher-order aberrations by ZyWave in pupil zones >6.0 mm after LASIK performed with a mechanical microkeratome and an IntraLase femtosecond laser at 3 months after a standard ablation and found...
that higher-order aberrations increased in both groups without a statistically significant difference. However, the microkeratome group, statistically significantly, showed the most spherical aberration.

In this study, we compared corneal aberration changes induced by Hansatome mechanical microkeratome and IntraLase femtosecond laser flap creation 1 year after myopic LASIK performed with a non–wavefront-guided excimer laser. We examined the aberrometric pattern with pupil sizes relevant to daytime vision, in an attempt to look at flap contribution to vision. In this work, we did not consider 7.0-mm pupils because a treatment zone of 6.0 mm necessarily induce spherical aberration as well as coma aberration correlated to decentration, probably masking the real quality of the optical zone produced by each procedure. Buhren and Kohnen\(^4\) showed that the optical zone diameter did not have a significant effect on individual Zernike coefficients with the 3.5-mm pupil diameter, whereas with the 6.0-mm pupil diameter, they recorded a significant effect on the induction of spherical aberration, reporting that the optical zone diameter also had an effect on the induction of coma RMS.

In contrast to previous reports, we found that all corneal aberrations significantly changed after surgery and that, whereas the amount of spherical-like aberration is similar in Hansatome and IntraLase groups, the total and coma-like aberration amount appeared greatest in the Hansatome group. This study analyzed patients 12 months after surgery, whereas the follow-up reported by other articles was 3 months. The amount of higher-order corneal aberration changed similarly in both groups with 3.0- and 5.0-mm pupils from 3 to 12 months after surgery: The IF decreased for spherical-like aberration in both groups and, for coma-like aberrations, decreased with IntraLase and increased with Hansatome microkeratome. The time of effective corneal biomechanical stability after LASIK is not yet known; however, corneal changes occur 3 months after surgery. The refractive stability, a corneal steepening that decreases with time, and a significant increase in corneal thickness,\(^15\) as well as changes in the corneal epithelium, interface, and stroma,\(^16\) were observed between 3 and 6 months after LASIK. Dawson et al.,\(^17\) studying eyebank donor corneas that had undergone LASIK, observed the lack of a complete healing in flaps with postoperative intervals from 2 months to 6.5 years after surgery.

Some authors\(^10,18,19\) found that the increase in spherical aberration in LASIK could be attributed to a severing and retraction of the collagen lamellae caused primarily by the laser ablation and suggested that, even if the laser ablation induces most postoperative spherical aberrations, other factors could contribute to the final aberration pattern of the postoperative LASIK eye. The safety and efficacy of a thin flap in LASIK has been suggested,\(^20\) and Kezirian and Stonecipher\(^21\) reported that, with the IntraLase, the mean flap thickness was closest to the planned value and the range of the thickness varied less than with mechanical microkeratomes. The femtosecond laser appears better to preserve a thicker stromal bed. Potgieter et al.\(^22\) reported that spherical aberrations change in LASIK could be topographically explained with the central cornea flattening and midperipheral corneal steepening; they also proved that stromal bed thickness was a predictor of this aberrometric pattern.

Porter et al\(^15\) reported that changes in optical aberrations induced by the flap do not affect the final outcomes of LASIK. Our data show that in 12 months after surgery the coma-like aberration progressively increases in LASIK performed with the Hansatome microkeratome that creates flaps truncated at the hinge and not uniform for thickness and size, whereas decreases

| TABLE 3. IF Calculated for Total, Spherical-like, and Comalike Aberration Mean Value With a 3.0-mm Pupil 3 Months and 1 Year After LASIK Performed With the Hansatome Microkeratome and IntraLase Femtosecond Laser |
|-------------|---------------------|---------------------|
| IF for:     | Hansatome and IntraLase (3 mo) | Hansatome and IntraLase (1 y) |
| Total aberration | 1.1 | 1.3 |
|             | \(P > 0.05\), independent \(t\) test | \(P < 0.05\), independent \(t\) test |
| Spherical-like aberration | 1.8 | 2.0 |
|             | \(P > 0.05\), independent \(t\) test | \(P > 0.05\), independent \(t\) test |
| Comalike aberration | 1.4 | 1.7 |
|             | \(P > 0.05\), independent \(t\) test | \(P < 0.05\), independent \(t\) test |

| TABLE 4. IF Calculated for Total, Spherical-like, and Comalike Aberration Mean Value With a 5.0-mm Pupil 3 Months and 1 Year After LASIK Performed With the Hansatome Microkeratome and IntraLase Femtosecond Laser |
|-------------|---------------------|---------------------|
| IF for:     | Hansatome and IntraLase (3 mo) | Hansatome and IntraLase (1 y) |
| Total aberration | 1.7 | 1.8 |
|             | \(P > 0.05\), independent \(t\) test | \(P < 0.05\), independent \(t\) test |
| Spherical-like aberration | 3.2 | 2.6 |
|             | \(P > 0.05\), independent \(t\) test | \(P > 0.05\), independent \(t\) test |
| Comalike aberration | 1.7 | 2.8 |
|             | \(P < 0.05\), independent \(t\) test | \(P < 0.05\), independent \(t\) test |
in LASIK performed with the IntraLase that probably better preserve the symmetry of the flap, more regular for the hinge size and location, as well as for the morphology that appears as circular. The different flap thickness of the 2 groups could partially explain these aberrometric changes, since that thicker flaps may induce more aberrations because they cut through the tensile strength of the cornea.

Mrochen et al.\textsuperscript{23} found that subclinical decentration (<1.0 mm) is a major factor in increased comalike and spherical-like aberrations after corneal laser surgery. In this study, we evaluated the centration of ablation with a method developed by Mulhern et al.\textsuperscript{8} observing that, in both groups, the decentration was limited and both groups did not show significant differences in the centration of ablation. Also, the positive correlation between corneal aberration and decentration appeared similar in the 2 groups. These findings suggest that the decentration increases corneal comalike aberration similarly with a mechanical microkeratome and with femtosecond laser, but the different amount of increased corneal aberration could be caused mainly by the different flap creation procedures used in the LASIK surgery.

Because the excimer ablation increases higher-order aberrations with the spherical aberration that is dominant, because of the change of the corneal shape, the conversion of biodynamics, and the restructured corneal stroma,\textsuperscript{24} the optimal analysis of corneal aberration changes induced from the flap creation would have been performed before excimer treatment, which is not the approach used in our study.

In conclusion, wavefront corneal aberrations change significantly 1 year after myopic LASIK performed with the Hansatome microkeratome and the IntraLase femtosecond laser. Both procedures appear to induce a similar amount of spherical-like aberration in the anterior corneal surface, whereas comalike aberration increases with the mechanical microkeratome more than with the femtosecond laser. Because small amounts of induced aberrations may decrease the benefits of the custom ablation and higher-order aberrations are not predictable, the femtosecond laser could provide relatively more effective wavefront-guided corrections. However, further studies are needed to evaluate whether a slight improvement of the postoperative wavefront outcome affects postoperative visual quality.

REFERENCES