Factors Influencing Flap and INTACS Decentration After Femtosecond Laser Application in Normal and Keratoconic Eyes

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ABSTRACT

PURPOSE: To compare accuracy of LASIK flap and INTACS centration following femtosecond laser application in normal and keratoconic eyes.

METHODS: This is a retrospective case series comprising 133 eyes of 128 patients referred for refractive surgery. All eyes were divided into two groups according to preoperative diagnosis: group 1 (LASIK group) comprised 74 normal eyes of 72 patients undergoing LASIK with a femtosecond laser (IntraLase), and group 2 (INTACS group) consisted of 59 eyes of 39 patients with keratoconus for whom INTACS were implanted using a femtosecond laser (IntraLase). Decentration of the LASIK flap and INTACS was analyzed using Pentacam.

RESULTS: Temporal decentration was 612.56±384.24 µm (range: 30 to 2120 µm) in the LASIK group and 788.33±500.34 µm (range: 30 to 2450 µm) in the INTACS group. A statistically significant difference was noted between the groups in terms of decentration (P<.05). Regression analysis showed that the amount of decentration of the LASIK flap and INTACS correlated with the central corneal thickness in the LASIK group and preoperative sphere and cylinder in the INTACS group, respectively.

CONCLUSIONS: Decentration with the IntraLase occurred in most cases, especially in keratoconic eyes. The application performed for centralization during IntraLase application may flatten and shift the pupil center, and thus cause decentralization of the LASIK flap and INTACS. Central corneal thickness in the LASIK group and preoperative sphere and cylinder in the INTACS group proved to be statistically significant parameters associated with decentration. [J Refract Surg. 2008;24:797-801.]

Corneal surgical procedures require proper alignment on the cornea because even small decentrations from predetermined central reference points will introduce new types of optical aberrations.1-4 However, alignment of a measurement device is not a simple task because there are no direct target points on the transparent cornea.5 The femtosecond laser (IntraLase; IntraLase Corp, Irvine, Calif) creates a corneal resection by delivering laser pulses at a predetermined depth in the cornea. These pulses create microphotodisruption or expanding gas bubble and result in a plane of separation and planar flap.6 The femtosecond laser allows the flap and INTACS (Addition Technology, Des Plaines, Ill) channel diameter and depth to be manipulated. The pupil location is an important factor in determining effective optics.2-4

Although microkeratomes produce high-quality cutting, there are a variety of reasons for poor corneal flap creation using this method, including excessively steep or flat corneas, inadequate patient cooperation, deep-set eyes, prominent brows, and narrow palpebral fissures.7 Potential for development of new approaches in corneal refractive surgery exist due to the flexibility of the femtosecond laser delivery system. In addition to flap creation for LASIK, this laser has also been used to create corneal tunnels for the insertion of INTACS intracorneal ring segments.8 The creation of the intrastromal corneal tunnels with the IntraLase for INTACS insertion has become a prime topic.

We observed significant decentration of INTACS previously.9 The present study sought to determine pertinent factors influencing accuracy of centralization with the IntraLase femtosecond laser.

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PATIENTS AND METHODS
This is a retrospective comparative case series involving 133 eyes of 128 patients. The cases were divided into two groups according to surgical procedure, LASIK or INTACS implantation.

LASIK GROUP
This group comprised 74 normal eyes of 72 patients (30 men and 42 women; mean age: 33.6±8.7 years) who underwent LASIK with the IntraLase femtosecond laser between July and September 2006 at Kudret Eye Hospital.

Standard IntraLase flap thickness was set at 110 µm, flap-edge angle was set at 60°, and hinge size was 50° of arc. Laser energy of 1.90 µJ and side-cut energy of 1.00 µJ was applied at the bed and sides, respectively. Corneal thickness of at least 300 µm after ablation was planned in all eyes.

A disposable vacuum instrument was used to prevent movement of the eye and minimize any excessive decentration. The disposable glass lens was used to applanate the cornea and ideal centralization was performed using the specific device marker to indicate the center of the flap in the IntraLase monitor. Following flap creation using the IntraLase, the flap was reflected and the laser was applied.

One-month postoperative results were evaluated using the cross-sections of the horizontal meridians in the Scheimpflug photographs of the anterior segment taken by the Pentacam anterior segment analyzer (Oculus Optikgeräte GmbH, Wetzlar, Germany).

In the horizontal Scheimpflug photographs of the anterior segment taken by Pentacam, the pupil edge was considered the reference point in each image. Two vertical lines (nasal and temporal) were drawn from the pupil edges perpendicular to the cornea. The distance between the flap edges and these lines was measured and compared to calculate decentration on each side in each image. All measurements taken using the Pentacam were completed in standard illumination. The pupil center was not used as a reference point, because calculation according to the pupil edge is easier and more accurate (Fig 1).9

INTACS GROUP
This group comprised 59 eyes of 39 keratoconic patients (18 men and 21 women; mean age: 27.04±8.14 years) examined and operated at Kudret Eye Hospital between April 2005 and June 2006. Patients were examined pre- and postoperatively with the Pentacam.

In eyes with an inferior cone, a 0.45-mm INTACS insert was placed inferiorly to lift the conus, and a 0.25-mm INTACS insert was placed superiorly to flatten the cornea and decrease baseline keratoconic asymmetric astigmatism.

INTACS were inserted to 70% depth of cornea. Peripheral pachymetry was performed in all cases to ensure sufficient corneal thickness and placement of INTACS to the appropriate depth. No eyes in this study required more than 400-µm depth of implantation. The corneal thickness at the insertion sites ranged between 422 and 536 µm. A disposable vacuum instrument was inserted to prevent movement of the eye and minimize any excessive decentration. The disposable glass lens was used to applanate the cornea and ideal centralization was performed according to pupil edge using the IntraLase monitor (see Fig 1). The pulse duration was 600 fs with the inner to outer diameter of the INTACS tunnel set from 6.7 to 8.2 mm. Spot size was set to 1 µm and the energy was set at 6 µJ. The creation of the intrastromal tunnel with the IntraLase laser was completed within 15 seconds with no manipulation of the cornea. After reopening the original insertion with Sinskey hooks, INTACS segments were implanted inferiorly and superiorly.

One-month postoperative results were evaluated using the cross-sections of the horizontal and vertical meridians in the Scheimpflug photographs of the an-
terior segment taken by Pentacam (Fig 2) under equal illumination for all eyes. The pupil edge was considered the reference point in each image. Two vertical lines were drawn from the pupil edges perpendicular to the cornea. The distance between the inner edges of the INTACS segments and the two vertical lines was measured on each side in each image.

**RESULTS**

The preoperative corneal parameters are presented in Table 1. All parameters were statistically significantly different between the two groups.

The IntraLase monitor provided the best centralization for the LASIK procedure. All data were analyzed according to Pentacam measurements. Decentration was towards the temporal quadrant horizontally in all eyes. Mean amount of decentration temporally from the pupil edge was 612.56±384.24 µm (range: 30 to 2120 µm).

The IntraLase monitor also provided the best centralization for INTACS. All data were analyzed according to the meridians shown in the Pentacam. The direction of decentration was determined for each eye. Mean decentration was 788.33±500.34 µm (range: 30 to 2450 µm). The amount of temporal decentration in both groups is shown in Table 2 and Figure 3.

**STATISTICAL ANALYSIS**

Independent samples t test was performed to compare the amount of decentration between the groups. A significant difference was noted between the groups regarding decentration (P<.05).

Stepwise logistic regression analysis was performed for the determination of parameters that affect the amount of decentration for each group. The entrance and exit criteria were set at P=.05 for the stepwise logistic regression.

The significant parameters selected as dependent variables were central corneal thickness in the LASIK group and preoperative sphere and cylinder in the INTACS group. In the regression analysis, these parameters were found to be related to the decentration but the R² values in these analyses was small (10% [−2842.808 + (6.415 × pachymetry)] for the LASIK group and 27% [1478.246 − (112.536 × sphere) − (45.140 × cylinder)] for the INTACS group). This indicates that these variables are not the sole determinants of the difference in decentration.

**DISCUSSION**

In a previous study, we found clinically significant decentration occurred in eyes with keratoconus after INTACS implantation. In the same study, decentra-
tion of INTACS segments was reported to be the result of dilated pupil and corneal flattening during application. The pupil shifted towards the nasal quadrant during natural constriction and our results were consistent with the previous reports in this respect.10-12

In the present study, we observed a significant difference in decentration after INTACS implantation as opposed to LASIK, despite use of the same device and the same surgeon (A.E.). The pupil edge was used as a landmark to define the centration of the LASIK flap and INTACS; the corneal apex or limbus were not acceptable for analysis of centration. Change in pupil size was one factor that accounted for the decentration after LASIK and INTACS with the IntraLase laser; however, this was not statistically significant between the groups. Other parameters were assessed such as mean keratometry value, central corneal thickness, anterior chamber depth, and sphere and cylinder, which could potentially cause decentration. The pupil size changed, and the cornea flattened during the application process. This fact led us to analyze the effects of corneal parameters on corneal flattening in normal and keratoconic eyes.

Traditional mechanical technique for tunnel creation has some complications including epithelial defects at the keratotomy site; anterior and posterior perforations while creating the channel; extension of the incision toward the central visual axis or toward the limbus; shallow, asymmetric, and/or uneven placement of the INTACS segments; decentration; infectious keratitis with the introduction of epithelial cells into the channel during channel dissection; persistent incisional gaping; stromal thinning; and corneal stromal edema around the incision and channel from surgical manipulation.13-16

The suction ring was inserted using the limbus as the reference point before the centralization process of the IntraLase laser, and asymmetric and relatively thin keratoconic cornea was flattened by use of a glass lens. When the application is complete, the pupil slightly dilates. Pupil dilation may be the result of compression applied by the suction ring or flattening of the cornea with the glass application lens. Pupil dilation was observed during the centralization process and during flattening of the asymmetric cornea in keratoconic eyes. The cornea and pupil returned to their natural positions after the application was released and thus the geometric center of cornea shifted.

The following axes are defined in the eye: optical axis, line of sight, visual axis, pupillary axis, and corneal reflex. Definitions of axes are based on characteristic values of the eye, such as the corneal center of curvature and the position of the fovea. The exact orientation of each axis and the location of its corneal intercept depend on a number of variables such as corneal refractive power, lens power, anterior chamber depth, and axial length. Unlike most optical devices, the human eye is not a centered optical system and does not contain a true optical axis because the cornea and lens are slightly decentered and tilted relative to each other.5 The location of INTACS and flap edges is determined while the cornea is flat during application, so these loci change considerably in both keratoconic and normal eyes when the cornea returns to its normal curvature. This change was more prominent in eyes with keratoconus.

Corneal parameters were found to be related to the decentration, but the R2 values of these analyses were small (R2: 10% LASIK group; R2: 27% INTACS group), which indicates that these variables are not the sole determinants of the difference in decentration.

Surgeon- and patient-related factors may also influence decentration. Patient head position should be adjusted before application, as incorrect head position results in inappropriate placement of the suction ring and application. The application point should not be in the paracentral area of the cornea. If application is paracentral, the glass lens should not be moved on the cornea using the joystick otherwise the friction be-

<p>| TABLE 2 |
| Amount of Temporal Decentration in the LASIK and INTACS Groups |</p>
<table>
<thead>
<tr>
<th>Decentration (µm)</th>
<th>LASIK Group (n=74)</th>
<th>INTACS Group (n=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 500</td>
<td>32 (43.24)</td>
<td>19 (32.1)</td>
</tr>
<tr>
<td>501 to 1000</td>
<td>31 (41.89)</td>
<td>21 (35.6)</td>
</tr>
<tr>
<td>1001 to 2000</td>
<td>10 (13.51)</td>
<td>16 (27.11)</td>
</tr>
<tr>
<td>&gt;2001</td>
<td>1 (1.3)</td>
<td>3 (5.1)</td>
</tr>
</tbody>
</table>

Figure 3. Comparison of temporal decentration in the INTACS and LASIK flap groups.
between the flattened cornea and the glass lens will cause decentralization. If paracentral applanation is suspected, applanation should be repeated and excessive use of the joystick should be avoided. Pressure of 30 to 35 mmHg created by the suction ring may also be another factor causing decentration. As shown in Figure 4, the superior sclera can not be seen on the monitor clearly. This results from inappropriate centration. Although the IntraLase monitor seems to show central localization of the pupil, applanation has tilted the cornea and thus has caused misalignment of the cornea and pupil. The glass lens should be applanated as close to the center as possible and should not be manipulated excessively. In addition, miotic agents can be used for proper centralization; the pupil center can be marked with a pen before applanation. Tight eyelids and inappropriate head positions should also be considered.

This study shows that decentration of the LASIK flap or INTACS implantation with the IntraLase femtosecond laser may result from pupil size as well as corneal parameters and surgeon- and patient-related factors. Other means of determining the pupil center accurately should be sought, especially in eyes with keratoconus.

REFERENCES