Laser in situ Keratomileusis for Hyperopia and Hyperopic and Mixed Astigmatism With LADARVision Using 7 to 10-mm Ablation Diameters

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ABSTRACT

PURPOSE: To evaluate the results of laser in situ keratomileusis (LASIK) performed to correct hyperopia, and hyperopic and mixed astigmatism using wider ablation diameters (optical zone diameter and overall ablation diameter) than those commonly used with the same and other lasers.

METHODS: After flap creation using an Alcon SKBM microkeratome set for a 10-mm flap diameter, 53 eyes (33 patients) with a mean spheroequivalent attempted correction of +2.34 ± 2.09 D underwent LASIK (Alcon LADARVision 4000) using a 7-mm optical zone diameter and a 3-mm transition zone for an overall 10-mm total ablation diameter. The nasal hinge was prevented from undesired ablation by the use of proprietary hinge protector software. Eyes were followed for 6 months after surgery.

RESULTS: Six months after surgery, mean spherical equivalent refractive error was -0.22 ± 0.41 D. There were 79.2% of eyes within ±0.50 D, and 98.1% within ±1.00 D of intended correction. Uncorrected visual acuity of 20/20 or better was achieved by 28 eyes (53%) and 20/40 or better by 50 eyes (94.3%). No meaningful visual complaints during nighttime hours, such as haloes or glare, were subjectively reported by patients.

treated between April and December 2001. Mean patient age was 40 ± 10 years (range 20 to 58 yr). Inclusion criteria were spherical refractive error in the range +0.50 to +6.00 D with or without cylinder refractive error (expressed in minus value) in the range 0 to -6.00 D, for a defocus equivalent attempted correction of 1.50 D or more. Exclusion criteria were systemic or ocular diseases potentially interfering with the healing process of the cornea (collagenopathies, diabetes, dry eye syndrome, anterior or posterior uveitis, etc), keratoconus and other ectatic diseases (detected by videokeratography), corneal dystrophy or degeneration (anterior basement membrane dystrophy included), glaucoma, retinal disease, lens opacity, history of severe ocular trauma, or previous ocular surgery. Eyes with 20/25 or better uncorrected visual acuity (UCVA) were not included, nor were eyes with best spectacle-corrected visual acuity (BSCVA) worse than 20/50. Eyes with corneal curvature of 38.00 D or less and 48.00 D or more were also excluded.

Before and after surgery, a detailed ophthalmic examination was performed that included manifest and cycloplegic refraction (cycloplegic refraction only was considered for data analysis), slit-lamp microscopy, tonometry, and corneal topography assessment. UCVA and BSCVA were tested at 4 meters distance using the ETDRS visual acuity charts (The Lighthouse, New York, NY). Corneal topography was assessed using a Keratron (Optikon 2000, Rome, Italy). Pupillary diameter was assessed using the Procyon P2000 infrared pupillometer (London, England) at three luminance levels (scotopic 0.04 lux, mesopic low 0.4 lux, mesopic high 4 lux). Eyes with scotopic pupillary diameter greater than 6.5 mm were excluded from treatment. Follow-up examinations were planned at 1 day after surgery and then at 2 weeks, 1, 3, and 6 months. Patients presenting with immediate complications on the first postoperative day, such as epithelial damage or epithelial loss due to microkeratome pass, diffuse lamellar keratitis (DLK) etc., were examined daily until complete resolution. Patients presenting with late complications such as epithelial ingrowth, significant striae or folds, etc., were managed as required.

**LASIK**

LASIK was performed by two surgeons (FC and LV). The SKBM Microkeratome (Alcon Laboratories, Forth Worth, TX) was used with the hyperopic, 160-µm-gap head and either a 20 or 21.3 suction ring. The ring was chosen according to eye anatomy in order to obtain the widest flap dimension. The hinge was positioned on the nasal side and its length was intended to be 0.3 mm. To ensure a residual stromal thickness of at least 250 µm after ablation, corneal thickness was measured by ultrasound pachymetry immediately before the lamellar cut, and immediately after the flap lift (before ablation). Subtraction of these two measurements was used to assess flap thickness. The LADARVision 4000 excimer laser (Alcon Laboratories, Forth Worth, TX) was used to perform the ablation, and for all eyes the optical zone diameter (central spherical part) was 7.0 mm, with a 3.0-mm-diameter transition zone for an overall ablation diameter of 10.0 mm. To avoid undesired ablation of the hinge due to the large overall ablation diameter, immediately before laser treatment the extension of the ablation on the cornea was evaluated at the laser computer monitor using specific software. In all eyes where the hinge was exposed to ablation, we masked the hinge using protector software, which disables the laser from firing on the masked area (Fig 1). Eyes that had undesired ablation of the lamellar cut edge and surrounding epithelium due to an obtained flap smaller than 10.0 mm were recorded to track undesired side effects and complications. In all eyes, ablation was assisted by active eye-tracking.

After surgery the eyes received antibiotic-corticosteroid eyedrops (tobramycin sodium and dexamethasone sodium) four times daily for the first postoperative week. Lubricant artificial tears...
(sodium hyaluronate) were also prescribed for a longer period (1 month). Patients with dry eye symptoms were instructed to use artificial tears for a prolonged time, and more severe cases also received silicone punctal plugs.

**RESULTS**

All LASIK procedures were uneventful, with no severe intraoperative complications. The hinge protector software was used for all laser treatments. Five eyes (9.4%) had some intraoperative epithelial damage following the microkeratome pass, which resolved within 3 days. No eyes had either DLK or other immediate postoperative complications on the first postoperative day. During the 6-month follow-up period, eight eyes (15.1%) showed some amount of epithelial ingrowth that was confined to the peripheral part of the flap in five eyes (9.4%), and three eyes (5.7%) required flap lifting and scraping of the interface for central progression. No other flap or interface complications such as striae or folds were reported. Corneal topography showed well-centered ablations over the center of the pupillary entrance (target of centration), or with a negligible error (less than 0.5 mm).

Before surgery, mean spherical equivalent refractive error was +2.34 ± 2.09 D (range -1.75 to +6.00 D), mean sphere was +3.51 ± 1.76 D (range +0.50 to +6.00 D), mean cylinder was -2.34 ± 1.77 D (range 0 to -6.00 D), and mean defocus equivalent was 4.68 ± 1.84 D (range 1.50 to 8.75 D). There were 44 eyes with a spheroequivalent refractive error in the plus range (+0.125 to +6.00 D), 2 eyes with mixed astigmatism had a spheroequivalent refractive error of 0 D, and the remaining 7 eyes were in the minus range (-0.25 to -1.75 D). For all 53 eyes included in this analysis the goal of the treatment was plano refraction. Four eyes (7.5%) were treated for the correction of spherical hyperopia. The other 49 eyes had either simple hyperopic astigmatism (2 eyes, 3.8%), mixed astigmatism (18 eyes, 34%), or compound hyperopic astigmatism (29 eyes, 54.7%).

Before surgery, 10 eyes (18.9%) had at least 20/40 UCVA, and 30 eyes (56.6%) had 20/100 or better UCVA. Thirty-eight eyes (71.7%) had preoperative 20/20 or better BSCVA, and 52 eyes (98.1%) had 20/40 or better BSCVA.

Figure 2 shows refractive outcome over time. There was an early overcorrection that slightly decreased over the 6-month follow-up period. Six months after surgery, mean spherical equivalent refraction was -0.22 ± 0.41 D (range -1.75 to +0.75 D), mean sphere was +0.01 ± 0.47 D (range -1.50 to +1.00 D), mean cylinder was -0.47 ± 0.44 D (0 to -1.50 D), and mean defocus equivalent was 0.42 ± 0.38 D (range 0 to 1.75 D). Figure 3 shows the attempted vs. achieved correction (spheroequivalent) and Figure 4 presents the stratified cycloplegic spherical equivalent refractive outcome. There were 42 eyes (79%) within ±0.50 D of intended correction and 52 eyes (98%) within ±1.00 D of intended correction. To give a better idea of the real difference between the attempted and the achieved correction, regardless of plus or minus signs, which may mask some residual difference, the scattergram in Figure 5 presents the defocus equivalent refractive error.

For the 49 eyes that received an astigmatic correction, the Table provides statistical results of vector analysis of refractive astigmatism. Figure 6 presents the double angle scatterplot of the difference between surgically induced astigmatism (SIA) and target induced astigmatism (TIA). All astigmatism...
vector analyses were carried out according to the Alpins’ method.\textsuperscript{12}

Uncorrected visual acuity results at 6 months after LASIK are presented in Figure 7. All eyes had 20/63 or better, and 52.8% had 20/20 or better uncorrected visual acuity.

Figure 8 presents BSCVA changes from preoperative to 6-month follow-up. There were no eyes with
BSCVA loss greater than one line, 2 eyes (4%) lost one line (both eyes were 20/16 before LASIK and 20/20 at 6 months), 15 eyes (28%) gained one line, and 3 eyes (6%) gained two lines. All 33 remaining eyes (62%) were unchanged.

**DISCUSSION**

The correction of hyperopic and mixed refractive errors (hyperopia, simple or compound hyperopic astigmatism, and mixed astigmatism) either by PRK or LASIK has proven to be more challenging than that of simple or compound myopic refractive errors. There are reports of treatments performed using 6.0 mm or smaller optical zone diameters, but to the best of our knowledge there are no peer-reviewed publications that present results of treatments performed with optical zone diameters greater than 6.0 mm. The use of larger optical and overall ablation zone diameters may lead to better outcomes, as the comparison between the results we obtained in this study and those of previously published ones seem to indicate.

The eyes we treated showed early refractive stability with a cycloplegic spherical equivalent refraction change of less than 0.20 D (average value) in the period between 15 days and 6 months after surgery (Fig 2), when 79% were within ±0.50 D and 98% were within ±1.00 D of intended correction. These percentages compare favorably to those from other studies for similar ranges of correction. Salz and colleagues, using the same laser for a similar group of eyes but with smaller optical zone diameters (6.0 mm) and smaller overall ablation diameters (9.0 mm), had 60.5% to 65% of eyes within ±0.50 D and 87.4% to 88.7% of eyes within ±1.00 D; Rashad, using the Keracor 117C laser with a 6.0-mm optical zone diameter and 9.0-mm overall ablation diameter reported 61.2% of eyes within ±0.50 D and 89.4% of eyes within ±1.00 D; Lindstrom and colleagues, using the VISX Star 2 laser with a 6.0-mm optical zone diameter reported 63% of eyes within ±1.00 D; Pineda-Fernandez and colleagues, using the Nidek EC-5000 laser with a 5.5-mm optical zone diameter and 7.5-mm overall ablation diameter reported approximately 50% of eyes within ±0.50 D and 70% within ±1.00 D.

The excellent refractive results we obtained in terms of cycloplegic spherical equivalent refraction were also confirmed by the defocus equivalent results. Although not routinely used for analysis of postoperative refractive data, this parameter gives a better understanding of the accuracy of a procedure for correcting the entire refractive error. The individual data scatterplot in Figure 5 shows the magnitude of residual defocus equivalent error for all eyes but two (51 eyes, 96%) within ±1.00 D and 34 eyes (64%) within ±0.50 D of intended correction.

The vector analysis of cylinder showed overall satisfactory results with a relatively good index of success. The analysis of surgically induced astigmatism and target induced astigmatism disclosed the presence of some systematic induced cylinder (Fig 6), with a constant trend toward the 90° axis. This may be related to the position of the hinge (always nasal) or it may be due to the hinge protection software. However, in a previous study performed on eyes after PRK using a different laser, we reported the same trend of cylinder induction toward the 90° axis, which was obviously unrelated to flap creation or the use of hinge protection software. Thus, we believe that the explanation for this phenomenon may be related to modification of biomechanical properties of the cornea after surgery. A possible reason for the induced astigmatism could be given by the weakening of the corneal wall subsequent to the ablation, reducing the corneal rigidity against deformations. The constant trend toward the 90° axis could be exerted by eyelid pressure with daily blinking over a weakened corneal cap.

As with the refractive results, the visual outcomes we report look more satisfactory than those of previous studies. At 6 months we had 28 eyes (53%) with 20/20 or better UCVA and 50 eyes (94%) with 20/40 or better UCVA. These numbers look even better if we consider that before surgery only 38 eyes (72% of the total group) could see 20/20 or better with their best prescription spectacles. This means that of the 38 eyes potentially able to see 20/20 uncorrected after surgery, 28 (74%) actually reached
this target. Salz\textsuperscript{13}, using the same laser with smaller ablation diameters, reported percentages of eyes with 20/20 or better UCVA ranging between 43.2% and 49.6% for the eyes with preoperative BSCVA of 20/20 or better, and ranging between 37.3% and 48.8% for the whole group. Rashad\textsuperscript{14} reported 24.7% and 92.9% of eyes with UCVA of 20/20 and 20/40, respectively. Lindstrom\textsuperscript{15} reported 79% of eyes with 20/40 or better UCVA. Pineda-Fernandez\textsuperscript{16} reported 44.4% to 80% of eyes with UCVA of 20/40 or better, and 0% to 14% of eyes with 20/20 or better, depending on the correction delivered (low to medium hyperopia, with or without astigmatism).

Improvements in BSCVA were favorable, with no loss greater than 1 Snellen line at 6 months after surgery and two eyes (4%) with a 1-line loss. Salz\textsuperscript{13} reported 4.1% of eyes with a loss of 2 Snellen lines, Rashad\textsuperscript{14} reported 1.2% or eyes with a 2-line loss and 10.6% with a 1-line loss, Pineda-Fernandez\textsuperscript{16} described 5% of eyes with a 2-line loss and 10% to 30% of eyes with a 1-line loss. Compared to other studies, the lower rate of BSCVA line loss we report may not be related to the larger ablation diameter we used. Other surgical factors may produce a loss of BSCVA, such as intraoperative and postoperative complications, abnormal healing response, etc. However, Davidorf and colleagues also reported a higher incidence of BSCVA loss after LASIK for hyperopia when using smaller ablation diameters.\textsuperscript{17}

From our data analyses, the advantages of hyperopic and astigmatic or mixed-astigmatism ablations performed with larger diameters than those commonly used include faster refractive stability with less early overcorrection, better predictability, and more positive visual outcomes. Even though there was no standardized questionnaire, patients did not appear to report problems with their night vision, probably because the optical treatment diameter was at least 0.5 mm larger than the scotopic pupil size in all eyes. Also, the overall quality of vision was reported to be very satisfactory, with no complaints. We believe that on the basis of such high-quality visual results the dimension and the regularity of the induced steepening of the cornea play an important role. In fact, the postoperative corneal topography of most of the treated eyes showed not only the wide central steepening, but also a smooth and regular surface (Fig 9).

We did not encounter any significant drawbacks in attempting such large overall ablation diameters. To fit the entire 10.0-mm overall ablation diameter we had to create large flaps. We set the SKBM microkeratome using the combination of heads and suction rings to produce the largest flap possible for every eye. The flap dimensions we achieved were within 9.3 mm and 10.8 mm, which led to more frequent bleeding during surgery. To avoid any invasion of blood toward the stroma during ablation, we systematically used circular merocel sponges to absorb the blood, with no complications. Another issue with the use of large ablation diameters is related to the possible ablation of the hinge and the peripheral gutter and epithelium surrounding the flap cut, in those eyes where the flap was smaller than the overall ablation diameter. The software hinge protector we used in all treatments was effective in avoiding undesired ablation of the hinge and flap stroma. Indeed, in most of the postoperative topographic maps a small and well-defined linear steepening at the hinge region was visible (where...
laser ablation was masked) (Fig 9). However, this steepening was always very peripheral. Regarding the gutter and the epithelium, we realized that in eyes where the flap was smaller than the ablation diameter, we had some undesired ablation. It has been postulated that epithelial ingrowth may be more common in these eyes. Even though this study reported a relatively high rate of epithelial ingrowth (15%), eyes that received undesired ablation of the epithelium did not show higher incidence of ingrowth. Alternatively, the cause for this high rate may be related to the relatively large flaps that were attempted, or the relatively high rate of epithelial micro defects, which again were probably related to the large flaps.

Although the estimated ablation depth was quite deep for the higher corrections (the thickest ablation was 130 µm for a +6.00-D correction; cylinder corrections delivered in a cross-cylinder fashion to spare ablated tissue), limited preoperative corneal thickness was never a restriction in this series of eyes because the thicker ablation point was never central (as it is for correction of myopia), but instead in the mid-periphery where the cornea is naturally thicker. Thus, we were able to maintain a residual stromal thickness of at least 250 µm in all eyes.

The use of ablation diameters implies greater tissue removal and consequently longer ablation times. Using the LADARVision laser with a 7.0-mm optical zone for an overall ablation diameter of 10.0 mm, a +6.00-D correction takes more than 3 minutes to complete. This longer duration may result in changes in stromal hydration and more frequent eye movements during ablation. However, the results of this study indicate that the hypothetical changes in stromal hydration during ablation (if any) did not negatively influence clinical outcomes. Likewise, eye movements during such long ablation times did not result in any complications such as irregular ablation bed, decentration of the treatment, etc., probably thanks to the fast and effective eye-tracking device of this laser.

The results of this study point out that correction of hyperopia and hyperopic and mixed astigmatism with the LADARVision excimer laser using larger ablation diameters (optical zone and overall diameter) than those previously used with the same and with other lasers leads to higher predictability and efficacy with better visual performance, without any apparent additional safety concern.

REFERENCES