

# Hyperopic Laser in situ Keratomileusis With 5.5-, 6.5-, and 7.0-mm Optical Zones

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## ABSTRACT

**PURPOSE:** To evaluate the results of laser in situ keratomileusis (LASIK) for the correction of hyperopia and hyperopic astigmatism using a large 7.0-mm optical zone and to compare them with treatments using a 5.5- and 6.5-mm optical zone.

**METHODS:** One hundred sixty-one eyes of 89 patients with a mean preoperative spherical equivalent refraction of  $+2.44 \pm 1.32$  diopters (D) (range:  $+0.00$  to  $+5.62$  D, cylinder 5.25 to 0.00 D) were treated for hyperopia and hyperopic astigmatism using a 7.0-mm optical zone and were analyzed retrospectively. Postoperatively, patients were examined after 1 day, 1 week, 1 month, 3 months, and 1 year. Eyes treated previously at the same center by the same surgeons with 5.5- and 6.5-mm optical zone applications were used as controls. All treatments were performed with the Nidek EC 5000 CXII excimer laser system (Nidek, Gamagori, Japan). A nasal hinged flap was created using the Nidek MK 2000 microkeratome in all cases.

**RESULTS:** The mean postoperative spherical equivalent refraction after 1 month ( $n=89$ ) was  $+0.12 \pm 0.72$  D (range:  $-1.75$  to  $+2.75$  D),  $+0.13 \pm 0.74$  D (range:  $-1.88$  to  $+1.62$  D) at 3 months ( $n=70$ ), and  $+0.20 \pm 0.69$  D (range:  $-1.62$  to  $+1.12$  D) at 1 year ( $n=33$ ). Regression between 1 month and 1 year was 0.08 D in the 7.0-mm optical zone group. Regression was 0.25 D in the 5.5-mm group and 0.02 D in the 6.5-mm optical zone group between 1 month and 1 year. In both the 5.5- and 6.5-mm optical zone groups, 13% of eyes lost one line in visual acuity (2% in the 7.0-mm optical zone group). The gain of one or more lines in visual acuity was 19% in the 5.5-mm group, 17% in the 6.5-mm group, and 27% in the 7.0-mm optical zone group. All data represent primary cases without retreatment.

**CONCLUSIONS:** Increasing the optical zone size from 5.5 mm to 6.5 mm and to 7.0 mm seems to improve refractive results, stability, and safety of hyperopic and hyperopic-astigmatic LASIK treatments. Although some hyperopic and astigmatic eyes are endangered by loss of lines in best spectacle-corrected visual acuity, more eyes gain one or more lines. [*J Refract Surg*. 2005;21:52-58.]

Until recently, results of hyperopic laser in situ keratomileusis (LASIK) have not reached the quality or level of myopic treatments. One reason for this may be the more complex shape of the ablation profile that is needed to achieve the necessary corneal steepening. Hyperopic ablation profiles usually consist of a central optical zone surrounded by a peripheral transition zone (Fig 1). The relation between optical zone and transition zone within the total ablation area varies between different manufacturers and has changed during recent years of development.<sup>1-4</sup> Rosa and Febraro<sup>5</sup> were not satisfied with the results of 5.0/7.5 mm optical zone/transition zone hyperopia treatments and found an improvement when using a 5.5/9.0 mm optical zone/transition zone as did Argento and Cosentino<sup>6</sup> when going from smaller optical zones to 5.9 mm. Ibrahim,<sup>7</sup> who used a 5.5/7.5 combination of optical zone/transition zone, stated that the ablation profile still needed to be improved. Better results were reported when using 6.0/9.0 mm and 6.5/9.4 mm optical zone/transition zone combinations.<sup>8,9</sup>

The concept of "bigger is better" and further increasing the treatment zones may be the way to go; however, the maximal available ablation diameter is either limited by the laser hardware, especially in broad beam type lasers, or by the actual flap diameter when performing LASIK. Thus the optimal size and shape of the transition zone has yet to be determined. In this study, we compared the outcomes of hyperopic LASIK of three different ablation profiles performed by the same surgeons using the same laser.

## PATIENTS AND METHODS

In this retrospective study, we analyzed the results of our latest series of 7.0-mm optical zone hyperopia treatments.

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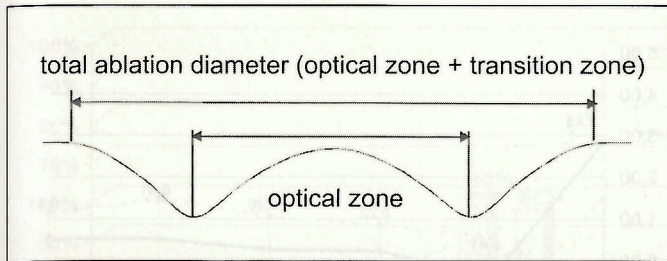
*The authors have no proprietary interest in the materials presented herein.*

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**Figure 1.** Hyperopic ablation profile cross-section. Central optical zone surrounded by peripheral transient zone.

One hundred sixty-one eyes of 89 patients with a mean refractive error (spherical equivalent refraction) of  $+2.44 \pm 1.32$  diopter (D) (range:  $+0.00$  to  $+5.62$  D) were treated with LASIK. The preoperative cylinder ranged from  $0.00$  to  $-5.25$  D with a mean value of  $-1.12 \pm 0.96$  D. Average patient age was 43 years (range: 19 to 63 years). There were slightly more right eyes, with 55.3% right versus 44.7% left eyes, and 50.3% women versus 49.7% men.

Patients were examined preoperatively, on day 1, 1 week, and 1, 3, and 12 months after surgery. Preoperative examinations included mesopic pupil size measurement, tear film testings, manifest and cycloplegic refraction, analysis of the eye's fixation landmarks with regard to the eye's visual axis and a possible offset from the center of the entrance pupil as visible through the operating microscope (defined as line of sight),<sup>10</sup> corneal topography, corneal pachymetry, and optical path difference measurement. Statistical analysis was performed with Datagraph-Med outcomes analysis software version 2.9 (Pieger GmbH, Wendelstein, Germany).

In most cases, manifest refraction (best spectacle-corrected visual acuity) was taken for the laser setting. In cases with significant differences between manifest and cycloplegic refraction ( $>+1.00$  D), half of the value of the difference was added to the manifest refraction.

We used a Nidek EC 5000 CX excimer laser (Nidek, Gamagori, Japan) with software version 1.24 and video-based active eye tracking. This system uses a rotating slit scanning technique capable of creating up to 7.0-mm diameter optical zones surrounded by a 2.0- to 2.5-mm wide transition zone.

Laser in situ keratomileusis was performed with the Nidek MK 2000 microkeratome using either an 8.5- or 9.5-mm diameter suction ring and a 130- or 160- $\mu$ m head, depending on actual preoperative pachymetry, the corneal radii, and available clear corneal diameter.

Most of the procedures were bilateral LASIK performed under the same sterile conditions as used in cataract surgery. Eyelashes were taped and a suction speculum was inserted during the wet-technique procedure.

Centration target was set on the center of the entrance pupil as visible through the laser's operating microscope (line of sight). In patients with significant eccentricity of their visual axis ( $>0.5$  mm off the line of sight), the eye tracker target was placed halfway between the visual axis and the line of sight.

Immediately postoperatively, all patients were asked to keep their eyes closed for at least 6 hours. Patients received dexamethasone 0.1% and gentamycin 0.3% (IsoptoMax; Alcon, Freiburg, Germany) eyedrops 3 times a day for 1 week, a bandage contact lens was applied when necessary. From postoperative day 1, different artificial tears were advised according to the subjective need of the patient. Most patients needed 3 to 5 drops per day for up to 12 weeks, some patients used the artificial tear drops hourly for up to 4 weeks.

These results were compared with our own results previously achieved with the same laser using a 5.5- and 6.5-mm optical zone. The 5.5-mm optical zone comparison group consisted of 132 eyes with a mean preoperative spherical equivalent refraction of  $+2.85 \pm 1.44$  D (range:  $+0.50$  to  $+8.63$  D, cylinder  $-5.75$  to  $0.00$  D). The 6.5-mm optical zone group had 130 eyes with a mean preoperative spherical equivalent refraction of  $+2.83 \pm 1.25$  D (range:  $+0.50$  to  $+6.0$  D, cylinder  $-4.75$  to  $0.00$  D). Age, gender, and left and right eye distribution were comparable. The inclusion criteria were identical for all three groups and based on the recommendations of the Commission for Refractive Surgery of the German Professional Association of Ophthalmologists for legal indications for LASIK.

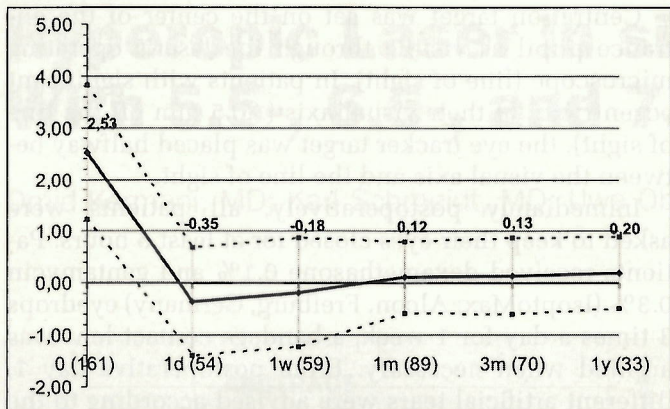
## RESULTS

One month postoperatively, 89 eyes (follow-up rate 55.3%) with a mean postoperative spherical equivalent refraction of  $+0.12 \pm 0.72$  D (range:  $-1.75$  to  $+2.75$  D) were examined in the 7.0-mm optical zone group. The mean postoperative cylinder was  $-0.56 \pm 0.61$  D (range:  $-4.50$  to  $0.00$  D). After 3 months, we examined 70 (43.5%) eyes and the mean spherical equivalent refraction was  $+0.13 \pm 0.74$  D (range:  $-1.88$  to  $1.62$  D). The mean cylinder at 3 months decreased to  $-0.52 \pm 0.52$  D (range:  $-2.50$  to  $0.00$  D).

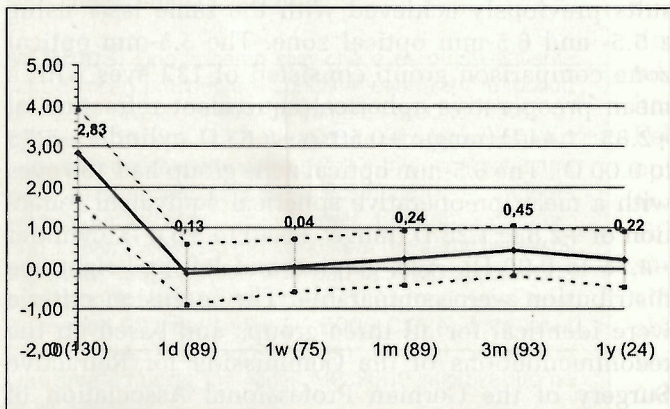
The mean spherical equivalent refraction for 33 (20.5%) eyes at 1 year was  $+0.20 \pm 0.75$  D (range:  $-1.62$  to  $+1.12$  D). The mean cylinder stayed constant at  $-0.52 \pm 0.42$  D (range:  $-1.50$  to  $0.00$  D). All data represent primary cases without retreatment (Fig 2).

Regression between day 1 and 3 months was 0.47 D and remained stable between 1 month and 3 months (0.01 D) postoperatively. Regression between 1 month and 1 year was 0.08 D. In the 5.5- and 6.5-mm optical zone groups, regression was 0.92 and 0.58 D (Figs 3





**Figure 2.** Stability. Spherical equivalent refraction over time, 7.0-mm optical zone group. Regression between day 1 and 3 months postoperatively: +0.49 D. (Number of eyes examined at each postoperative time point are shown in parentheses.)



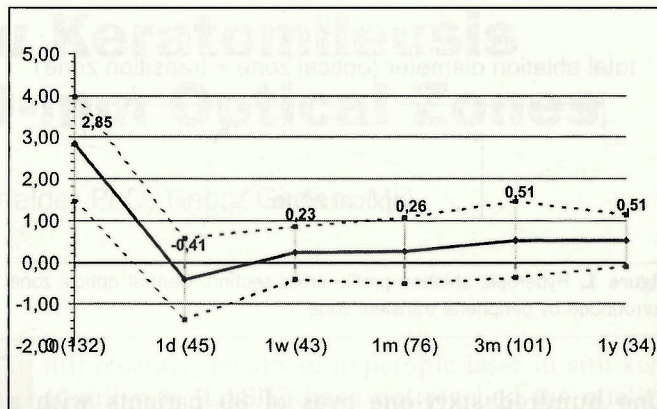
**Figure 4.** Stability. Spherical equivalent refraction over time, 6.5-mm optical zone group. Regression between day 1 and 3 months postoperatively: +0.58 D. (Number of eyes examined at each postoperative time point are shown in parentheses.)

and 4) from day 1 to 3 months, respectively, and 0.25 and 0.02 D from 1 month to 1 year, respectively.

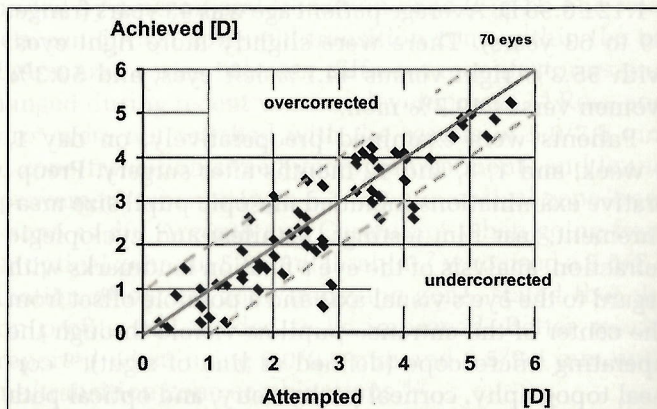
The attempted versus achieved scatter plot for predictability in the 7.0-mm optical zone group at 3 months postoperatively is depicted in Figure 5.

Of eyes treated with 7.0-mm optical zone, 60% were within  $\pm 0.50$  D 3 months after surgery and 85% within  $\pm 1.00$  D of attempted correction. In the 5.5-mm optical zone group, 41% were within  $\pm 0.50$  D and 73% within  $\pm 1.00$  D 3 months after surgery. Using the 6.5-mm optical zone, 57% were within  $\pm 0.50$  D and 82% were within  $\pm 1.00$  D attempted correction 3 months after treatment (Fig 6).

Safety data and the gain and loss of lines in visual acuity are depicted in Figure 7. The loss of one line in visual acuity in the 5.5-mm optical zone group was 13%. In the 6.5-mm optical zone group, 13% had one line of visual acuity lost compared to 2% in the



**Figure 3.** Stability. Spherical equivalent refraction over time, 5.5-mm optical zone group. Regression between day 1 and 3 months postoperatively: +0.92 D. (Number of eyes examined at each postoperative time point are shown in parentheses.)



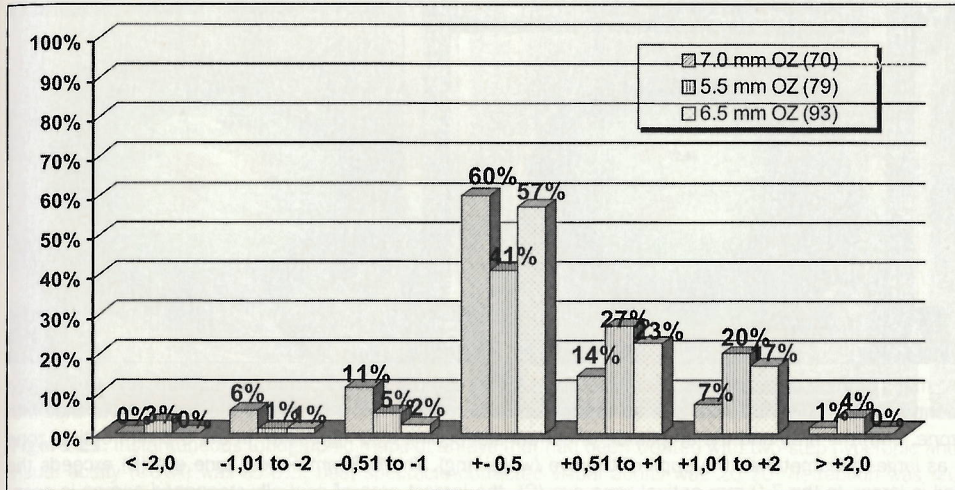
**Figure 5.** Predictability. Attempted vs achieved correction (spherical equivalent refraction) 3 months postoperatively (7.0-mm optical zone).

7.0-mm optical zone group. At the same time, some eyes gained one or more lines of visual acuity, 19% in the 5.5-mm, 17% in the 6.5-mm, and 27% in the 7.0-mm optical zone groups (see Fig 7).

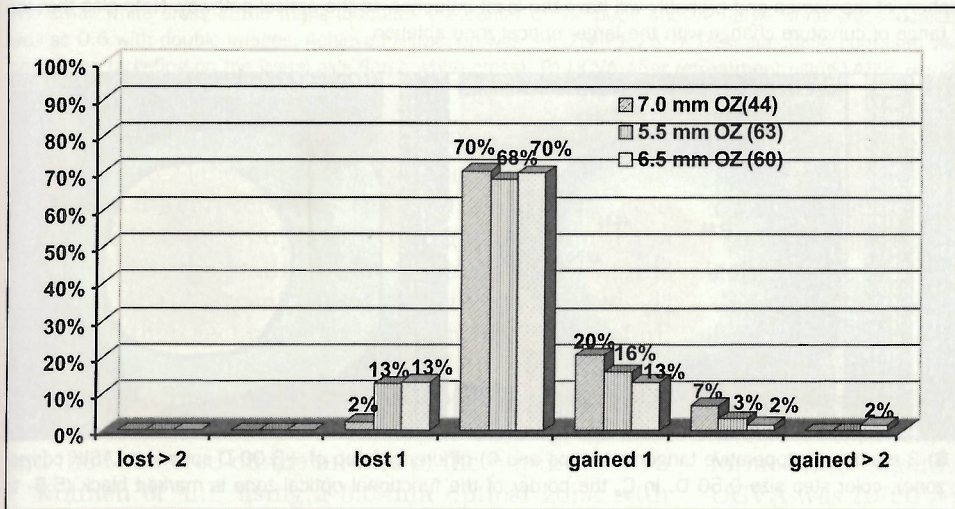
Postoperative topographic examinations (Nidek OPD Scan, instantaneous topographic maps) confirm the increased effected and probably optically functional zones of 5.5-, 6.5-, and 7.0-mm optical zone treatments (Fig 8). The functional optical zone was defined as the region of central corneal steepening in comparison to the preoperative topography as Rojas and Manche<sup>11</sup> proposed. With the 7.0-mm optical zone, treatment diameter of the effective optical zone is 5.5 to 6.0 mm (Fig 9).

Symptoms such as double images or night vision disturbances were reported in 5% of cases in the 7.0-mm optical zone group. Night vision disturbances were noted in 7% of cases in the 6.5-mm optical zone group and





**Figure 6.** Refractive outcome. Percentage of eyes with residual spherical equivalent refractive error 3 months postoperatively. The 5.5-, 6.5-, and 7.0-mm optical zone groups are compared. (Number of eyes examined are shown in parentheses.)



**Figure 7.** Safety. Gain and loss of lines in best spectacle-corrected visual acuity for the 5.5-, 6.5-, and 7.0-mm optical zone groups 3 months postoperatively. (Number of eyes examined are shown in parentheses.)

in 27% of cases in the 5.5-mm optical zone group in the 3-month postoperative interval.

Surgical complications are summarized for all three groups ( $n=432$  eyes). Epithelial defects with need of therapeutic contact lens application were noted in 1.8% of all surgical protocols. There were 8 cases with flap displacement and 11 cases with epithelial ingrowth that needed treatment. There were 7 cases with minor and 4 cases with major flap striae that had to be repaired. No infections or cases of diffuse intralamellar keratitis were noted in any of the three groups. No difference in quantity and severity of tear film problems was seen in the three different optical zone groups that were compared in this study. Almost all cases needed substantial support with artificial tears, some cases additionally received punctual plugs.

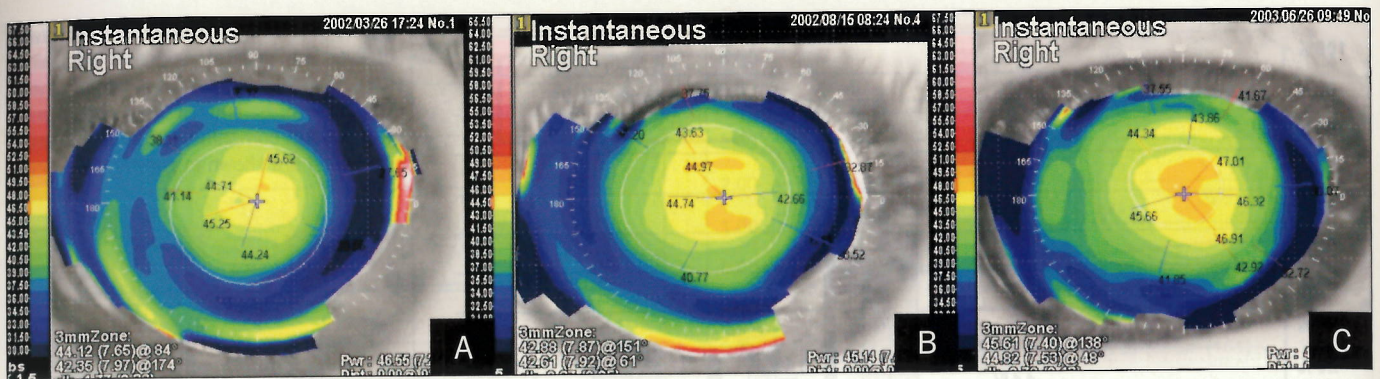
## DISCUSSION

The number of eyes examined during follow-up does not allow a reasonable statistical analysis considering

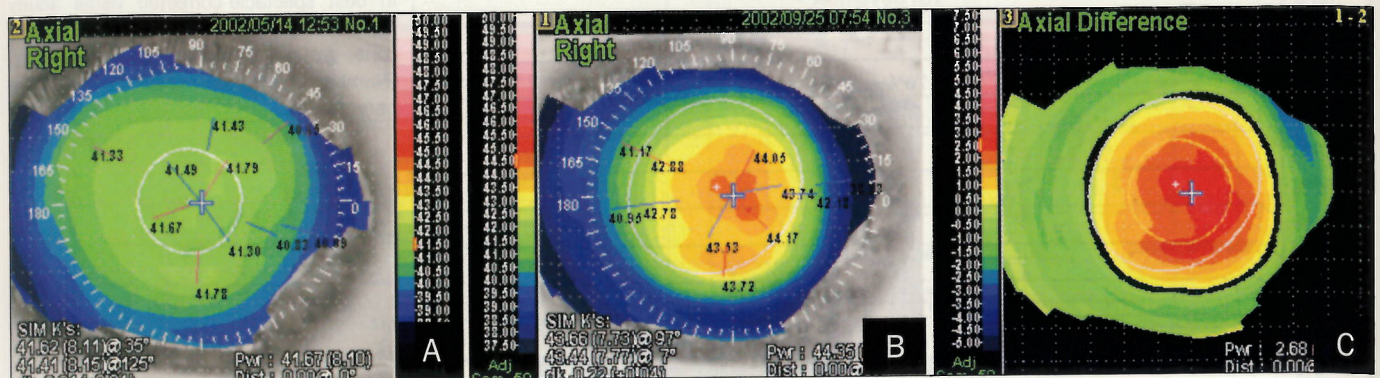
variability and sample size. Furthermore, the standard of the surgical technique might have improved over time when changing from 5.5- to 6.5-mm and finally to 7.0-mm optical zone treatments. We believe, however, that the data presented in this study provide useful information about the effect of optical zone size in hyperopic LASIK. The comparison of cohort groups of eyes that showed up at all given follow-up dates confirms the trend of the results: larger optical zones seem to improve the refractive outcome in hyperopic and hyperopic-astigmatic LASIK (Fig 10).

Such a trend (bigger is better) can also be interpreted by looking at earlier publications regarding hyperopic LASIK. Rashad<sup>8</sup> reported that 61.2% (60% of our 7.0-mm optical zone group after 3 months without retreatment) of hyperopic and astigmatic eyes treated with a 6.0-mm optical zone (9.0-mm transient zone) were within  $\pm 0.50$  D 1 year after treatment. In Rashad's study,<sup>8</sup> however, retreatments were included in the data. Argento and Cosentino<sup>6</sup> compared 5.9-mm optical





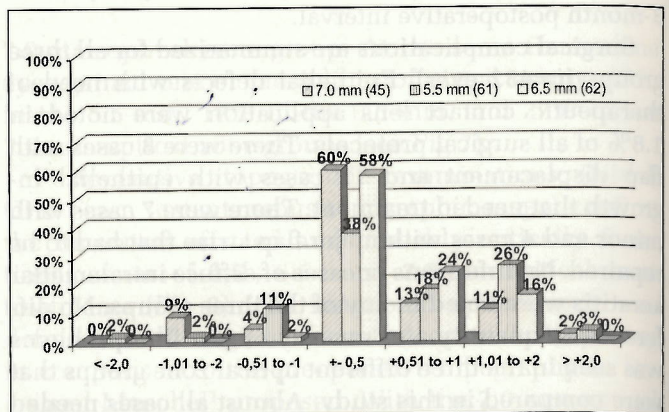
**Figure 8.** Nidek OPD instantaneous, topographic maps of three different eyes after hyperopic LASIK treated with **A)** 5.5-mm, **B)** 6.5-mm, and **C)** 7.0-mm optical zones. The OPD maps were taken 6 months post LASIK. Achieved and attempted correction was +3.00 D in all three cases. Note that with an increasing diameter of the applied optical zone, both the area and the amplitude of central steepening also increased. In the 5.5-mm optical zone eye (A), the central corneal steepening is just as large in diameter as the pupil of the eye (white ring). The 6.5-mm optical zone eye (B) exceeds the eye of the pupil significantly although the pupil is larger. In the 7.0-mm optical zone eye (C), the largest area of centrally steepened cornea is seen. The transition zone is positioned in the midperiphery of the cornea and probably will have the least influence on the optical pathway. Note also that the color steps in all three eyes indicate a greater range of curvature change with the larger optical zone ablation.



**Figure 9.** Comparison of **A)** preoperative and **B)** 3 months postoperative tangential maps and **C)** difference map of +3.00 D spherical LASIK correction (7.0-mm optical zone, 9.5-mm transient zone), color step size 0.50 D. In C, the border of the functional optical zone is marked black (5.5- to 6.0-mm diameter).

zone treatments with 4.4- and 5.5-mm optical zones in hyperopic LASIK and also reported that larger optical zone results are more stable, predictable, and safe.

In hyperopic LASIK, centration and regression are important aspects that must be considered. Bueeler et al<sup>12</sup> pointed out in their work on maximum permissible lateral decentration in corneal ablation that rough centration based on the surgeon's judgment might not be accurate enough to achieve significantly improved optical quality in a high percentage of treated eyes. The tolerance of lateral decentration is believed to be <0.07 mm in eyes with 7.0-mm pupil size. With smaller pupil sizes, they note, tolerance will increase. We conclude, that with a given pupil size the increase of the applied optical zone might as well increase the tolerance for lateral decentration. Centration is even more critical in the hyperopic and astigmatic eye compared to the myopic, as safety data are worse than what we experience in myopic LASIK treatments. The smaller



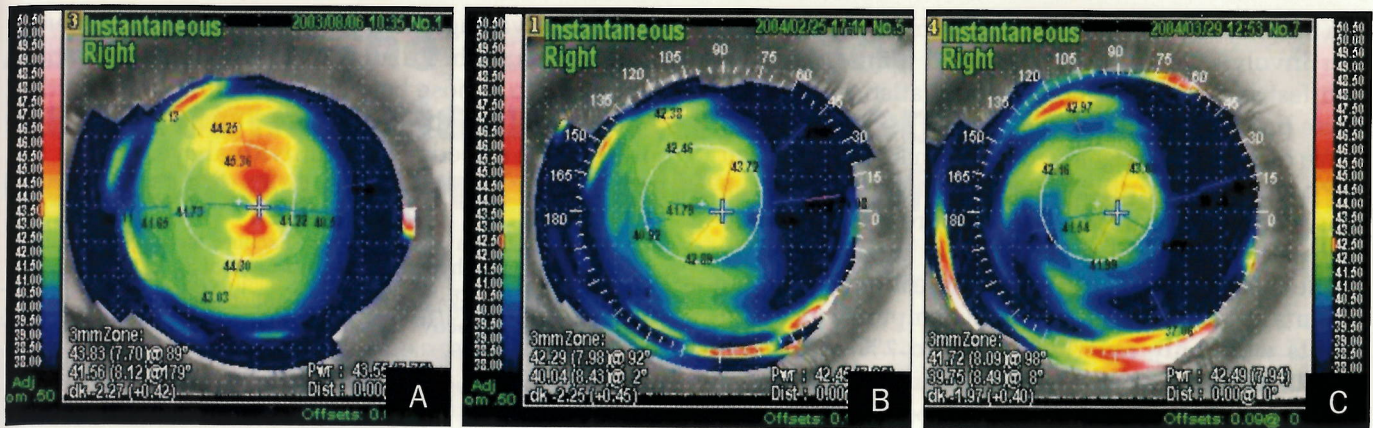
**Figure 10.** Refractive outcome of the control eyes with 5.5-, 6.5-, and 7.0-mm optical zones 3 months after LASIK. The data includes only those eyes that presented at all follow-up time periods (ie, 1 day, 1 week, 4 weeks, and 3 months). (Number of eyes examined are shown in parentheses.)



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**Figure 11.** Instantaneous topographic maps of an eye that had been treated with two-step hyperopic and astigmatic LASIK. **A)** Preoperative uncorrected visual acuity (UCVA) was sc 0.3, best spectacle-corrected visual acuity was 20/20. Refraction was  $+0.75/-3.0 \times 8$  as was the treatment setting for targeting emetropia. Alignment was centered on the middle of the entrance pupil, although there was an offset from the visual axis (0.6 mm at  $156^\circ$ ). The small white cross in the maps identifies the center of the pupil and the large white cross localizes the actual visual axis. **B)** Post LASIK, UCVA was sc 0.6 with double images. Achieved refraction was  $+1.25/-1.25 \times 0$ . Best spectacle-corrected visual acuity remained 20/20. A retreatment was performed targeting on the visual axis (large white cross). **C)** UCVA after retreatment using LASIK was 20/20 with  $+0.25/0 \times 0$  objective refraction.

functional zone as shown in Figure 10 and as discussed by Rojas and Manche<sup>11</sup> may be one reason.

Should the surgeon target the eye-tracker on the center of the entrance pupil (line of sight) or should the visual axis be the landmark for eye-tracker centration? Brancato et al,<sup>9</sup> Argento and Cosentino,<sup>6</sup> and Rashad<sup>8</sup> described their technique of beam centration in detail. Brancato et al<sup>9</sup> and Rashad<sup>8</sup> used the middle of the entrance pupil for centering the laser beam. Argento and Cosentino<sup>6</sup> used the visual axis to have the eye fixated and then centered on the middle of the pupil.

Kohnen et al,<sup>13</sup> using a 6.0-mm optical zone with a 9.0-mm transient zone, described the technique of centration more precisely. They consequently used the visual axis for centering the hyperopic ablation. However, only 38% of the eyes were within  $\pm 0.50$  D after 4 months in this study, indicating that centering on the entrance pupil might lead to better results with regard to target refraction.

With a large eccentricity of fixation, many hyperopic eyes show a visual axis that can be  $>1.0$  mm off the center of the pupil. Centering on the visual axis in those eyes can—in cases of iatrogenic or technically caused problems—lead to significant decentration. Furthermore, once the flap is lifted, the exact visual axis can not be defined with precision because vision is deteriorated. Localization has to be estimated. Therefore, we were uncomfortable centering the eye-tracker on the visual axis.

A case example illustrates the problem. In Figure 11, the instantaneous topographic maps of an eye that had been treated with two-step hyperopic and astig-

matic LASIK are shown. Preoperative uncorrected visual acuity (UCVA) was sc 0.3, best spectacle-corrected visual acuity (BSCVA) was 20/20. Refraction was  $+0.75/-3.0 \times 8$  and so was the treatment setting for targeting emetropia. Alignment was centered on the middle of the entrance pupil, although there was an offset from the visual axis (0.6 mm at  $156^\circ$ ). After LASIK, UCVA was sc 0.6 with double images. Achieved refraction was  $+1.25/-1.25 \times 0$ . Best spectacle-corrected visual acuity remained 20/20. A retreatment was performed now targeting on the visual axis. After re-LASIK UCVA was 20/20 with  $+0.25/0 \times 0$  objective refraction.

We now prefer to center the laser midway between the pupil center and the visual axis. Such a strategy has been described by Seiler.<sup>14</sup> For eyes with an effective optical zone smaller than the mesopic pupil size, centration is of major importance. To increase the effective optical zone to 6.0 mm, a 7.0-mm optical zone treatment is necessary. Such an increase, however, reduces the potential impact of decentration problems, as most of the treated hyperopic eyes show equal or smaller mesopic pupil sizes.

The safety data presented in this study confirm that loss of BSCVA remains a matter of concern. Centration is one key to improving safety in hyperopic LASIK. The safety results improved when larger optical zones were applied; however, the number of cases with loss of lines of sight is a matter of concern. This may be attributed to the variation in compliance of laser center staff with regard to postoperative controls and visual acuity measurements. Once the patients are satisfied and can read 20/20 uncorrected, no further investiga-



tion of BSCVA is performed. Furthermore, many of the eyes involved in this study showed a mild to severe manifest amblyopia. Therefore, the statistics may seem worse than they actually are.

We did not investigate contrast sensitivity on a routine basis in this study. In cases of night vision problems, corneal topography and wavefront analysis (optical path difference) usually reveal the cause of the problem. The administration of a questionnaire to our patients showed that night vision symptoms and complaints were only reported in 5% to 7% of cases in the 7.0- and 6.5-mm optical zone groups, whereas 27% of patients treated with the small 5.5-mm optical zone noticed a negative impact on night vision quality.

Another important issue in the treatment of hyperopia with LASIK is regression. Similarly, most authors report a significant amount of regression in the treatment of hyperopia.<sup>6-8</sup> Regression in hyperopic LASIK is likely due to epithelial hyperplasia in the groove between the optical zone and transition zone.<sup>15</sup> The main regression is noted within the first 3 months after treatment also indicating that the epithelium is playing a key role. Increasing the optical zone pushes the hyperopic groove to the periphery of the total treatment zone. Thus, regression is reduced when larger optical zones are applied. It is not clear, however, whether 6.5 or 7.0 mm is preferred and whether the size and shape of the transition zone impacts the amount of regression. Our data did not show significant differences between the 6.5- and 7.0-mm optical zone groups. In any case, the total treatment zone is limited by the diameter of the flap. Thus to date, applicable optical zones will range between 6.5 and 7.5 mm with a transition zone that will end at 8.5 to 9.5 mm total diameter.

Although long-term follow-up for a large number of patients is missing, the results of this study support the thesis that refractive outcome and stability are improved when optical zones that are  $\geq 6.5$  mm with transition zones up to 9.5 mm total diameter are applied. The increased ablation depth required for the larger optical zone does not limit the amount of correction, as the deepest point of ablation is in the periphery where the cornea is naturally thicker. Ongoing studies must determine whether the application of a 7.0-mm optical

zone has advantages that would legitimate a higher total ablation depth. Finally, it might be helpful to have the option to choose between 6.5- and 7.0-mm optical zones as well as the shape of the transition zone according to the needs of the individual eye.

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