Using InterWave Aberrometry to Measure and Improve the Quality of Vision in LASIK Surgery

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Objective: To compare visual outcomes in eyes undergoing aberrometry-guided (InterWave) LASIK with those in eyes undergoing standard LASIK treatment based upon refractive measures.


Participants: Four hundred two consecutive eyes undergoing LASIK were analyzed retrospectively. One group, 106 eyes undergoing primary LASIK and 224 eyes undergoing LASIK enhancement, was treated with standard LASIK treatment using a 5.5-mm optical zone, 1.5-mm transition zone laser with the settings determined by manifest refraction. The second group, 44 untreated (primary) eyes and 28 previously treated (enhancement) eyes, received a multipass, multistage treatment in which the laser settings for each stage were determined by aberrometry measurements. Eyes with desired monovision (undercorrected) outcome and preoperative hyperopia were excluded from the study.

Intervention: An aberrometry-guided laser treatment (InterWave LASIK) was compared with the standard LASIK treatment based upon the manifest refraction.

Main Outcome Measures: Uncorrected visual acuity (VA), manifest refraction, best spectacle-corrected VA (BSCVA), severity of halos, and root mean square (RMS) retinal blur area measured at 3 months postoperatively.

Results: Three months postoperatively there was no difference in uncorrected VA, BSCVA, refraction, or RMS retinal blur areas for pupil sizes of 3.5 mm between eyes treated by InterWave and those treated by standard LASIK. However, InterWave LASIK reduced the retinal blur area by 48% (P<0.0103) and 58% (P<0.0004) in primary cases and 43% (P<0.0430) and 74% (P<0.0271) in enhancement cases, respectively, for pupil sizes of 4.5 and 6.5 mm relative to standard LASIK treatments. Patients undergoing InterWave-guided treatment reported less severity of halo (0.37 vs. 0.98 [P<0.016] for primary cases and 0.35 vs. 0.73 [P<0.04] for enhancement cases).

Conclusion: InterWave LASIK achieved acuity and refractive results equivalent to those of standard LASIK treatment based upon refraction, but resulted in superior quality mesopic vision. Ophthalmology 2004;111:1368–1379 © 2004 by the American Academy of Ophthalmology.

Over 1 million LASIK procedures were performed in the United States in 2001. It has been projected that 3 million LASIK procedures will be performed in 2006, surpassing the number of cataract procedures performed annually. Although most patients are satisfied with their vision after LASIK, some patients experience glare, halos, and ghost images, particularly at night or in dim conditions. Visual aberrations after LASIK surgery have received increased attention in the news media and scientific literature and on internet sites dedicated to patients who have experienced poor visual outcomes after surgery.

Many patients who complain of visual aberrations after refractive surgery have visual acuities of 20/20 and refractions near plano, making it impossible to evaluate their symptoms with conventional measures of acuity or refraction. Corneal topographers measure the optical power of the corneal surface and provide a qualitative indication of the presence of irregular astigmatism. Quantitative indices, such as the Topographic Irregularity Index developed by Maloney, have been reported to predict visual performance. However, corneal topographic measures alone cannot describe aberrations, because information about the refractive power of the posterior corneal surface, the crystalline lens, and the focal length of the eye is lacking. Description of aberrations requires measuring the effect of all of the eye’s optical components and their interrelationships on the quality of the retinal image.

Aberrometers, or wavefront sensors, are diagnostic in-
Instruments that measure the wavefront error of the eye. The wavefront error is a mathematically derived description of the 3-dimensional shape of a wave of light after it is altered by the eye’s optical system. The wavefront error is referenced in the x–y dimension to the pupillary plane and in the z dimension to anterior or posterior deviations from a theoretical wavefront that produces a perfect, diffraction-limited image on the retina. Unlike corneal topography, which measures only the surface power of the cornea, the wavefront error describes how an image on the retina is altered by all of the eye’s optical elements. Unlike spherocylindrical refractive measurements, the wavefront error is not restricted to axisymmetric shapes; it can describe both refractive error (defocus) and higher order aberrations such as coma and spherical aberration, which are common after refractive surgery. Aberrometry may provide more detailed information about visual performance than acuity and refraction. Aberrometry may be useful in refractive surgery in measuring the quality of vision and in creating laser treatments that minimize postoperative aberrations.

The InterWave Scanner is a visual aberrometer developed by researchers at Emory Vision, General Electric Company Research Center, Harvard, and the Massachusetts Institute of Technology during the past decade. An updated, solid-state version of the InterWave Scanner suitable for use in our refractive surgery referral practice at Emory Vision was built and registered with the Food and Drug Administration in April 2001 as a 510(k) exempt device. In this study, we used the aberrometer’s wavefront error measurements to derive parameters of visual performance and optical power specific to 3 pupillary zones (central, 0–3.5 mm, and 3.5–4.5-mm and 4.5–6.5-mm annular zones), and we correlated them to acuity, refraction, and severity of halos reported by patients after LASIK surgery. A method for customizing laser treatment using the zonal optical power measurements determined by InterWave aberrometry is described, and the visual results using InterWave-guided treatment are compared with those of conventional LASIK treatment based upon refraction.

Materials and Methods

InterWave Scanner

The optical design of the InterWave Scanner has been described previously. Briefly, the scanner employs the Scheiner principle (Fig 1) to measure the aberrations of the patient’s visual system. The instrument is equipped with a Badal optometer that corrects the spherical equivalent (SE) refractive error of the eye from −15 to +7 diopters (D). The images of the test spot and the alignment reticle are delivered through 2 independent optical channels that pass through 0.5-mm-diameter regions of the cornea. A third channel (housing a charged coupled device camera) acts as a passive pupil-monitoring system that records the patient’s pupil image, measures its diameter, and tracks its location during the entire measurement session.

Clinical Measurements

The scanner is approximately the size of a common autorefractor and is operated by a technician (Fig 2). InterWave aberrometry is performed 20 minutes after the instillation of 1 drop of 1% cyclopentolate (Cyclogyl, Alcon Laboratories Ltd., Fort Worth, TX) to obtain measurements through a widely dilated pupil and to negate the effects of accommodation. The patient’s task is to align the test spot within the center of the reticle using a joystick, and then to click a button when he or she deems the alignment satisfactory. This measurement is made for both the x and the y directions (an angle pair). The testing takes approximately 3 minutes per eye in most subjects to measure 50 to 75 testing points.

Aberrometry Analysis

The angle pair measured at each testing point represents the local derivatives of the wavefront error of the visual system at each pupillary locus. A least-squares procedure, written in MATLAB, was used to fit the slope measurements to the derivatives of the Zernike polynomials using the method described by Webb. We used the derived coefficients to provide estimates of the weight of individual aberrations and to reconstruct the overall wave aberration of the eye. The measurement technique and analysis routines were validated as described in He et al. From the wavefront aberration measurements for the entire pupil, we derived 3 parameters for the 3 pupillary zones described in the introduction (Fig 2A): the Pupillary Zone Blur Anatomy, the zonal root mean square (RMS) retinal blur area, and the zonal optical power, as described below.

InterWave Aberrometry Parameters

Pupillary Zone Blur Anatomy. The Pupillary Zone Blur Anatomy (Fig 2B, middle) is an alternative to the Point Spread Function (Fig 2B, left). It is an optical ray-trace of a grid of 100×100 rays, from the object (a point source located at infinity), through the entrance pupil of the eye, and to the focal plane. This depiction provides a simultaneous estimate of vision quality color-coded for each of 3 different pupil diameters. We established a calibration circle around the center of the map at 8.7 milliradians (Fig 2B), which is the angle subtended by the full moon when ≥45° above the horizon, to add a familiar perspective of blur size for clinicians and patients in describing the aberrations.

This figure is identical to an optical spot diagram, except that light passing through the central part and the paracentral and peripheral pupil is color-coded blue, green, and red, respectively. The Blur Anatomy cannot show the small-scale ripple associated with the diffraction and interference effects; however, it can correctly reveal the large-scale intensity distribution through the ray density in ray-hits per square milliradians at the focal plane. This is principally true when the wavefront error is large relative to the wavefront of light, which is true in most clinical situations. In these circumstances, blur diameter predictions calculated using diffraction-based methods or ray-based methods yield similar results.

Although the Zone Blur Anatomy is not an exact representation of the intensity distribution, it has the following distinct advantages over the Point Spread Function: if an irregular defect in the wavefront causes a strongly distorted spot in the image quality, the Blur Anatomy can immediately reveal what portion of the pupil is responsible for the defect. It also reveals the pupil diameter at
The subject uses a joystick control to move the spot from position 1 to position 2.

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### InterWave® Scanner

### B. Pupillary Zone Blur Anatomy

#### A. Pupillary Zones

#### C. RMS Retinal Blur Area by Pupillary Zone

#### D. Spherocylindrical Optical Power by Pupillary Zone

<table>
<thead>
<tr>
<th>Zone</th>
<th>Zone Diameter</th>
<th>Sphere (Diopters)</th>
<th>Cylinder (Diopters)</th>
<th>Axis (Degrees)</th>
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<tr>
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<td>-1.45</td>
<td>0.66</td>
<td>178.0</td>
</tr>
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<td>-1.56</td>
<td>0.76</td>
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<tr>
<td>3</td>
<td>4.5-6.5</td>
<td>-2.66</td>
<td>0.86</td>
<td>3.3</td>
</tr>
</tbody>
</table>
related to the patient.

Zonal-optimized spherocylindrical corrections could be easily correlated to the patient’s reports of glare, halos, or ghost images.

Zonal Root Mean Square Retinal Blur Area. The zonal RMS retinal blur area is a calculation of the area of the blur pattern on the retina, in square microns, produced by light passing through each of the pupillary zones. The RMS is a standard statistical method used to compute a mean where the variable in question has both positive and negative values; it is the square root of the sum of squares divided by the number of observations. The RMS retinal blur area is a parameter derived from InterWave measures that depicts the size of the retinal blur caused by a point source of light at infinity. The smaller the RMS retinal blur, the sharper and crisper the retinal image. The larger the RMS retinal blur, the more diffused the retinal image and the more likely that the patient will report a halo or glare.

Zonal Optical Power. We determined the sphere, cylinder, and axis that minimized the RMS retinal blur area for each zone. Zonal-optimized spherocylindrical corrections could be easily correlated to the patient’s refraction, and the zonal optical powers were used to program the laser settings in a multipass, multistage InterWave LASIK treatment.

Each zone was independently optimized using a conventional optimization algorithm that input the sphere, cylinder, and axis of a hypothetically applied correction. The algorithm determined the resultant RMS blur area as an output figure of merit. The resulting zonal optical power predicts the best spherocylindrical correction for each zone, independent of the other zones.

For example, the zonal optical power profile of an eye with a refraction of $-1.50 +0.50 \times 180$ is shown in Figure 2D. This profile shows that the optical power changes from $-1.45 +0.66 \times 178$ in zone 1 (3.5 mm diameter) to $-2.66 +0.86 \times 3.3$ in the annual zone 3 (4.5–6.5 mm diameter). This reflects increasing myopia in the periphery of the eye’s optical system consistent with the presence of spherical aberration.

Correlation of Pupillary Zonal Root Mean Square Retinal Blur Areas to Acuity and to Severity of Halos

InterWave aberrometry was performed on 1424 eyes being evaluated for LASIK. The refraction of the eyes varied from an SE of $-14.25$ D to $+6.63$ D, with astigmatism up to $+5.75$ D. The zonal RMS retinal blur area for the 3 pupillary zones was calculated and compared with uncorrected visual acuity (VA) measured by the Early Treatment Diabetic Retinopathy Study chart and with the SE of the manifest refraction using an analysis of variance regression model (PROC REG, SAS 8.01).

For 177 eyes that were examined with the InterWave Scanner at 3 months after LASIK, we asked the patient to rank the severity of their halos at night ($0 = \text{no halo}, 4 = \text{severe halo}$). The zonal RMS retinal blur areas for the 3 pupillary zones were derived from aberrometry and compared with the patient’s score of halo severity. A statistical regression model was used to determine the relationship between the severity of halos and the zonal RMS retinal blur area for each pupillary zone.

Standard LASIK Technique

Conventional LASIK treatment is based upon a single spherocylindrical measurement determined by the manifest refraction, the cycloplegic refraction, or a consensus between the two. The refractive setting is entered into the laser’s computer that controls the diameter of the optical and transition zones and the spherocylindrical treatments that are applied to those zones. The surgeon may use a nomogram or a look-up table to modify the manufacturer’s laser settings based upon the type of surgery to be performed and prior results.

In 1997, we began LASIK treatments with an EC-5000 excimer laser (Nidek Co., Fremont, CA) using a first-generation nomogram developed by Salah and Waring that used a 5.5-mm optical zone and a 7.0-mm transition zone. Huang and Stulting determined the coupling effects between the spherical and cylindrical components by regression analysis and created a second-generation nomogram in 1998. Patients treated with the second-generation nomogram obtained more accurate postoperative refractions, fewer overcorrections, and improved unaided Snellen acuities relative to patients treated with the first-generation nomogram (Invest Ophthalmol Vis Sci 40[suppl]:S588, 1999). Since that time, the second-generation nomogram has been used as a standard in our LASIK procedures.

InterWave LASIK Technique

Pop and Payette reported a multipass, multistage laser technique for photorefractive keratectomy that improved results over a single-pass treatment. Pop and Payette divided the laser treatment into several stages and applied treatment in a sequential manner. We adopted Pop and Payette’s multipass, multistage technique that used distinct laser treatment settings for pupillary zones of 3.5, 4.5, and 6.5 mm, as determined by the zonal optical power.
powers from InterWave aberrometry. A transition zone with an outer diameter of 8.0 mm was used. No information from the manifest or cycloplegic refraction was used to program the laser in the InterWave LASIK technique (Table 1, Fig 3).

Table 1. Comparison of Standard and InterWave LASIK Techniques

<table>
<thead>
<tr>
<th>Laser settings based upon</th>
<th>Standard LASIK</th>
<th>InterWave LASIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser settings</td>
<td>Manifest and</td>
<td>Zonal optical</td>
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<tr>
<td></td>
<td>cycloplegic refraction</td>
<td>power derived</td>
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<td></td>
<td></td>
<td>by aberrometry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>wavefront</td>
</tr>
<tr>
<td></td>
<td></td>
<td>measurements</td>
</tr>
<tr>
<td>No. of stages</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Zones</td>
<td>5.5-mm optical, 7.0-mm</td>
<td>3.5-, 4.5-, 6.5-mm</td>
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<tr>
<td></td>
<td>transition</td>
<td>transition zone</td>
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<tr>
<td>Description</td>
<td>Single treatment</td>
<td>Three treatment</td>
</tr>
<tr>
<td></td>
<td>applied across the</td>
<td>zones tailored to correct</td>
</tr>
<tr>
<td></td>
<td>pupil with transition</td>
<td>variation in optical</td>
</tr>
<tr>
<td></td>
<td>zone</td>
<td>power across 3 zones of</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.5-, 4.5-, 6.5-mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>diameter</td>
</tr>
</tbody>
</table>

InterWave LASIK versus Standard LASIK in Primary and Enhancement Surgery

Forty-four untreated (primary) eyes and 28 previously treated (enhancement) eyes underwent InterWave LASIK treatment at Emory Vision. We compared these results at 3 months postoperatively to those of a consecutive series of 106 patients undergoing primary LASIK and 224 eyes undergoing LASIK enhancement surgery with our current standard (single stage) LASIK technique during the same period (August–September 2001) by the same surgeon (KPT). Patients undergoing enhancement surgery were initially treated with a myopic LASIK procedure using a 5.5 optical zone and a 7.0 transition zone using our second-generation nomogram with a Nidek EC-5000 laser. The analysis for the enhancement cases was further controlled for the original (untreated) manifest refraction of the patient and the time since the initial treatment. The 4 cohorts excluded eyes with a desired monovision outcome (undercorrected) and those with preoperative hyperopia. Informed consent, approved by the Emory University institutional review board, was obtained, and institutional review board approval was obtained for this research. On their 3-month visit after treatment, acuity, refraction, and InterWave aberrometry were

InterWave® LASIK Technique

A. Individual aberrometry measurements are recorded by the InterWave Scanner, and the wavefront error is calculated.

B. The wavefront error is divided into 3 pupillary zones of 0- to 3.5-mm, 3.5- to 4.5-mm, and 4.5- to 6.5-mm diameters.

C. Each zone undergoes an optimization routine to determine the best spherocylindrical optical power.

D. Each zone is then independently programmed into the Nidek EC-5000 excimer laser in the manner described by Pop and Payette, and treatment is delivered to the eye in a multipass, multistage treatment that tailors the laser correction to the variations in the optical power across the pupil.
recorded. At that visit, patients were asked to quantify the severity of halos at night using a scale of 0 (none) to 4 (intense). A regression model adjusting for preoperative refraction and surgically induced refractive changes in outcomes between the cohorts was used to analyze the results.

**Results**

**Correlation of Root Mean Square Retinal Blur Area to Acuity and to Severity of Halos**

Figure 4 shows the correlation for each of the zonal RMS retinal blur areas (for pupillary apertures of 0–3.5 mm, 3.5–4.5 mm, and 4.5–6.5 mm) to the uncorrected VA. The horizontal axis represents the denominator (20/x) of the Snellen acuity in a logarithmic scale, and the vertical axis represents the RMS retinal blur area for each of 3 zones. The dashed line represents the mean of the actual population, and the solid line represents the predictive relationship for each zone. The results show that the RMS retinal blur area for the 0- to 3.5-mm and 3.5- to 4.5-mm zones are good predictors of the uncorrected VA ($P<0.0001$ and $R^2 = 0.35$, and $P<0.0001$ and $R^2 = 0.36$, respectively). To a lesser degree, the RMS retinal blur area of the 4.5- to 6.5-mm zone is predictive of VA ($P<0.0001$ and $R^2 = 0.21$).

Table 2 shows the regression coefficients, $P$ values, and $R^2$ for the RMS retinal blur area for each of the pupillary zones as a predictor of the severity of halos reported by the patient. The RMS blur area of the inner 2 zones was not predictive ($P>0.05$). Neither the unaided Early Treatment Diabetic Retinopathy Study acuity nor the manifest refraction was predictive of halo severity ($P>0.05$). These results were analyzed further for the subset of patients with unaided 20/20 acuity postoperatively. For this group, we also found the RMS blur area in the outer zone to be highly predictive of the report of halos, as shown in Table 2.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Zonal RMS Diameters</th>
<th>All Cases</th>
<th>Patients with 20/20 Acuity</th>
<th>Coefficient</th>
<th>$P$</th>
<th>$R^2$</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>0–3.5 mm</td>
<td>0.34</td>
<td>0.08</td>
<td>0.14</td>
<td>0.23</td>
<td>0.23</td>
</tr>
<tr>
<td>2</td>
<td>3.5–4.5 mm</td>
<td>0.20</td>
<td>0.19</td>
<td>0.05</td>
<td>0.33</td>
<td>0.07</td>
</tr>
<tr>
<td>3</td>
<td>4.5–6.5 mm</td>
<td>0.22</td>
<td>0.03</td>
<td>0.24</td>
<td>0.20</td>
<td>0.03</td>
</tr>
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</table>

Table 2. Correlation of Zonal Root Mean Square Retinal Blur Area to Severity of Halos
Correlation of Zonal Optical Power to Manifest Refraction

Figure 5 shows the relationship between the SE of the optical power of zone 1 (0–3.5-mm diameter) determined by InterWave aberrometry and the SE of the patient’s manifest refraction. The correlation coefficient was 0.965.

InterWave LASIK 3-Month Results

The general demographics and preoperative measurements of patients undergoing primary and enhancement treatment with the standard and InterWave LASIK techniques are shown in Table 3. Table 4 lists the preoperative refractive error and the time between primary and enhancement surgery.

Figure 6 shows the mean postoperative acuity obtained for patients undergoing primary and enhancement surgery with InterWave and standard LASIK techniques. Both treatment modalities produced similar results in average unaided VA and in average best spectacle-corrected VA (BSCVA) ($P>0.05$). No eyes lost >2 lines of BSCVA. After enhancement surgery, 81% of patients obtained 20/20 acuity or better.

InterWave aberrometry was used to compute zonal optical power (SE) as a function of pupillary diameter. These values are shown in Figure 7 for the 2 treatment methods for both primary and enhancement surgery. We found that there was no difference in the residual refractive error in the first 3 mm of pupil diameter; however, with pupil sizes larger than 3 mm, InterWave LASIK provided a more uniform correction of refractive error across the entire pupil, and it corrected more of the refractive error in the periphery of the pupil. At a pupillary diameter of 7 mm, InterWave LASIK eyes showed an average of 1.4 D less residual myopia than eyes undergoing standard LASIK treatment.

We compared the reported severity of halos after surgery (0 = none, 4 = severe) between the 2 treatment modalities. Patients who underwent standard treatment reported an average halo severity score of 0.98, whereas the patients who underwent InterWave LASIK had an average halo severity score of 0.37 ($P<0.02$), as shown in Figure 8. Fifty-three percent of the patients who received standard treatment reported no halos, versus 68% for the patients who underwent InterWave LASIK. We also found that the percentage of patients who reported halo severity of 3 or 4 was significantly lower for the patients who underwent InterWave LASIK (1.3%), versus the patients receiving standard LASIK (12.9%, $P<0.05$).

The RMS retinal blur area for each pupillary zone is shown in Figure 9 for patients undergoing primary and enhancement surgery with both types of treatment. In primary surgery, there was no difference in retinal blur areas produced by the 2 treatments for pupil sizes of up to 3.5 mm. However, InterWave LASIK treatments reduced retinal blur area by 48% ($P<0.01$) and 58% ($P<0.0004$), respectively, for pupil sizes of 4.5 and 6.5 mm relative to standard LASIK treatments. We found similar results in patients undergoing enhancement surgery.
Several aberrometers have recently become commercially available. Most are based upon the Shack–Hartmann method, in which a beam of light is reflected from the posterior eye wall and captured by an array of small lenses that focus the reflected light onto a charged coupled device chip for analysis. During the past decade, we designed an instrument that measures the aberrations of the entire visual system, from the cornea to the visual cortex. Unlike aberrometers that reflect light from the posterior eye wall, the InterWave Scanner incorporates a patient feedback task to locate the retinal plane and to account for any neural processing of aberrations by the intraretinal layers and the higher visual pathways. In this sense, the process performed by the InterWave scanner is similar to a manifest refraction, whereas the process performed by Shack–Hartmann aberrrometers is similar to that performed by an autorefractometer. The InterWave Scanner’s Badal slide neutralizes the eye’s spherical error, the dominant component of the wave-front error in most eyes. This allows the dynamic measurement range of the instrument to be used to measure higher order aberrations. The sequential nature of the test reduces the effect of transient dry spots and debris in the tear film that can cause errors with instantaneous reflection-based methods. Finally, we designed the instrument with a measurement range of 20 D, which permits measurement of highly aberrated eyes without errors induced by image crossover, which have been reported by investigators using Shack–Hartmann aberrometry. These design advantages came at the expense of a testing time that requires approximately 3 minutes per eye, versus only a few seconds for a Shack–Hartmann aberrometer. In addition, an InterWave scan requires an alert, attentive, and cooperative patient to perform the testing task.

We then used the wavefront error measurements from the InterWave scanner to graphically depict visual aberrations, to predict visual performance, and to determine the optical (spherocylindrical) power within 3 pupillary zones in patients undergoing LASIK surgery.

### Discussion

#### InterWave Aberrometry

Several aberrometers have recently become commercially available. Most are based upon the Shack–Hartmann method, in which a beam of light is reflected from the posterior eye wall and captured by an array of small lenses that focus the reflected light onto a charged coupled device chip for analysis. During the past decade, we designed an instrument that measures the aberrations of the entire visual system, from the cornea to the visual cortex. Unlike aberrometers that reflect light from the posterior eye wall, the InterWave Scanner incorporates a patient feedback task to locate the retinal plane and to account for any neural processing of aberrations by the intraretinal layers and the higher visual pathways. In this sense, the process performed by the InterWave scanner is similar to a manifest refraction, whereas the process performed by Shack–Hartmann aberrrometers is similar to that performed by an autorefractometer. The InterWave Scanner’s Badal slide neutralizes the eye’s spherical error, the dominant component of the wave-front error in most eyes. This allows the dynamic measurement range of the instrument to be used to measure higher order aberrations. The sequential nature of the test reduces the effect of transient dry spots and debris in the tear film that can cause errors with instantaneous reflection-based methods. Finally, we designed the instrument with a measurement range of 20 D, which permits measurement of highly aberrated eyes without errors induced by image crossover, which have been reported by investigators using Shack–Hartmann aberrometry. These design advantages came at the expense of a testing time that requires approximately 3 minutes per eye, versus only a few seconds for a Shack–Hartmann aberrometer. In addition, an InterWave scan requires an alert, attentive, and cooperative patient to perform the testing task.

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### InterWave Parameters

After LASIK surgery, many patients report that their vision is satisfactory in daytime conditions, but that they experience halos, glare, ghost images, and other aberrations at night or in dim conditions. The Blur Anatomy map depicts the aberrations experienced by the patient, relates them to pupil size, and compares their size and configuration to a familiar astronomical object. Figure 10 shows visual aberrations in the right eye of one of the authors (KPT) before and after InterWave LASIK.

We validated that the zonal RMS retinal blur area (an InterWave-derived metric) was predictive of visual performance for each pupillary aperture by correlating the RMS retinal blur area to acuity, refraction, and the severity of halos. As expected, we found that the RMS retinal blur area for the 2 inner zones was most predictive of unaided Snellen acuity and the SE of the manifest refraction. The RMS blur area of the outer (4.5–6.5 mm) zone was predictive of the severity of halos reported by patients who had undergone LASIK surgery. Even in a subgroup of postoperative pa-
Patients with 20/20 unaided acuity, the RMS retinal blur area of zone 3 was predictive of halo severity. Therefore, the zone 3 RMS retinal blur area can be used as a unique benchmark to refine the quality of mesopic vision because it was predictive of the patient’s severity of halos, whereas acuity and refraction were not. Even though there was a correlation between the patient’s halo severity and the pupillary zonal blur area, a cause and effect relationship was not established in our study. Factors other than those we studied (age, preoperative manifest refraction, and mesopic pupil size) could have caused a correlation between halo severity and the RMS retinal blur area. However, determination of a cause–effect relationship will require further study.

From the InterWave wavefront measurements, we derived the zonal optical power for pupillary apertures of 0 to 3.5 mm central, 3.5 to 4.5 annular, and 4.5 to 6.5 mm annular zones. Whereas the RMS retinal blur area is predictive of visual performance specific to the 3 pupillary apertures, the zonal optical power is predictive of refractive power specific to the 3 pupillary apertures. As expected, the zonal optical power for the inner zone (0–3.5 mm) was highly predictive of the SE of the manifest refraction. Vari-
ations in the optical power across the pupil indicate the presence of higher order aberrations. For example, myopia that increases in the outer pupillary zone is an indication of the presence of spherical aberration, common in most myopic eyes. The zonal optical power measurements were used to create laser settings for the Nidek EC-5000 laser in a multipass, multistage treatment method that we termed InterWave LASIK.

InterWave LASIK

In conventional LASIK surgery, the manifest (cycloplegic) refraction is used to program the laser, which delivers the desired treatment to a single optical and transition zone. However, refraction provides only an average measure of the spherocylindrical error across the pupil; it does not measure the variation in optical power across the pupil, which is the cause of visual aberrations. Because the InterWave LASIK technique tailors the laser dosing to the variations in optical power across 3 discrete pupillary zones as measured by aberrometry, we expected to decrease the patient’s postoperative visual aberrations as compared with patients undergoing the standard LASIK treatment method.

Three months after surgery, InterWave LASIK patients undergoing primary and enhancement surgery achieved acuity and refractive results identical to those of patients undergoing standard LASIK treatment. After enhancement surgery, 81% of patients achieved 20/20 acuity. This indicates that the laser settings derived from InterWave aberrometry were at least as accurate as the manifest and cycloplegic refractions that we use in our standard LASIK treatment.

Figure 8. Mean severity of halos, 3 months after surgery. Patients reported the severity of halos after surgery (0 = none, 4 = severe). Patients undergoing InterWave LASIK reported less severity of halos than patients undergoing standard treatment in both primary surgery (reduction of 62%) and enhancement (reduction of 52%) surgery.

Figure 9. From the root mean square blur angle, we compute the average area (bars) at the retinal plane of the blur (relative size, circles) produced by a distant point source produced by the eye’s wavefront error for each of 3 pupil sizes. For primary and enhancement cases, there was no difference in blur areas produced by the 2 treatments for pupil sizes of 3.5 mm (as expected). However, InterWave LASIK reduced retinal blur area by 48% (P < 0.01) and 58% (P < 0.0004), respectively, for pupil sizes of 4.5 and 6.5 mm compared with standard LASIK treatments in primary surgery. InterWave LASIK reduced retinal blur area by 43% (P < 0.0430) and 74% (P < 0.0271), respectively, for pupil sizes of 4.5 and 6.5 mm compared with standard LASIK treatment in enhancement surgery. Sample size: standard LASIK, 106 eyes; InterWave LASIK, 44 eyes.
However, patients undergoing InterWave LASIK achieved a higher quality of vision than did patients who underwent standard LASIK treatments in both primary and enhancement surgery, as measured by a reduction in the mean severity of halos and a reduction in the zone 3 RMS retinal blur area. The RMS blur area predicts that a point source of light would be, on average, 4 times as bright in mesopic conditions in patients undergoing InterWave enhancement surgery as that in patients who underwent standard enhancement surgery.

Were the results of InterWave LASIK attributed solely to the increase in optical or transition zone size? We separately analyzed 23 patients who underwent the standard LASIK technique using a 6.5-mm optical zone and an 8.0-mm transition zone (N3 nomogram), the same diameters that are used in InterWave LASIK. Patients undergoing InterWave LASIK had significantly less severity of halos and a smaller RMS retinal blur area in zone 3 than patients undergoing treatment with standard LASIK ($P<0.04$ and $P<0.03$, respectively). This suggests that the improvements in visual performance were a result of the aberrometry-guided laser treatment, which corrected for variations in optical power across the pupil, and not simply due to the increased diameter of the optical and transition zones.

The InterWave LASIK technique required an average of 40 seconds more treatment time and an approximately 20%
greater depth of tissue per diopter than the single-zone treatment nomogram. Yet, for most patients with myopia up to 8 D with a preoperative corneal thickness of more than 500 μm, the additional ablation did not exceed the 250-μm limit to the posterior stroma, and adequate tissue was available for enhancement treatment. Although the benefit of significant improvement in the quality of vision may be worth the extra tissue required, surgeons must balance the improvement in quality of vision gained against the decreased tissue available for enhancement and the possible increased risk for ectasia inherent in deeper ablations. Our results were obtained without the benefit of refining the laser nomogram. It is likely that visual outcomes could be further improved by modifying the laser settings by applying Huang’s method of regression analysis to each treatment zone.

This study was performed before Food and Drug Administration approval of a laser for custom ablation in the United States, and the Nidek EC-5000 laser that was used is limited to creating sphero-cylindrical ablations. Non-axisymmetric aberrations such as coma cannot be corrected with this laser. In the future, flying spot laser systems will permit treatment of higher order, non-axisymmetric aberrations. With these lasers, we can use the wavefront error from the aberrometer directly to determine the laser ablation pattern. Thus, we view InterWave LASIK with the EC-5000 as a simple method for customizing treatment with aberrometry that will be supplanted as more sophisticated flying spot laser technology becomes approved and available. Nevertheless, the techniques described in this study were used effectively to improve the quality of vision for our patients.

References