Outcomes of NIDEK Optical Path Difference Custom Ablation Treatments (OPDCAT) for Myopia With or Without Astigmatism

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ABSTRACT

PURPOSE: To report refractive and visual acuity outcomes using wavefront-guided optical path difference custom ablation treatments (OPDCAT; NIDEK Co Ltd) for myopia and myopic astigmatism.

METHODS: One hundred eyes of 50 patients with preoperative manifest refraction spherical equivalent (MRSE) of $4.62 \pm 1.30$ diopters (D) (range: $-1.38$ to $-7.25$ D) with mean astigmatism of $0.57 \pm 0.37$ D (range: $0$ to $-1.75$ D) underwent LASIK with OPDCAT. Eyes that had $\geq 5$ µm of irregularity preoperatively underwent additional irregularity treatment (irregularity group) and were compared with eyes that did not undergo irregularity ablation (aspheric group). An independent-samples $t$ test was used to analyze refractive outcomes at 3 months postoperatively. A $P$ value $<.05$ was considered statistically significant.

RESULTS: The mean postoperative MRSE was $0.18 \pm 0.35$ D (range: $-0.63$ to $1.00$ D). Ninety-six (96%) eyes had uncorrected visual acuity of 20/20 or better and 87 (87%) eyes were within $\pm 0.50$ D of the intended correction. No eyes lost two or more lines of best spectacle-corrected visual acuity (BSCVA), 1 (1%) eye lost one line of BSCVA, and 99 (99%) eyes maintained gained lines of BSCVA. The MRSE changed $0.02$ D between 1 and 3 months postoperatively. A statistically significant increase was noted in higher order aberrations in the entire cohort ($P<.05$) with lower induced higher order aberration and coma aberrations in the irregularity group ($P<.05$).

CONCLUSIONS: LASIK using wavefront-guided OPDCAT ablation with or without irregularity is safe and efficacious for the treatment of myopia with astigmatism. The irregularity treatment induces fewer higher order aberrations than aspheric ablation. [J Refract Surg. 2009;25: S142-S147.]

Excimer laser treatment of myopia and myopic astigmatism has changed from using traditional Munnerlyn-based laser algorithms to the introduction of aspheric algorithms,1 wavefront-based algorithms,2 and topography-guided algorithms.3 Refractive outcomes have been excellent for all of these algorithms. Each algorithm can be used for a given subset of the population. For example, three separate studies of wavefront ablations using two different excimer laser platforms have indicated that eyes undergoing wavefront treatments with greater than approximately $0.30$ to $0.50$ µm of higher order aberration preoperatively tend to have less induction of higher order aberration postoperatively compared with eyes with lower higher order aberration.3-5 Based on these results, patients with $>0.50$-µm higher order aberration may be candidates for wavefront correction, whereas patients with $<0.50$-µm higher order aberration may do well with an aspheric treatment. Individuals with preexisting topographic irregularities would be candidates for topography-guided treatments. Greater induction of higher order aberrations after LASIK can lead to a reduction in visual performance.6

This study presents the results of a non-registered ancillary study of the treatment of the optical path difference customized aspheric transition zone (OPDCAT; NIDEK Co Ltd, Gamagori, Japan) algorithm for the treatment of myopia with and without astigmatism that was used to support the People’s Republic of China-regulated State Food and Drug Administration approval. In a substudy, we compared the treatment of eyes with and without higher order aberration treatment to determine whether there were any differences in the induction of higher order aberration.

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PATIENTS AND METHODS

In this prospective nonrandomized study, 50 patients (31 women and 19 men; 100 eyes) who underwent LASIK for myopia with or without astigmatism using the NIDEK Advanced Vision Excimer laser platform (NAVEX, NIDEK Co Ltd) with the OPDCAT algorithm were evaluated preoperatively and 3 months postoperatively to determine refractive outcomes and change in wavefront aberrations over time.

A subgroup of eyes (n=40) (irregularity group) with higher preoperative ocular optical irregularity (defined as ≥5 μm) detected with Final Fit ablation simulation software (NIDEK Co Ltd) that underwent irregularity ablation in addition to the OPDCAT ablation were compared with eyes that did not receive irregularity treatment (aspheric group).

PRE- AND POSTOPERATIVE EVALUATION

Patients were enrolled in the study if they had a stable refraction for 1 year before the study and discontinued contact lenses for at least 3 to 14 days (depending on contact lens type) before preoperative examination. Patients with an acute illness, calculated postoperative residual stromal bed thickness <280 μm after ablation, preoperative central corneal thickness <480 μm, or those who underwent previous ophthalmic surgery, had abnormal corneal topography, and recurrent or active eye disease were excluded from the study.

Preoperatively, all patients underwent an ophthalmic assessment that included pupillometry, corneal topography, wavefront aberrometry (5-mm pupil plotted to the sixth Zernike order) using the OPD-Scan II (NIDEK Co Ltd), uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, corneal pachymetry, Goldmann tonometry, slit-lamp microscopy of the cornea, and anterior segment and dilated fundus examination. Postoperative examinations were conducted at 1 week, 1 month, and 3 months after surgery. Postoperative examinations were identical to the preoperative examination with the exception of dilated retinal examination, which was conducted only at 3 months postoperative and earlier if required.

TREATMENT SIMULATIONS

All treatments were simulated and the shot data prepared using Final Fit ablation planning software version 1.11. Final Fit is treatment-planning software that allows the surgeon to modify a range of parameters including optical zone, transition zone, aspheric laser profile, and amount of ocular irregularity treatment. Once the treatment parameters are finalized, a simulation of postoperative corneal topography was generated, and the shot data were exported to the EC-5000 CXIII excimer laser (NIDEK Co Ltd) via a universal serial bus drive. Asymmetric irregularities detected by wavefront acquisition were treated using multipoint spot ablation; these are called “irregularity” in the Final Fit software denoting either the lack of symmetry in the aberration or a treatment other than lower order aberration (sphere and cylinder).

An aspheric ablation profile is used in the optical and transition zones in the OPDCAT algorithm. The NIDEK EC-5000 CXIII offers seven different profiles, each of which becomes increasingly aspheric the higher the number. In this study, profile numbers 5 (98 eyes) and 6 (2 eyes) were used for all transition zones. All eyes were targeted for emmetropia, with sphere and cylinder values based on the preoperative manifest refraction modified using the S095-C118-S30 nomogram. Only an irregularity component simulated in Final Fit >5 μm was treated using multipoint ablation. Based on previous experience, 70% of the calculated irregularity was treated.

In this study, the following optical zones were programmed into the laser: 4.00 mm (5 eyes), 4.20 mm (1 eye), 4.50 mm (3 eyes), 5.00 mm (34 eyes), 5.50 mm (53 eyes), and 6.00 mm (4 eyes). Transition zones programmed in the laser were 8.00 mm (1 eye) and 8.50 mm (99 eyes). Irregularities were treated using a 6.00-mm optical zone and an 8.50-mm transition zone for all eyes. A satisfactory simulated result was one in which the corneal topography minimized the gradient of corneal curvature change, maximized the effective optical zone, and maintained adequate residual corneal tissue in the stromal bed. All treatment simulations were centered on the “visual axis” (estimated by the coaxially sighted corneal reflex) as described below (line of sight [LOS] function checked in Final Fit).

SURGERY

Eyes undergoing surgery were prepared using an alcohol scrub to cleanse the eyelids. Two drops of topical anesthetic were instilled, and a sterile drape was used to isolate the surgical field. A lid speculum was inserted to maintain constant globe exposure during surgery. Additional topical anesthetic was instilled in the upper and lower fornices. A superior hinged corneal lamellar flap was made using a Moria II microkeratome (Moria, Antony, France) with suction rings size from +2 to −1 according to the keratometric values and expected blade depth of 130 μm (96 eyes) or 110 μm (4 eyes).

Alignment of the eye with the laser was achieved with a 200-Hz infrared eye tracker built into the laser console and centered on the visual axis using the
offset function of the eyetracker. The offset value programmed into the eyetracker was set between the line of sight and the visual axis, based on the surgeon’s (Q.W.) previous experience. Torsion errors were corrected by enabling the torsion error correction function of the laser before and during ablation that monitored and actively compensated for cyclotorsion. The torsion error correction function has been described previously.7 The flap was lifted, and the excimer laser ablation was delivered to the stroma. Patients fixated on a red fixation light throughout the ablation, allowing the tracker to remain centered on the visual axis. The flap was repositioned, and the interface was irrigated with a balanced salt solution to remove any debris. After the LASIK procedure, the eyes were occluded with a pair of transparent plastic shields. Antibiotic (tobramycin 0.3%; Tobrex, Alcon Laboratories Inc, Ft Worth, Tex) and corticosteroid drops (fluorometholone 0.1%; FML, Allergan Inc, Irvine, Calif) were prescribed for all patients for instillation four times a day for 7 days.

**DATA ANALYSIS**

Three-month postoperative data are presented. The safety index was determined by mean postoperative BSCVA/mean preoperative BSCVA. The efficacy index was determined by mean postoperative UCVA/mean preoperative BSCVA. Statistical analyses were conducted using SPSS version 13.0 for Windows XP (SPSS Sciences, Chicago, Ill). An independent-samples t test was used to analyze refractive outcomes. A P value <.05 was considered statistically significant.

**RESULTS**

**BASELINE DATA**

The mean preoperative manifest refraction spherical equivalent (MRSE) was $-4.62\pm1.30$ D (range: $-1.38$ to $-7.25$ D) with mean astigmatism of $-0.57\pm0.37$ D (range: 0 to $-1.75$ D). Mean logMAR BSCVA was $-0.07\pm0.06$ (range: 0.1 to $-0.2$). Mean simulated keratometry obtained from the OPD-Scan II was $43.51\pm1.69$ D (range: 39.13 to 49.20 D). Mean preoperative corneal thickness was $538\pm25$ µm (range: 484 to 589 µm).

**THREE-MONTH POSTOPERATIVE DATA**

**Refractive Outcomes.** Postoperatively, 100 (100%) eyes were available for follow-up at 3 months. Manifest refraction spherical equivalent was $0.18\pm0.35$ D (range: $-0.63$ to $1.00$ D). Mean astigmatism was $0.18\pm0.25$ D (range: $-0.75$ to 0 D). Uncorrected visual acuity was $-0.09\pm0.06$ (range: 0.1 to $-0.2$) at 3 months, and BSCVA was $-0.10\pm0.06$ (range: 0.1 to $-0.2$).

No eyes lost two or more lines of BSCVA, 1 (1%) eye lost one line of BSCVA from 20/16 to 20/20, 62 (62%) eyes maintained BSCVA, and 37 (37%) eyes gained BSCVA (Fig 1). The safety index was 1.09. The safety index was not statistically significantly different between groups ($P>.05$). Nine (9%) eyes had better UCVA postoperatively compared with preoperative BSCVA of 20/12.5. The efficacy is shown in Figure 2. The efficacy index for the entire cohort was 1.04. The efficacy index of the irregularity group was 1.07 and 1.02 for the aspheric group. Predictability is plotted in Figure 3. All eyes were within $\pm1.00$ D of the intended correc-
tion. Eighty-seven (87%) eyes were within ±0.50 D of the intended correction. There was a −0.13 D change in MRSE from 1 week to 1 month postoperatively (Fig 4). From 1 month to 3 months postoperatively, the change in MRSE was +0.02 D, representing a change of 0.01 D/month (see Fig 4). Between 1 and 3 months, 85 (85%) eyes had a change of MRSE within ±0.50 D. The defocus equivalent analysis shows that 94% of eyes were within ±1.00 D of the intended correction, and 54% of eyes were within ±0.50 D of the intended correction (Fig 5).

Wavefront Aberrations. The induction of wavefront aberrations 3 months postoperatively for the entire cohort is reported in Table 1. Statistically significant increases were noted in all aberrations analyzed, ranging from a 0.38-fold increase to a 1.6-fold increase ($P < .05$) (Table 1). The difference in induced aberrations over time between the aspheric and irregularity groups is shown in Table 2. The irregularity group had a statistically significantly lower induction of total higher order aberrations, coma-like aberrations, and coma 3 months postoperatively ($P = .001$).

**DISCUSSION**

The outcomes of this investigation of LASIK for the treatment of myopia with or without astigmatism found the OPDCAT algorithm to be safe and efficacious. For example, no eyes lost two or more lines of BSCVA post-
operatively, and the safety index was 1.09. The efficacy index was 1.04, and at 3 months postoperatively, 87% of eyes were within ±0.50 D of the intended MRSE. This indicated that nomogram adjusted values for laser data entry provided excellent predictability (Fig 2).

Using aspheric algorithms with or without the treatment of irregularity, refractive outcomes were found to be equivalent to those reported for custom ablation algorithms. A recent study of conventional and custom ablation treatments performed by a single surgeon on a similar range of refractive error found that 90% of eyes were within 0.50 D of the intended MRSE, which is similar to our results of 87% at 3 months postoperatively.8 Similarly, in a prospective randomized study of the two custom ablation platforms, 80% of eyes achieved UCVA of 20/20, which is lower than our results of 96%.9

The OPDCAT algorithm uses aspheric optical and transition zones that are programmed into the laser.5 Aspheric transition zones reduce the steep corneal curvature gradients caused by the excimer laser ablation.10 This reduces the magnitude of postoperative higher order aberrations. The use of aspheric transition zones with the NIDEK excimer laser has shown a reduction in induced higher order aberrations, an increase in effective optical quality, and an increase in visual quality compared with conventional treatments.11,12 A recent US Food and Drug Administration investigation of a topography-guided aspheric ablation algorithm found a 23% decrease in patients reporting difficulties in night driving compared with preoperatively.13 Whether contrast sensitivity compared with preoperatively remains unaffected is the subject of a separate investigation. Previous findings of conventional LASIK have reported a decrease in contrast sensitivity postoperatively.14 Possibly, the maintenance of the aspheric profile of the cornea results in better visual performance compared with conventional laser algorithms, which result in an oblate cornea and greater induced changes in corneal curvature.11

The addition of irregularity treatments combined with an aspheric profile may serve to further decrease the induction of higher order aberrations and increase contrast sensitivity. In this study, we found a greater reduction in induced total higher order aberrations, coma-like aberrations, and coma postoperatively in the irregularity group (P<.05). This difference between groups is a result of the treatment of asymmetric aberrations such as coma and trefoil due to the irregularity ablation. This finding indicates that eyes with ≥5-µm irregularity may be candidates for OPDCAT with irregularity treatment. Higher levels of asymmetric aberrations such as coma can be another selection criterion.

By analyzing outcomes from an experienced LASIK surgeon, the data more accurately reflect the performance of each laser algorithm without confounding variables such as inter-surgeon variability. The primary goal of any refractive surgery, conventional or custom, is the reduction or elimination refractive error to provide excellent functional vision with minimal risk. From this perspective, the OPDCAT algorithm with or without irregularity treatment met this goal (see Figs 1 and 2).

### TABLE 1
Change in Wavefront Aberrations to the 6th Zernike Order at 3 Months Postoperative of 100 Eyes That Underwent OPDCAT

<table>
<thead>
<tr>
<th>Aberrations (µm)</th>
<th>Preop</th>
<th>Postop</th>
<th>Increase (3 mo postop – preop)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total HOA</td>
<td>0.24±0.08</td>
<td>0.35±0.12*</td>
<td>0.6×</td>
</tr>
<tr>
<td>S3</td>
<td>0.21±0.08</td>
<td>0.29±0.12*</td>
<td>0.38×</td>
</tr>
<tr>
<td>S4</td>
<td>0.08±0.03</td>
<td>0.15±0.06*</td>
<td>0.88×</td>
</tr>
<tr>
<td>SA</td>
<td>0.05±0.03</td>
<td>0.13±0.06*</td>
<td>1.6×</td>
</tr>
<tr>
<td>Coma</td>
<td>0.11±0.06</td>
<td>0.18±0.10*</td>
<td>0.64×</td>
</tr>
</tbody>
</table>

HOA = high order aberrations including the 3rd, 4th, 5th, and 6th Zernike order; S3 = coma-like aberrations; S4 = spherical-like aberrations; SA = spherical aberration comprising the 12th = Z4 and 24th = Z6

*Statistically significant (P<.01).

### TABLE 2
Change in Wavefront Aberrations to the 6th Zernike Order at 3 Months Postoperative of Eyes That Underwent OPDCAT With (Irregularity Group) or Without Irregularity (Aspheric Group) Treatment

<table>
<thead>
<tr>
<th>Aberrations (µm)</th>
<th>Aspheric Group (n=60)</th>
<th>Irregularity Group (n=40)</th>
<th>P Value (3 mo postop – preop)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOA</td>
<td>0.15±0.10</td>
<td>0.03±0.11</td>
<td>.01</td>
</tr>
<tr>
<td>S3</td>
<td>0.13±0.10</td>
<td>0.1±0.12</td>
<td>.01</td>
</tr>
<tr>
<td>S4</td>
<td>0.07±0.06</td>
<td>0.06±0.05</td>
<td>.174</td>
</tr>
<tr>
<td>SA</td>
<td>0.09±0.07</td>
<td>0.06±0.06</td>
<td>.084</td>
</tr>
<tr>
<td>Coma</td>
<td>0.10±0.11</td>
<td>0.03±0.12</td>
<td>.006</td>
</tr>
</tbody>
</table>

HOA = total high order aberrations including the 3rd, 4th, 5th, and 6th Zernike order; S3 = coma-like aberrations; S4 = spherical-like aberrations; SA = spherical aberration comprising the 12th = Z4 and 24th = Z6

Note. All measurements are reported for a 5-mm pupil diameter.
This investigation found that the use of the OPDCAT algorithm with or without additional irregularity treatment was safe, resulted in good visual acuity, and was predictable. The additional treatment of the irregularity component resulted in greater reduction of higher order aberrations compared with the aspheric algorithm.

REFERENCES