TOPOGRAPHICALLY GUIDED LASIK FOR MYOPIA USING THE NIDEK CXII CUSTOMIZED ASPHERIC TREATMENT ZONE (CATZ)

BY **George Waring MD,*** Paul J. Dougherty MD, Arturo Chayet MD, Jeffery Fischer MD, Barbara Fant PharmD, Gary Stevens PhD, AND Harkaran S. Bains

ABSTRACT

Purpose: To assess the efficacy, predictability, and safety of topography-guided laser in situ keratomileusis (LASIK) for the surgical correction of low to moderate myopia with astigmatism using the Nidek CXIII excimer laser equipped with the customized aspheric treatment zone (CATz) algorithm.

Methods: In a multicenter US Food and Drug Administration study of topography-guided LASIK, 4 centers enrolled 135 eyes with manifest refraction sphere that ranged from -0.50 to -7.00 D (mean, -3.57 ± 1.45) with up to -4.00 D of astigmatism (mean, -1.02 ± 0.64 D). The intended outcome was plano in all eyes. Refractive outcomes and higher-order aberrations were analyzed preoperatively and postoperatively. Patient satisfaction was assessed using both the validated Refractive Status and Vision Profile (RSVP) questionnaire and a questionnaire designed for this study. Six-month postoperative outcomes are reported here.

Results: By 6 months postoperatively, the manifest refraction spherical equivalent (MRSE) for all eyes was -0.09 ± 0.31 D. Six months postoperatively, 116 of 131 eyes (88.55%) had an uncorrected visual acuity of 20/20 or better, and 122 of 131 eyes (93.13%) had a MRSE within ±0.50 D. Distance best spectacle-corrected visual acuity (BSCVA) increased by 2 or more lines in 21 of 131 eyes (19.01%), and no eyes lost 2 lines or more of BSCVA. The total ocular higher-order aberrations root-mean-square increased by 0.04 μm postoperatively. Patients reported significantly fewer night driving and glare and halo symptoms postoperatively than preoperatively.

Conclusions: Nidek CXIII CATz treatment of myopia with astigmatism is safe, efficacious, and predictable, and it reduces patient symptoms associated with night driving and glare and halo symptoms.

Trans Am Ophthalmol Soc 2007;105:240-248

INTRODUCTION

Customized excimer laser ablations using laser in situ keratomileusis (LASIK) or photorefractive keratectomy can be based on corneal topography, whole-eye wavefront, or corneal wavefront. Topography-based ablations treat irregularities in corneal elevation in addition to the spherocylindrical refractive error.Wavefront-based treatments address the wavefront aberrations of the cornea or the entire eye in addition to the refractive error. A number of studies have demonstrated that topography-based ablations are safe and effective in the treatment of primary myopia and astigmatism. [1-9]

Custom ablation, whether topography-based or ocular wavefront-based, has been developed to address some of the disadvantages of conventional spherocylindrical ablation. The unoperated, normal cornea is prolate with an average positive asphericity of approximately +0.24. Conventional myopic ablations create an oblate cornea, increasing corneal asphericity and inducing positive spherical aberration, which can cause bothersome mesopic and scotopic symptoms such as glare and halos and difficulty driving.[10-12]

Topography-guided treatments have advantages over wavefront-guided treatments: (1) topographers can measure a wider area on the cornea than aberrometers, (2) topographers can accurately measure highly aberrated eyes, and (3) topographers have a higher number of data points than aberrometers.

A disadvantage of topography-based treatments is that they do not incorporate all of the refracting elements of the eye into the treatment, which leads to a decoupling of lenticular and corneal aberrations and may alter visual quality postoperatively. Corneal and lenticular spherical aberrations compensate for each other in the normal myopic eye up to approximately age 30.[13] Therefore, treating only the corneal spherical aberration may unmask lenticular spherical aberrations, which could cause halos at night.[13] One ablation strategy that may reduce this unmasking is the use of aspheric treatment zones that attempt to induce less change in corneal curvature and less spherical aberration.

The customized aspheric treatment zone (CATz) ablation of the NIDEK CXII excimer laser employs aspheric treatment zones. The CATz ablation architecture uses a combination of optical and transition zones, which gradually taper the corneal curvature paracentrally and peripherally, creating a single treatment zone, as defined by Hori-Komai and colleagues.[14] The aspheric transition zone has been referred to as optimized aspheric transition zone (OATz). In CATz, this aspheric ablation is combined with the treatment of corneal elevation irregularities.

The current study evaluated the efficacy, predictability, safety, wavefront induction, and patient satisfaction of LASIK to correct low to moderate myopia with astigmatism using the customized aspheric treatment zone algorithm of the Nidek CXIII excimer laser in an ongoing US Food and Drug Administration (FDA) trial.

From the Department of Ophthalmology, Emory University, Atlanta, Georgia (Dr Waring); InView Vision, Atlanta (Dr Waring); Dougherty Laser Vision Institute, Camarillo, California (Dr Dougherty); Jules Stein Eye Institute, Los Angeles, California (Dr Dougherty); CODET/Aris Vision Institute, Tijuana, Mexico (Dr Chayet); Fischer Laser Eye Center, Willmar, Minnesota (Dr Fischer); and Clinical Research Consultants Inc, Cincinnati, Ohio (Drs Fant and Stevens).

*Presenter.

Bold type indicates AOS member.

METHODS

PATIENT POPULATION AND EXAMINATION

Four investigative sites were involved in this FDA trial of the treatment of myopia with astigmatism using the Nidek EC-5000 CXIII excimer laser (CXIII) (NIDEK Co Ltd, Gamagori, Japan) with the CATz algorithm. Institutional review board approval was obtained for all investigative sites. Written informed consent was obtained from all study subjects.

One hundred thirty-five eyes of 68 patients (1 patient was treated unilaterally) were treated with LASIK for myopia with astigmatism. The average age was 36 ± 11.2 years (range, 23-64 years). All patients included in the study were 21 years of age or older and had spherical manifest refractive error ranging from -0.50 to -7.00 D with 0.50 D to 4.00 D of astigmatism. Patients were enrolled in the study if they had a stable refraction for 1 year prior to the study and discontinued contact lenses for at least 3 days to 28 days (depending on contact lens type) prior to preoperative examination in order to stabilize keratometry and corneal topography. Patients were required to have normal keratometry and topography with less than 10 μm of corneal irregularity as determined by the OPD-Scan. (NIDEK Co Ltd, Gamagori, Japan). Patients who had an acute illness, a calculated postoperative corneal bed thickness less than 250 μm after ablation, preoperative central corneal thickness of less than 475 μm, any prior ophthalmic surgery, or abnormal corneal topography were excluded from the study.

Preoperatively, the mean manifest refraction spherical equivalent (MRSE) was -3.57 ± 1.45 D, the mean sphere was -3.06 ± 1.39 D, and the mean cylinder was -1.02 ± 0.64 D. Preoperative ophthalmic examination included distance uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), MRSE, slit-lamp examination, corneal topography and aberrometry (6-mm pupil) using the OPD-Scan, pupillometry using the OPD-scan, ultrasound pachymetry (instruments varied by site), keratometry, and a dilated fundus examination by the surgeon. The same measurements (with the exception of dilated funduscopy and pupillometry unless warranted) were performed at 1 week, 1 month, 3 months, and 6 months postoperatively.

The quality of vision was assessed using the validated Refractive Status and Vision Profile (RSVP)[15] and a questionnaire that was designed for the specific needs of this study. This questionnaire was a 10-point self- administered questionnaire. Patients were asked to rate the presence or absence of each visual complaint in their CATz-treated eye(s) at baseline before the CATz-guided LASIK treatment and at each postoperative visit, beginning at month 1. Subjects were instructed to rate the absence of a complaint as "none" and the presence of a complaint as "mild," "moderate," "marked," or "severe."

TREATMENT SIMULATIONS AND ABLATION DATA PREPARATION

All treatments were simulated and the shot data prepared using the Final Fit (NIDEK Co Ltd, Gamagori, Japan) ablation planning software. Final Fit software is a treatment planning software that allows the surgeon to modify various parameters, including optical zone, transition zone, laser profile, and amount of corneal irregularity treatment. Once the treatment parameters are finalized, a simulation of postoperative corneal topography is generated and the shot data are exported to the CXIII excimer laser. Asymmetric irregularities detected with corneal topography were treated using the MultiPoint spot ablation of the CXIII excimer laser system.

CATz differs from a conventional spherocylindrical ablation in that the treatment area that lies between the outer edge of the optical zone (OZ) and the outermost area of the entire ablation zone is adjustable, based on the diameter of the OZ and transition zone (TZ) that are selected. In the transition zone, the volume of ablation gradually decreases as the ablation expands peripherally to minimize changes in corneal curvature. The use of an OZ with the TZ architecture described above is called OATz (optimized aspheric treatment zone),[14] and the treatment of corneal surface irregularities in addition to OATz is called CATz. The Nidek EC5000 CXIII offers 7 different profiles for the transition zone, and the OATz profile No. 5 was used for all treatments. All eyes were targeted for emmetropia with sphere and cylinder values based on the preoperative manifest refraction. The corneal irregularity simulated in Final Fit could not exceed an elevation of 10 μm. Based on previous experience, 80% of the calculated irregularity treatment was selected, of which 50% was actually programmed for treatment. This conservative calculation prevented overtreatment in eyes with prominent irregularity.

In this study all eyes underwent the refractive treatment using a 5.00-mm-diameter optical zone and an 8.50-mm transition zone. Corneal surface irregularities were treated using a 6.00-mm OZ and an 8.50-mm TZ for all eyes. The combination of optical and transition zones and the irregularity ablation constituted the total treatment zone and created the refractive correction of the eye. The sphere and cylinder input values were not modified according to the magnitude or pattern of corneal irregularity. A satisfactory simulated result was one in which the corneal topography minimized the gradient of corneal curvature change, maximized the effective optical zone, and reduced or eliminated the corneal irregularities, yet maintained adequate residual corneal tissue in the stromal bed. The surgeon, NIDEK engineer, and Clinical Research Consultants staff all reviewed and agreed on the final ablation pattern prior to treatment.

SURGICAL TECHNIQUE

The eyes undergoing surgery were prepared as customary for each center. One or 2 drops of topical anesthetic were instilled, and a sterile drape was used to isolate the surgical field. An eyelid speculum was inserted to allow maximum exposure of the globe. Additional topical anesthetic was applied. Automated mechanical microkeratomes were used to create nasal or superior lamellar hinged flaps that were 9 mm or greater in order to accommodate the transition zone ablation. Each site used a different microkeratome: MK-2000 (NIDEK Co Ltd, Gamagori, Japan), Moria M2 (Moria, Antony, France), Amadeus (Ziemer Ophthalmic Systems AG, Port, Switzerland), and Hansatome (Bausch & Lomb Inc, Rochester, New York).

Proper 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 pupil. Torsional errors were corrected by enabling the torsion error detection function of the laser prior to the ablation for improved registration. The flap was lifted, and the excimer laser ablation was delivered to the stoma. Patients fixated on a red fixation light, coaxial with the surgeon's line of sight and the excimer laser beam, throughout the ablation, allowing the tracker to remain centered on the pupil. The flap was repositioned, and the interface was irrigated with balanced saline solution, removing any debris. Patients received topical fluoroquinolone antibiotic and corticosteroid drops 4 times per day for 5 days.

EXCIMER LASER

The laser ablation algorithms used a rotating scanning slit and expanding diaphragm delivery system that corrected the sphere first, followed by the cylinder; the multipoint ablation module in the laser corrected the corneal irregularities using 1-mm spot ablation.

DATA ANALYSIS

Refractive outcomes, changes in higher-order aberrations, and the results of the RSVP and custom questionnaires were analyzed by a biostatistician (G.S.) using SAS software (SAS Institute Inc, Cary, North Carolina). Pooled analysis of the entire cohort was also performed. Data for 1 week, 1 month, 3 months, and 6 months after LASIK are presented here.

RESULTS

The mean MRSE for the entire cohort was 0.00 ± 0.38 D at 1 week, -0.04 ± 0.31 D at 1 month, -0.06 ± 0.29 D at 3 months, and -0.09 ± 0.31 D at 6 months. The mean postoperative sphere was 0.11 ± 0.39 D at 1 week, -0.07 ± 0.31 D at 1 month, 0.04 ± 0.32 D at 3 months, and 0.06 ± 0.31 D at 6 months. The mean postoperative manifest refractive cylinder was -0.21 ± 0.27 D at 1 week, -0.23 ± 0.25 D at 1 month, -0.22 ± 0.26 D at 3 months, and -0.25 ± 0.27 D at 6 months. For the entire cohort of 133 eyes, 116 eyes (87.20%) had a MRSE refraction within ±0.50 D, and 131 of 133 eyes (98.5%) were within ±1 D at 1 week. At 1 month, 126 of 135 eyes (93.30%) were within ±0.50 D and all eyes were within ±1 D. At 3 months, 117 of 127 eyes (92.10%) were within ±0.50 D and all eyes were within ±1 D. Of 131 eyes, 122 (93.13%) were within ±0.50 D and 130 (99.24%) were within ±1 D at 6 months postoperatively. Six months after surgery, 116 of 131 eyes (88.55%) had UCVA of 20/20 or better (Figure 1).

At 6 months postoperatively, there was a higher percentage of eyes with better UCVA than preoperative BSCVA at the 20/20 or better levels of acuity (Figure 1). Clinically significant loss of BSCVA is considered a loss of 2 or more Snellen lines. Six months after surgery, no eyes lost 2 or more lines of BSCVA (Figure 2). BSCVA increased by 2 or more lines in 21 of 131 eyes (16.03%) 6 months after surgery (Figure 2). Figure 3 plots the attempted vs achieved results for all eyes at 6 months postoperatively. At 6 months postoperatively, 114 of 131 eyes (87%) had a defocus equivalent of 0.50 D or better (Figure 4).

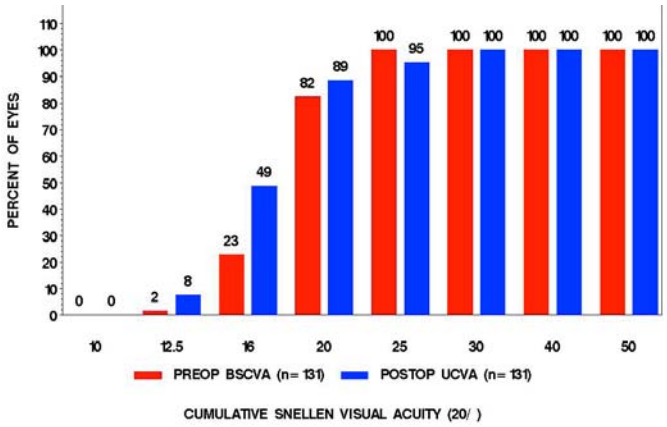

FIGURE 1

Preoperative best spectacle-corrected visual acuity (BSCVA) compared to 6 months postoperative uncorrected visual acuity (UCVA) after myopic laser in situ keratomileusis using the Nidek topographically guided custom aspheric treatment zone (CATz) algorithm. Postoperative UCVA is better than preoperative BSCVA.

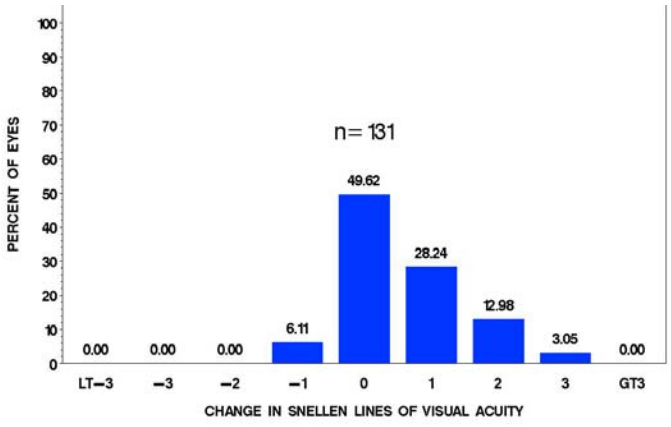

FIGURE 2

Change in best-corrected visual acuity 6 months after myopic laser in situ keratomileusis using the Nidek topographically guided custom aspheric treatment zone (CATz) algorithm. No eyes lost 2 or more lines.

Refractive stability postoperatively was evaluated by assessing the percentage of eyes with a change in MRSE of 1.00 D at 3-month intervals, as well as a mean rate of change in MRSE of 0.5 D or less per year (0.04 D per month). There was a mean change in MRSE of -0.03D ± 0.39 D occurring between the first week and 1 month postoperatively. The MRSE changed by -0.02 D from the first month to the third month and by -0.04 D from the third month to 6 months (Figure 5).

Mean root-mean-square (RMS) value for the total higher-order aberrations changed from 0.250 ± 0.103 µm preoperatively to 0.290 ± 0.099 µm 6 months postoperatively. The change in RMS for higher-order aberrations was statistically significant (P = .002).

Spherical aberration changed from 0.003 ± 0.065 µm preoperatively to 0.056 ± 0.069 µm 6 months postoperatively. The change in spherical aberrations was statistically significant (P = .000). Mean coma changed from 0.107 ± 0.062 µm preoperatively to 0.137 ± 0.088 µm 6 months postoperatively. The change in coma was statistically significant (P = .001).

Table 1 shows the patient satisfaction obtained using the custom-designed questionnaire at 3 months, the point of refractive stability. Table 2 shows the percent change in patient satisfaction from baseline to 3 months.

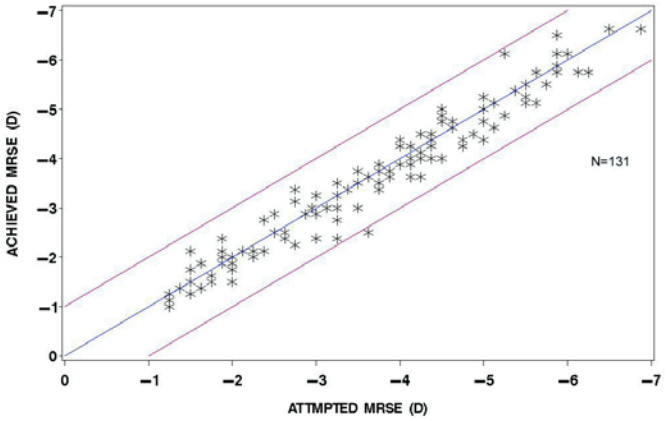

FIGURE 3

Attempted vs achieved manifest refraction spherical equivalent (MRSE) 6 months after myopic laser in situ keratomileusis using the Nidek topographically guided custom aspheric treatment zone (CATz) algorithm. There is a slight trend toward undercorrection.

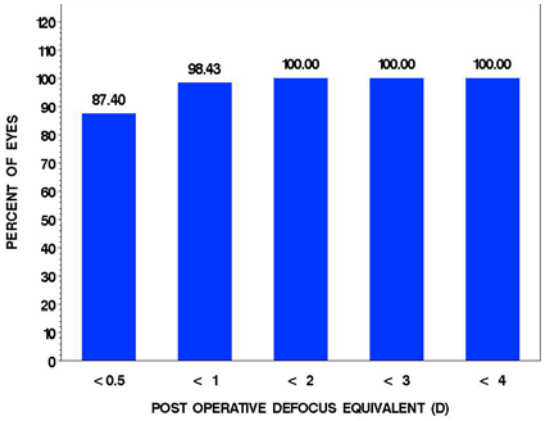

FIGURE 4

Defocus equivalent 6 months after myopic laser in situ keratomileusis using the Nidek topographically guided custom aspheric treatment zone (CATz) algorithm.

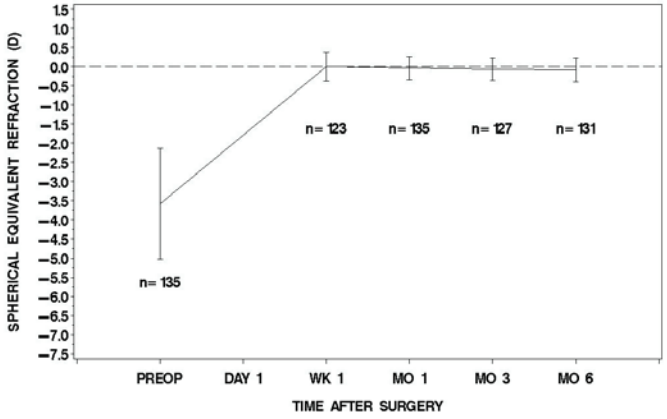

FIGURE 5

Change in manifest refraction spherical equivalent from preoperatively to 6 months after myopic laser in situ keratomileusis using the Nidek topographically guided custom aspheric treatment zone (CATz) algorithm. The refraction is stable over 6 months.

TABLE 1. RESULTS OF CUSTOM-DESIGNED SELF-ADMINISTERED PATIENT QUESTIONNAIRE RATING VISUAL COMPLAINTS IN 68 PATIENTS WHO UNDERWENT MYOPIC LASIK USING THE NIDEK CATz ALGORITHM*

VISUAL COMPLAINT	VISIT	RATING				
		NONE	MILD	MODERATE	MARKED	SEVERE
Light sensitivity	Screening	94/127 (74%)	20/127 (16%)	7/127 (6%)	4/127 (3%)	2/127 (2%)
	Month 3	92/122 (75%)	24/122 (20%)	4/122 (3%)	2/122 (2%)	0/122 (0%)
Difficulty with night driving	Screening	64/126 (51%)	15/126 (12%)	18/126 (14%)	21/126 (17%)	8/126 (6%)
	Month 3	107/122 (88%)	13/122 (11%)	2/122 (2%)	0/122 (0%)	0/122 (0%)
Difficulty reading	Screening	110/128 (86%)	11/128 (9%)	7/128 (5%)	0/128 (0%)	0/128 (0%)
	Month 3	97/122 (80%)	16/122 (13%)	6/122 (5%)	2/122 (2%)	1/122 (1%)

TABLE 1(continued). RESULTS OF CUSTOM-DESIGNED SELF-ADMINISTERED PATIENT QUESTIONNAIRE RATING VISUAL COMPLAINTS IN 68 PATIENTS WHO UNDERWENT MYOPIC LASIK USING THE NIDEK CATz ALGORITHM*

VISUAL COMPLAINT	VISIT	RATING				
		NONE	MILD	MODERATE	MARKED	SEVERE
Double vision	Screening	126/128 (98%)	2/128 (2%)	0/128 (0%)	0/128 (0%)	0/128 (0%)
	Month 3	117/122 (96%)	3/122 (2%)	2/122 (2%)	0/122 (0%)	0/122 (0%)
Fluctuation in vision	Screening	106/128 (83%)	16/128 (13%)	6/128 (5%)	0/128 (0%)	0/128 (0%)
	Month 3	95/122 (78%)	22/122 (18%)	5/122 (4%)	0/122 (0%)	0/122 (0%)
Glare	Screening	110/128 (86%)	13/128 (10%)	2/128 (2%)	3/128 (2%)	0/128 (0%)
	Month 3	91/122 (75%)	24/122 (20%)	7/122 (6%)	0/122 (0%)	0/122 (0%)
Halos	Screening	113/128 (88%)	12/128 (9%)	3/128 (2%)	0/128 (0%)	0/128 (0%)
	Month 3	87/122 (71%)	30/122 (25%)	3/122 (2%)	2/122 (2%)	0/122 (0%)
Starbursts	Screening	112/128 (88%)	13/128 (10%)	2/128 (2%)	1/128 (1%)	0/128 (0%)
	Month 3	92/122 (75%)	24/122 (20%)	4/122 (3%)	2/122 (2%)	0/122 (0%)
Dryness	Screening	96/128 (75%)	29/128 (23%)	3/128 (2%)	0/128 (0%)	0/128 (0%)
	Month 3	47/122 (39%)	45/122 (37%)	26/122 (21%)	2/122 (2%)	2/122 (2%)
Pain	Screening	119/125 (95%)	6/125 (5%)	0/128 (0%)	0/128 (0%)	0/128 (0%)
	Month 3	113/122 (93%)	9/122 (7%)	0/122 (0%)	0/122 (0%)	0/122 (0%)
Foreign body	Screening	112/128 (88%)	16/128 (13%)	0/128 (0%)	0/128 (0%)	0/128 (0%)
	Month 3	101/120 (84%)	17/120 (14%)	2/120 (2%)	0/120 (0%)	0/120 (0%)
Other†	Screening	35/37 (95%)	0/37 (0%)	0/37 (0%)	2/37 (5%)	0/37 (0%)
	Month 3	31/35 (91%)	3/35 (6%)	0/35 (0%)	1/35 (3%)	0/35 (0%)

CATz, customized aspheric treatment zone; LASIK, laser in situ keratomileusis.
*Any variation in the N for an observation at a specific timepoint is due to one or more subjects omitting the rating for that symptom at that timepoint.
†Other complaints were marked headaches at screening (both eyes of 1 subject); mild headache (both eyes of 1 subject); marked "focusing" at 3 months (1 subject); and mild occasional pain at 3 months (OS, 1 subject).

TABLE 2. PATIENT SATISFACTION AT BASELINE AND 3 MONTHS ACCORDING TO CUSTOM-DESIGNED SELF-ADMINISTERED QUESTIONNAIRE RATING VISUAL COMPLAINTS IN 68 PATIENTS WHO UNDERWENT MYOPIC LASIK USING THE NIDEK CATZ ALGORITHM

VISUAL COMPLAINT	BASELINE RATING		3-MONTH RATING		DIFFERENCE IN MARKED TO SEVERE (%)	*P* VALUE
	NONE TO MODERATE (%)	MARKED TO SEVERE (%)	NONE TO MODERATE (%)	MARKED TO SEVERE (%)		
Light sensitivity	95.28	4.72	98.36	1.64	-3.09	.1682
Difficulty night driving	76.98	23.02	100.0	0.00	-23.0	.0000
Difficulty reading	100.0	0.00	97.54	2.46	2.46	.0795
Double vision	100.0	0.00	100.0	0.00	0.00	…
Fluctuation in vision	100.0	0.00	100.0	0.00	0.00	…
Glare	97.66	2.34	100.0	0.00	-2.34	.0871
Halos	100.0	0.00	98.36	1.64	1.64	.1539
Starbursts	99.22	0.78	98.36	1.64	0.86	.5396

TABLE 2 (continued). PATIENT SATISFACTION AT BASELINE AND 3 MONTHS ACCORDING TO CUSTOM-DESIGNED SELF-ADMINISTERED QUESTIONNAIRE RATING VISUAL COMPLAINTS IN 68 PATIENTS WHO UNDERWENT MYOPIC LASIK USING THE NIDEK CATZ ALGORITHM

	BASELINE RATING		3-MONTH RATING		DIFFERENCE IN	
VISUAL COMPLAINT	NONE TO MODERATE (%)	MARKED TO SEVERE (%)	NONE TO MODERATE (%)	MARKED TO SEVERE (%)	MARKED TO SEVERE (%)	*P* VALUE
Dryness	100.0	0.00	96.72	3.28	3.28	.0420
Pain	100.0	0.00	100.0	0.00	0.00	…
Foreign body	100.0	0.00	100.0	0.00	0.00	…
Other*	94.59	5.41	97.14	2.86	-2.55	.5914

CATz, customized aspheric treatment zone; LASIK, laser in situ keratomileusis.
*Other complaints were marked headaches at screening (both eyes of 1 subject); mild headache (both eyes of 1 subject); marked "focusing" at 3 months (1 subject); and mild occasional pain at 3 months (OS, 1 subject).

DISCUSSION

In this investigation of LASIK for the treatment of low to moderate myopia with astigmatism using the Nidek CXIII excimer laser with the topographically guided CATz software, all of the refractive and visual acuity outcomes exceeded the FDA criteria at 6 months postoperatively. Safety was demonstrated, with no eyes losing 2 or more lines of BSCVA 6 months after surgery (Figure 3).

The results in this study are consistent with previous studies of topography-guided LASIK treatment of myopia with astigmatism that found it to be safe and effective.[2,3] Two separate studies of CATz with smaller sample sizes yet a larger treatment range than in this study found that no eyes lost 2 or more lines of BSCVA.[2,3] Kermani and colleagues[3] found that 90% of the eyes undergoing CATz were within 0.50 D of the intended MRSE, which is similar to results of 93% in this study. Although the outcomes reported in this study surpass FDA criteria for approval, refractive outcomes can be improved with nomogram refinement. The trend toward undercorrection plotted in Figure 3 could be addressed using either revised software in the laser or individual center nomogram calculations.

The outcomes of this study confirm that topography-guided LASIK is a clinically valuable alternative to ocular wavefront–guided treatment of primary myopia and astigmatism. For example, within 6 months after surgery, 89% of the eyes had UCVA of 20/20 or better without correction (Figure 1). Additionally, at 20/16 or better levels, 6-month postoperative UCVA exceeded preoperative BSCVA in over 25% of cases. There was a clinically significant gain of 2 lines or more of BSCVA in 16% of the eyes (Figure 2). Awwad and colleagues[16] treated a similar range of primary myopia as in this study, but used the VISX CustomVue and Alcon CustomCornea wavefront platforms, and found that 89% of eyes saw 20/20 without correction. Similarly, in a prospective, randomized study of the Wavelight and CustomCornea platforms, 80% of eyes achieved UCVA of 20/20.[17] Comparison of our outcomes to the aforementioned studies indicates that the CATz outcomes are equivalent to those reported for wavefront-guided treatments.[18]

In this study, an aspheric treatment zone was utilized to treat myopic astigmatism. Use of aspheric treatments reduces the steep changes in corneal curvature, which may reduce the induction of aberrations compared to conventional ablation. In this study, we found a mild increase in total higher-order aberration RMS of 0.04 µm, a mild increase in spherical aberration of 0.053 µm, and a mild but statistically significant increase of 0.03 µm in coma. Analyzing conventional ablations for myopia and myopic astigmatism, with the Nidek CXIII excimer laser, Du and colleagues[6] reported an increase in RMS of 0.241 µm for ocular higher-order aberrations, an increase of 0.139 µm of spherical aberration, and an increase of 0.183 µm of coma. The outcomes presented by Du and colleagues show a significant increase in higher-order aberrations compared to the values obtained for CATz in our study. Du and colleagues also found a statistically significant increase in higher-order aberrations in conventional ablations compared to CATz treatments.[6] This reduced induction of higher-order aberrations may allow better visual quality after CATz ablation compared to conventional ablation.

Visual symptoms after CATz treatment were generally mild. Most strikingly, we found a 23% decrease in patients reporting marked to severe difficulties in night driving, and less than 3% of patients reported an increase in moderate to severe mesopic/scotopic symptoms such as halos, glare, or starburst postoperatively (Tables 1 and 2). Using the RSVP questionnaire in patients who underwent conventional ablation, Schein and colleagues[15] found a worsening of scotopic symptoms by an average of 14.5% and driving by 29.5%, although it is unclear if this was specifically night driving. One study[14] found statistically significantly better visual quality after OATz treatments using the Nidek advanced vision excimer (NAVEX) laser platform compared to conventional treatments. The questionnaire results clearly indicate that CATz topography-guided LASIK gave excellent outcomes in terms of quality of vision and patient satisfaction. Contrast sensitivity testing and comparison to a control group would likely help verify the results obtained here.

The apparent use of small optical zones with CATz requires explanation. The optical zone and transition zone are misnomers when referring to CATz treatments because both zones combine to provide the refractive correction and should be referred to as the treatment zone. A small optical zone might be more prone to decentration, but we do not think the risk of decentration with CATz is any higher than the risk with the 6.50-mm optical zone and 7.50-mm transition zone commonly used in conventional treatments with the CXIII in North America, especially since the procedure used a 200-Hz eye tracker.

The 6-month results presented in this study indicate that topography-guided CATz treatment of myopic astigmatism with the Nidek CXIII is safe, gives excellent refractive and visual acuity results, increases higher-order aberrations minimally, maintains preoperative contrast sensitivity, and improves most patient symptoms compared to baseline.

ACKNOWLEDGMENTS

Funding/Support: None.
Financial Disclosures: Dr Dougherty is a consultant to NIDEK Co, Ltd, and Alcon, Inc. Mr. Bains is a consultant to NIDEK Co, Ltd. Dr Waring is a consultant to NIDEK Co, Ltd, Advanced Medical Optics, Inc, Acufocus, Inc, Calhoun Vision, Inc, and Schwind. Dr Chayet is a consultant to NIDEK Co, Ltd, and Calhoun Vision, Inc. Dr Fant is a consultant to NIDEK Co, Ltd, and has a financial interest in Clinical Research Consultants Inc. Dr Stevens is a consultant to NIDEK Co, Ltd, and Clinical Research Consultants Inc.
Author Contributions: *Design and conduct of the study* (G.W., H.S.B., B.F., G.S); *Collection, management, analysis, and interpretation of the data* (G.W., H.S.B, B.F., G.S); *Preparation, review, and approval of the manuscript* (G.W., P.J.D., H.S.B., J.F., A.C.).

REFERENCES

1. Kanjani N, Jacob S, Agarwal A, et al. Wavefront- and topography-guided ablation in myopic eyes using Zyoptix. *J Cataract Refract Surg* 2004;30:398-402.
2. Pop M, Bains HS. Clinical outcomes of CATz versus OPDCAT. *J Refract Surg* 2005;21:S636-639.
3. Kermani O, Schmiedt K, Oberheide U, Gerten G. Topographic- and wavefront-guided customized ablations with the NIDEK-EC5000CXII in LASIK for myopia. *J Refract Surg* 2006;22:754-763.
4. He R, Qu M, Yu S. Comparison of NIDEK CATz wavefront-guided LASIK to traditional LASIK with the NIDEK CXII excimer laser in myopia. *J Refract Surg* 2005;21:S646-649.
5. Kermani O, Schmiedt K, Oberheide U, Gerten G. Early results of Nidek customized aspheric transition zones (CATz) in laser in situ keratomileusis. *J Refract Surg* 2003;19:S190-194.
6. Du CX, Yang YB, Shen Y, Wang Y, Dougherty PJ. Bilateral comparison of conventional versus topographic-guided customized ablation for myopic LASIK with the NIDEK CXIII. *J Refract Surg* 2006;22:642-646.
7. Farooqui MA, Al-Muammar AR. Topography-guided CATz versus conventional LASIK for myopia with the NIDEK CXIII: a bilateral eye study. *J Refract Surg* 2006;22:741-745.
8. Yeung IY, Mantry S, Cunliffe IA, Benson MT, Shah S. Higher order aberrations with aspheric ablations using the Nidek CXIII CX II laser. *J Refract Surg* 2004;20:S659-662.
9. Mantry S, Yeung I, Shah S. Aspheric ablation with the Nidek EC-5000 CX II with OPD-Scan objective analysis. *J Refract Surg* 2004;20:S666-668.
10. Moreno-Barriuso E, Merayo-Lloves J, Marcos S, Navarro R, Llorente L, Barbero S. Ocular aberrations before and after myopic corneal refractive surgery: LASIK-induced changes measured with Laser Ray Tracing. *Invest Ophthalmol Vis Sci* 2001;42:1396-1403.
11. Marcos S, Barbero S, Llorente L, Merayo-Lloves J. Optical response to LASIK for myopia from total and corneal aberrations. *Invest Ophthalmol Vis Sci* 2001;42:3349-3356.
12. Holladay JT, Dudeja DR, Chang J. Functional vision and corneal changes after laser in situ keratomileusis determined by contrast sensitivity, glare testing and corneal topography. *J Cataract Refract Surg* 1999;25:663-669.
13. Artal P, Guirao A, Berrio E, Williams DR. Compensation of corneal aberrations by the internal optics in the human eye. *J Vis* 2001;1:1-8.
14. Hori-Komai Y, Toda I, Asano-Kato N, Ito M, Yamamoto T, Tsubota K. Comparison of LASIK using the NIDEK CXIII optimized aspheric transition zone (OATz) and conventional ablation profile. *J Refract Surg* 2006;22:546-555.
15. Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery: the Refractive Status and Vision Profile. *J Cataract Refract Surg* 2001;27:665-673.
16. Awwad ST, Bowman W, Cavanagh D, McCulley JP. Wavefront-guided LASIK for myopia using the LADAR CustomCornea and the VISX CustomVue. *J Refract Surg* 2007;23:26-38.
17. Brint S. Higher order aberrations after LASIK for myopia with the Alcon and Wavelight lasers: a prospective randomized trial. *J Refract Surg* 2005;21:S799-803.
18. Venter J. Wavefront-guided LASIK with the NIDEK NAVEX platform for the correction of myopia and myopic astigmatism with 6-month follow-up. *J Refract Surg* 2005;21:S640-645.

PEER DISCUSSION

DR DIMITRI T. AZAR: Waring and colleagues evaluated the efficacy, predictability, safety, wavefront induction, and patient satisfaction of LASIK for low-to-moderate myopia (with astigmatism) using the customized aspheric treatment zone (CATz) algorithm of the Nidek CXIII excimer laser. The treatment was performed using a 5.0-mm refractive optical zone (OZ) and an 8.5-mm transition zone (TZ). Corneal surface irregularities were treated using a 6.0-mm OZ and an 8.5-mm TZ. The quality of vision was assessed using the Refractive Status and Vision Profile and a 10-point self-administered questionnaire. The authors reported impressive results, including mean manifest refraction spherical equivalent of 0.00 ± 0.38 D for the entire cohort at 1 week, -0.04 ± 0.31 D at 1 month, -0.06 ± 0.29 D at 3 months, and -0.09 ± 0.31 D at 6 months; at 6 months postoperatively, there was a higher percentage of eyes with better uncorrected visual acuity than preoperative best spectacle-corrected visual acuity (BSCVA) at the 20/20 or better level of acuity, and no eye lost 2 or more lines of BSCVA.

The 6-month results presented in this study indicate that topography-guided CATz treatment of myopic astigmatism (1) is safe, (2) gives excellent refractive and visual acuity results, (3) results in minimal increase in higher-order aberrations, and (4) maintains preoperative contrast sensitivity. However, topography-based treatments have 3 major theoretical limitations: exclusion of the internal aberrations from the treatment (which may lead to decoupling of lenticular and corneal aberrations and may alter postoperative visual quality); arbitrary setting of the postoperative asphericity; and spherical refractive error estimation difficulties.

Although this study was not designed to compare topography-based to wavefront-based customized treatments,[1] topography-guided treatments should be helpful for the correction of postoperative refractive errors.[2,3] This approach would also be useful for patients with preoperative confirmation that aberrations are primarily corneal in origin (with absent lenticular astigmatism).

ACKNOWLEDGMENTS

Funding/Support: None.
Financial Disclosures: None.

REFERENCES

1. Sakimoto T, Rosenblatt MI, Azar DT. Laser eye surgery for refractive errors. *Lancet* 2006;367:1432-1447.
2. Jin GJ, Merkley KH. Retreatment after wavefront-guided and standard myopic LASIK. *Ophthalmology* 2006;113:1623-1628.
3. Jin GJ, Merkley KH. Conventional and wavefront-guided myopic LASIK retreatment. *Am J Ophthalmol* 2006;141:660-668.

DR. VERINDER S. NIRANKARI: Wonderful paper. Since you are looking at topographic versus wavefront analysis, would it not be better to consider surface ablation instead of LASIK because you would probably induce less aberration?

DR. ALLAN J. FLACH: I have no conflicts. I noticed one of the coauthors is a Doctor of Pharmacy. I occasionally teach in a school of pharmacy where I am employed and, in fact, I graduated with a PharmD degree four decades ago. I am curious to learn what the Doctor of Pharmacy did in your research project. I was shocked that the FDA does not want you to modify your technique, because if you were doing my care I would want you to make these changes. It brings to mind when the astronauts were about to embark to space travel they made it very clear they would not permit the government to treat them like a bunch of monkeys. They made it known that they were thinking people. I think you should make this same point very clear to the FDA. Their job is to provide safety for us and to guarantee some efficacy, but no one has ever said they should practice medicine. Can you comment on that?

DR. DANIEL S. DURRIE: I work with several excimer laser companies, so I do have a conflict. George bought up a very important point. This is just a comment about a significant problem we have with our present system of obtaining FDA approval for the next generation of software that will be used with the existing lasers. Because the required approval process is so lengthy and cost ineffective, companies are just not developing them now. I think we, as an industry, should start looking into the system. I believe that all of us in ophthalmology should be working on getting better devices and new software approved more quickly and cost effectively. Of the 7 excimer laser companies in the United States, only 2 of them that are looking into this particular application, although all of them could. Much of this has to do with difficulty of proceeding with clinical trials in the United States.

DR. WILLIAM M. BOURNE: I have no conflicts. George, I was not clear about the higher order aberrations you were measuring preoperatively and postoperatively. If the measurement was all topographic, as I assume, then you were not including the lens, so that especially the spherical aberration that you mentioned was not canceled out. Corneal aberrations are canceled out by the lens that is not that included in your analysis. If it is not included, then when a patient has a cataract removed, there is going to be a much different whole-eye higher order aberration present afterwards. Were you only including the cornea? That is what I was not clear about.

DR. GEORGE O. WARING, III: Dimitri, thank you. I would commend to you the review article that Dimitri wrote for the Lancet about a year ago. It is really superb. He discusses the whole field of laser vision correction and summarizes the literature for those of you who do not live in the cornea, but want to get up-to-date review. It is really the single best current reference for laser vision correction. Dimitri raises the question of topographically versus wavefront guided treatment. Usually by "wavefront" we mean "whole-eye wavefront", but one can also measure corneal wavefront. We are in the learning phase of this assessment for refractive surgery and I predict that this is not going to be either/or, but a both/and type of evaluation. We are going to learn how to determine which patients might do better with a corneal topography guided or corneal wavefront guided or whole-eye guided treatment. The big variable, of course, is the lens. The cornea remains fairly constant, even with healing after excimer laser surgery; however, the lens continues to change. As Bill Bourne points out, that is a confounding factor in studying these patients long-term. The question is

raised whether we should do surface ablation and not make a LASIK flap which can have some effect on wavefront. Fortunately, just dissecting a LASIK flap produces a minimal effect on the whole eye wavefront higher aberrations, if the flap is properly repositioned. Because visual acuity improves more quickly after LASIK than after PRK and the risk of infection is lower after LASIK than with PRK, LASIK is my preference. Allan, you picked up a Doctor of Pharmacy in the list of authors. Barbara Fant is the person that runs our clinical coordinating group that deals with the regulatory issues. The Doctor of Pharmacy helps us do a really good job in our clinical trials at the clinical centers. She does so much work that we put her on the paper and she certainly deserves to be included. Dan discussed the issue with the FDA problem, and that is a very difficult problem. The job of the FDA is to regulate safety and effectiveness. Regulation increases the likelihood that surgical treatments are safe and effective with devices in our world, and with medications in the drug world. The problem is that the FDA takes their responsibility seriously. We also ought to be sure that they know how the machines work. They want to fix the machines and that goes beyond safety and efficacy. The FDA wants to control how doctors use these machines and that goes beyond their mandate. The idea that a surgeon cannot make preoperative adjustments on a machine, so that each patient might be treated differently and more effectively, and that the FDA requires standardization to determine safety and efficacy, produces a big conundrum. Dan, you have participated in many FDA meetings and you have argued with these people. I believe that we must be very assertive and very participatory in this process. I will tell you there is a move in the FDA and in the world of conflict of interest to eliminate people who have a stated conflict of interest from serving on advisory panels. For example, neither Dan Durrie nor I can, could, or should serve on an ophthalmic devices advisory panel because we consult with commercial companies and have disclosed the level of our consultancy. Where does that leave those who make recommendations to the FDA? I contend that the less well informed individuals who are not really actively working in the field are selected for the panels and this generates is a big conundrum for dealing with the FDA. Bill, what we reported in this study are total-eye wavefront results, they are not “topographic wavefront results”. We corrected the cornea and did so the basis of our topographic measurements, but then we measured the total wavefront of the eye with the OPD. The changes are obviously changes in the cornea and not in the lens. If the lens changes later, then that confounds the long-term assessment with this technique. Thank you all for staying for the last presentation today. I appreciate the chance to respond the discussants.