Wavefront-guided Custom Ablation for Myopia Using the NIDEK NAVEX Laser System

Jan Venter, MD

ABSTRACT

PURPOSE: To determine the predictability, efficacy, safety, and stability of LASIK using custom ablation with the NIDEK Advanced Vision Excimer Laser System (NAVEX).

METHODS: One hundred twenty eyes underwent LASIK for myopia using the OPDCAT algorithm. Refractive outcomes and the change in higher order aberrations, coma, and spherical aberrations were analyzed. Postoperative follow-up ranged from 6 to 18 months.

RESULTS: Mean postoperative spherical equivalent refraction was −0.05 diopters (D) (range: −0.92 to +0.88 D). Uncorrected visual acuity was 1 or better in 109 (91%) eyes and 1.2 or better in 47 (39%) eyes. Postoperative spherical equivalent refraction was within ±0.50 D of intended correction in 110 (92%) eyes. Fifty-two (43%) eyes gained 1 or more lines of best spectacle-corrected visual acuity (BSCVA), and no eyes lost more than 1 line of BSCVA. Higher order aberrations root-mean-square increased by 0.053 µm postoperatively. Patients with preoperative higher order aberrations ⩾0.3 µm were less likely to have induced higher order aberrations.

CONCLUSIONS: Wavefront-guided OPDCAT treatments with the NIDEK NAVEX system for myopia are safe and effective with excellent visual acuity and refractive outcomes. Eyes with ⩾0.3 µm of higher order aberrations preoperatively will benefit more from OPDCAT treatment than eyes with a smaller amount of higher order aberrations. [*J Refract Surg.* 2008;24:487-493.]

Conventional excimer laser refractive surgery such as photorefractive keratectomy (PRK) and LASIK corrects lower order aberrations of the eye such as myopia, hyperopia, and astigmatism. Although the safety of these procedures has been well established,[1,2] there is a significant induction of higher order aberrations postoperatively.[3,4] Significant induction of higher order aberrations has been implicated in decreased visual quality of the eye.[4]

The recent introduction of wavefront-guided custom ablation has been shown to reduce the induced higher order aberrations postoperatively.[4-6] Custom ablation treats both lower order aberrations and higher order aberrations such as coma, trefoil, and spherical aberration. By targeting higher order aberrations, custom ablation can prevent or reduce these aberrations and thus reduce the risk of night vision disturbances postoperatively. The goal of custom ablation is to improve the optical performance of the eye compared to conventional surgery.

The purpose of this study was to determine the predictability, efficacy, safety, and stability of custom ablation LASIK with the NIDEK Advanced Vision Excimer Laser system (NAVEX; NIDEK Co Ltd, Gamagori, Japan). This study used the optical path difference custom aspheric treatment (OPDCAT) as the ablation algorithm. Optical path difference custom aspheric treatment uses an aspheric algorithm for the optical and transition zones to maintain the physiologic corneal shape and treats ocular higher order aberrations using MultiPoint spot ablation.

PATIENTS AND METHODS

Patient Population and Ophthalmic Examinations

In this retrospective study, 120 eyes underwent custom ablation with OPDCAT using the NAVEX system. The NAVEX

From Optimax Laser Eye Clinics, London, United Kingdom.

The author has no proprietary interest in the materials presented herein.

Correspondence: Jan Venter, MD, Optical Express, 5 Deerdykes Rd, Westfield Industrial Estate, Cumbernauld, Glasgow G68 9HF, United Kingdom. Tel: 0870 220 2020; Fax: 0123 673 0300; E-mail: javenter@onetel.com

Received: October 16, 2006

Accepted: April 24, 2007

Posted online: November 15, 2007

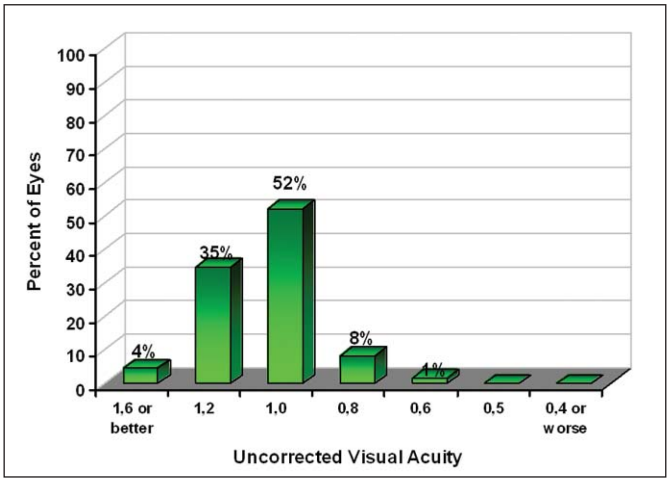

Figure 1. Efficacy graph shows the change in uncorrected visual acuity at a mean of 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

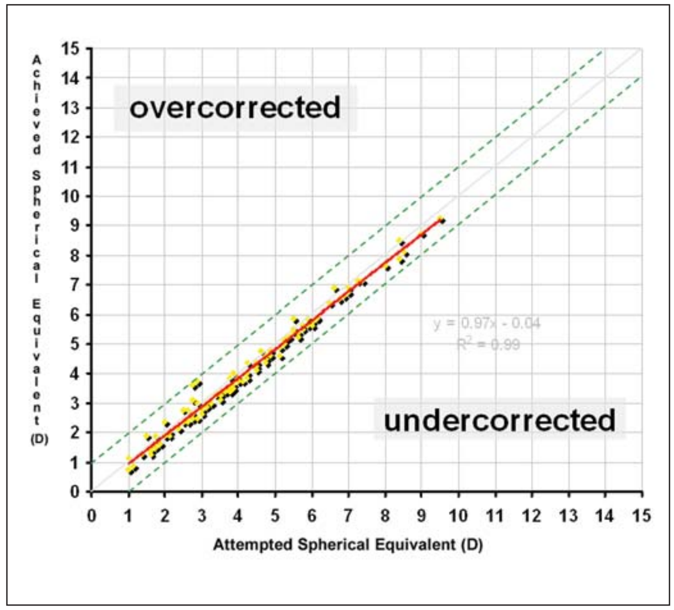

Figure 2. Predicability graph at 10 months postoperatively shows the attempted change in spherical equivalent refraction versus the achieved change for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

system consists of the OPD-Scan wavefront sensor and corneal topographer, the EC-5000CX excimer laser, the MK-2000 keratome, and Final Fit ablation planning and shot generation software.

Average patient age was 34 years (range: 20 to 61 years); 55.5% of patients (67 eyes; 35 patients) were women and 44.5% (54 eyes; 28 patients) were men. Right eye treatments comprised 50.8% (61 eyes) of cases and left eye treatments comprised 49.2% (59 eyes) of cases. Mean preoperative manifest refraction spherical equivalent was -3.88 ± 2.01 diopters (D) (range: -9.50 to -1.15 D). Mean preoperative sphere was -3.89 ± 1.96 D (range: -9.00 to -0.25 D), and mean preoperative cylinder was -0.67 ± 0.71 D (range: -4.50 to 0.00 D).

All patients underwent ophthalmic examinations preoperatively and 1 week and 1, 3, 6, 12, and 18 months postoperatively that included measurement of distance uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA), manifest and cycloplegic refractions, slit-lamp examination, corneal topography and aberrometry using the OPD-Scan, corneal thickness, keratometric power, and a dilated fundus examination. Postoperatively, a dilated fundus examination and cycloplegic refraction was conducted only if clinically warranted. Data for the last postoperative visit ranging from 6 to 18 months are reported. MultiPoint treatment rate and mean±standard deviation spot ablation depth data are not available because the author moved to a different surgical center.

Surgical Technique

All eyes underwent LASIK. Eyes were prepared in a sterile fashion for surgery. One or two drops of topical anesthetic were instilled, and a sterile drape was used to isolate the surgical field. A lid speculum was inserted to allow maximum exposure of the globe. An automated mechanical microkeratome was used to create the keratectomy. After reflection of the flap and prior to ablation, iridic landmarks of the eye in the supine position were compared to an OPD image using the torsion error detector function of the laser, and the eye was rotated to account for any cyclotorsion. Proper alignment of the eye with the laser was achieved with a 200-Hz infrared eye-tracker centered on the pupil. The flap was reflected back to expose the stroma, and the ablation was delivered to the stromal bed. Patients fixated on a red fixation light, coaxial with the surgeon's line of sight and the excimer laser beam, throughout the ablation. The flap was repositioned and the interface was irrigated with balanced salt solution to remove any debris. Postoperatively, patients received topical fluoroquinolone antibiotic and corticosteroid drops four times daily for 1 week.

All eye images acquired using the OPD-Scan were performed under scotopic conditions to ensure adequate physiologic pupil dilation for wavefront measurements. All maps were checked by the author for consistency and the lack of artifacts prior to simulating treatment using the Final Fit software. The SO 95-C120-S26 nomogram loaded into the Final Fit version 1.11 software was used for all treatments. The MultiPoint

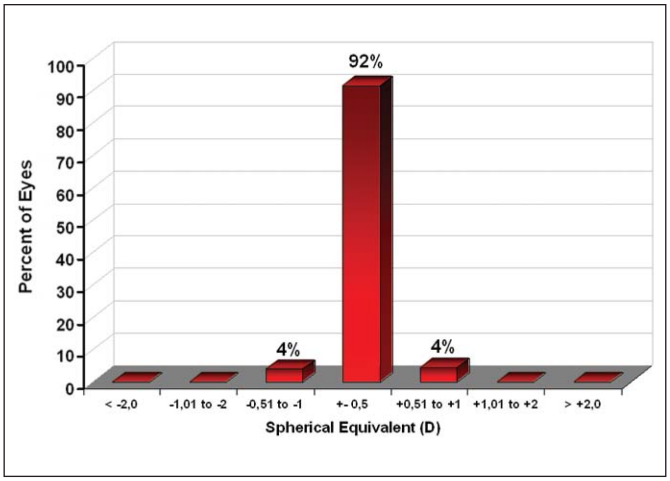

Figure 3. Refractive outcomes at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

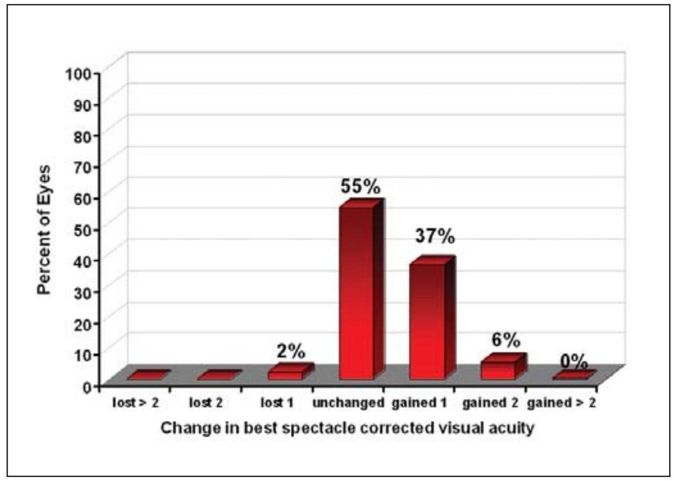

Figure 4. Safety graph at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

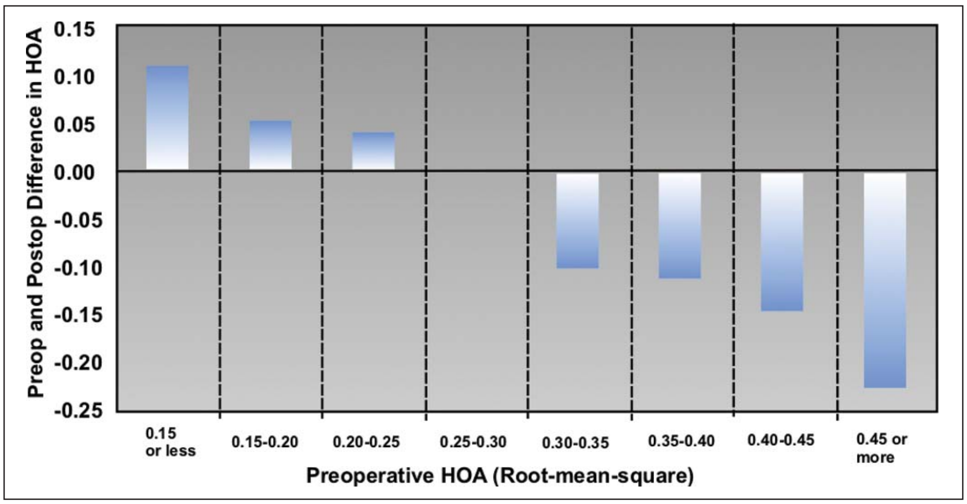

Figure 5. Preoperative higher order aberrations (HOA) (μm) compared to the induction of aberrations at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

treatment rate was 60% using a 1-mm spot diameter. All eyes were targeted for emmetropia after treatment.

RESULTS

Mean follow-up was 10.2±2.15 months. Mean postoperative manifest refraction spherical equivalent was −0.05±0.28 D (range: −0.92 to +0.88 D). Mean postoperative sphere was 0.06±0.28 D, and mean postoperative cylinder was −0.28±0.27 D. The efficacy graph shows 109 (91%) eyes had UCVA 1.0 or better and 47 (39%) eyes had UCVA of 1.2 or better (Fig 1). The predictability of the procedure shows a tight grouping of points with all data points well within the ±1.00 D standard deviation and an R^2 value of 0.99 (Fig 2). Postoperatively, manifest refraction spherical equivalent was within ±0.50 D of the intended correction in 110 (92%) eyes (Fig 3). Fifty-two (43%) eyes gained 1 line or more of BSCVA, and no eyes lost more than 1 line of BSCVA (Fig 4).

All root-mean-square (RMS) values are reported for a 6-mm pupil diameter. The higher order aberrations RMS changed from 0.410 µm preoperatively to 0.463 µm postoperatively. Lower amounts of preoperative higher order aberrations RMS had greater levels postoperatively. The baseline range in which this was observed was ⩾0.300 µm (Fig 5). As the magnitude of preoperative higher order aberrations RMS increased, there was an inverse linear correlation to the magnitude induced postoperatively (Fig 6). Eyes with lower levels of higher order aberrations RMS preoperatively (mean: 0.336 µm; range: 0.160 to 0.450 µm) showed an increase postoperatively, whereas eyes with higher levels preoperatively (mean: 0.629 µm; range: 0.451 to 0.860 µm) showed a decrease postoperatively (Fig 7).

Mean coma was 0.192 µm preoperatively and 0.245 µm postoperatively. Lower preoperative coma induced greater levels of coma postoperatively (Fig 8). For levels of coma >0.300 µm preoperatively, the

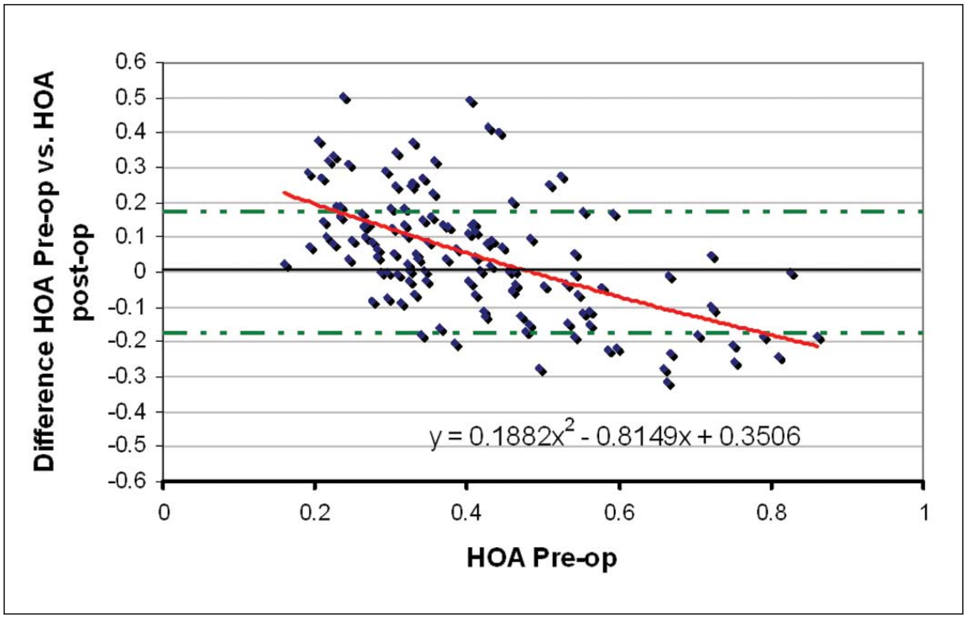

Figure 6. Scatterplot of preoperative higher order aberrations (HOA) root-mean-square (RMS) (μm) at 10 months postoperatively versus the difference in preoperative and postoperative HOA RMS for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

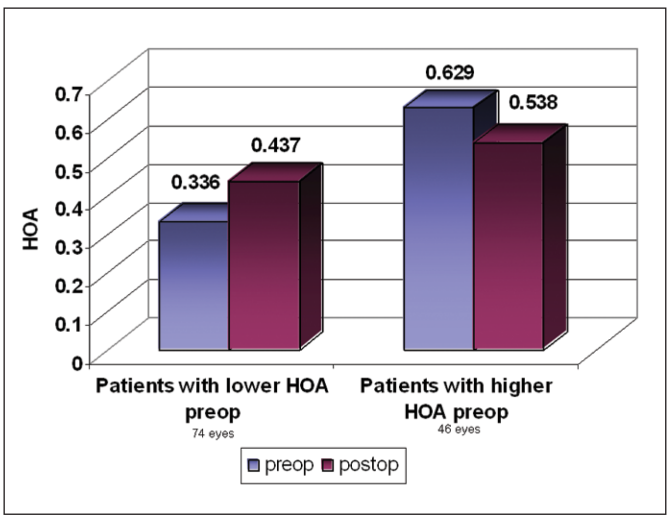

Figure 7. Comparison of the induction of higher order aberrations (HOA) root-mean-square (RMS) in eyes with lower preoperative levels of HOA RMS and eyes with higher preoperative HOA RMS at 10 months postoperatively (N = 120 eyes).

postoperative level of coma decreased in the majority of eyes (see Fig 8). As the magnitude of preoperative coma increased, there was an inverse linear correlation to the magnitude of coma induced postoperatively (see Fig 8).

Mean spherical aberration was 0.116 µm preoperatively and 0.177 µm postoperatively. Eyes with low preoperative levels of spherical aberration (range: 0.100 to 0.150 µm) had greater levels of spherical aberration postoperatively (Fig 9). As the magnitude of preoperative spherical aberrations increased, there was a mild inverse linear correlation to the magnitude of spherical aberrations induced postoperatively (see Fig 9).

There was no correlation between preoperative low to moderate myopic treatments and the induced higher order aberrations RMS postoperatively (Fig 10). Preoperative myopia >7.00 D had a trend toward greater induction of higher order aberrations (see Fig 10). Comparison of the mean preoperative sphere of eyes that had a reduction in higher order aberrations RMS postoperatively to the mean preoperative sphere of eyes that had an increase of higher order aberrations RMS found no statistically significant difference in sphere between these groups.

The modulation transfer function is a measure of image quality that plots the ability of the eye to transfer object contrast to the image. The area under average modulation transfer function curves increased after OPDCAT treatment (Fig 11). The ratio of A/B, representing the mean optical performance of all eyes compared to that of the best human eyes, increased significantly after OPDCAT treatment (see Fig 11). The ratio of H/B, representing the mean optical performance of all eyes due to higher order aberrations compared to the performance of the best human eyes, decreased slightly after OPDCAT treatment (see Fig 11). Postoperatively, the higher spatial frequencies from 25 cycles per degree to 60 cycles per degree increased for the curve representing the performance of all eyes due to higher order aberrations (purple curve in Fig 11) compared to preoperative performance (see Fig 11).

DISCUSSION

This investigation of the treatment of primary myopic eyes using the OPDCAT custom ablation algorithm shows the procedure was safe, with no eyes losing more than 1 line of BSCVA. Long-term efficacy was

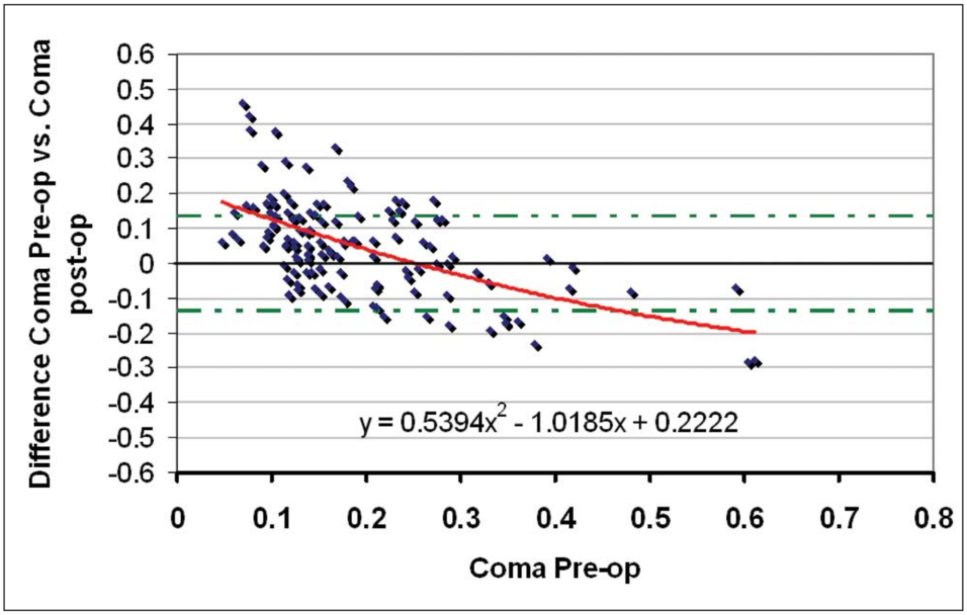

Figure 8. Scatterplot of preoperative coma (μm) versus coma at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

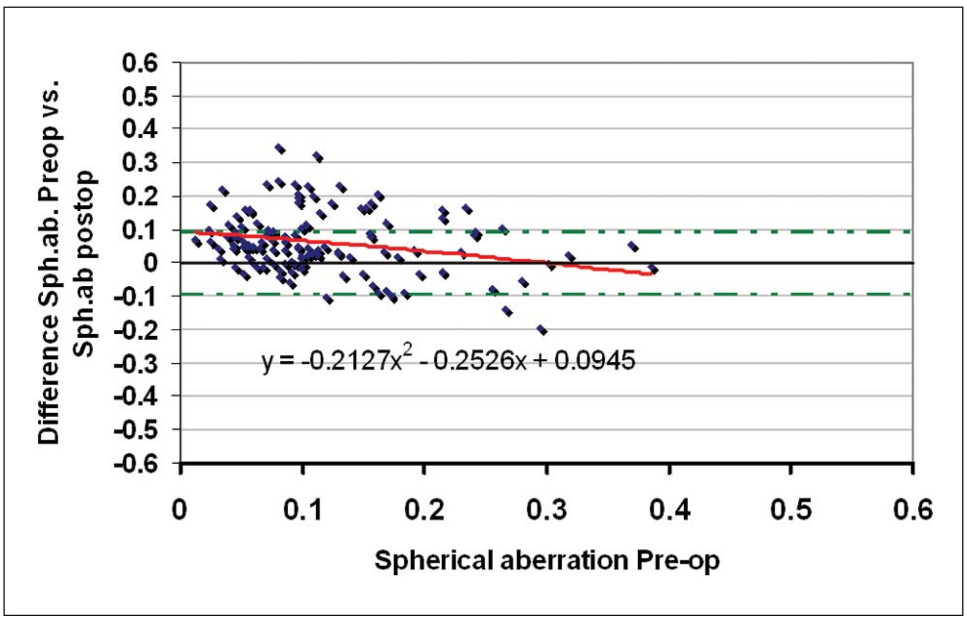

Figure 9. Scatterplot of preoperative spherical aberration (μm) versus spherical aberration at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

excellent, with 109 (91%) eyes having UCVA of 1.0 or better and 47 (39%) eyes having UCVA of 1.2 or better. The outcomes obtained in this study are consistent with previous studies that have shown OPDCAT to be safe and efficacious for the treatment of myopia with and without astigmatism.[7] In a single center study of 84 myopic eyes, Pop and Bains[7] reported 94.5% eyes with BSCVA of 1.0 or better.

The nomogram used in this study gave accurate results with no significant trend toward undercorrection or overcorrection (see Fig 2). The refractive outcomes in this study produced encouraging results. For example, the majority of eyes achieved functional UCVA of 0.8 (see Fig 1). Optical path difference custom aspheric treatment for myopia demonstrated excellent refractive outcomes, with postoperative manifest refraction spherical equivalent within ±0.50 D of the intended correction in 110 (92%) eyes (see Fig 3).

The outcomes reported in this study surpass the outcomes reported for conventional LASIK for myopia.[8,9] Conventional LASIK can increase the level of higher order aberrations 37% to 62%, resulting in decreased visual quality.[10,11] One of the most significant aberrations induced after conventional LASIK is spherical aberration, which causes halos and other night vision disturbances postoperatively.[12] The ability to lower the induced higher order aberration after excimer laser ablation is one of the advantages of custom ablation.

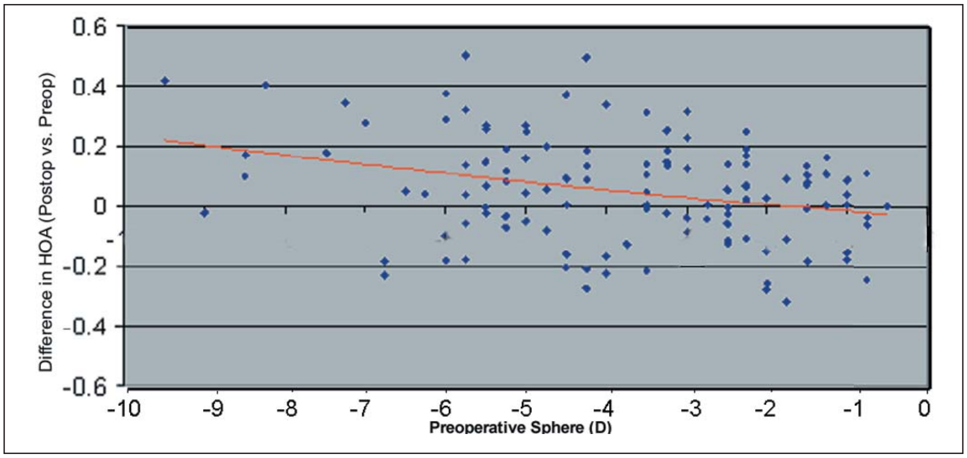

Figure 10. Scatterplot of preoperative myopic sphere compared to the induction of higher order aberration (HOA) at 10 months postoperatively for 120 eyes that underwent optical path difference custom aspheric treatment (OPDCAT).

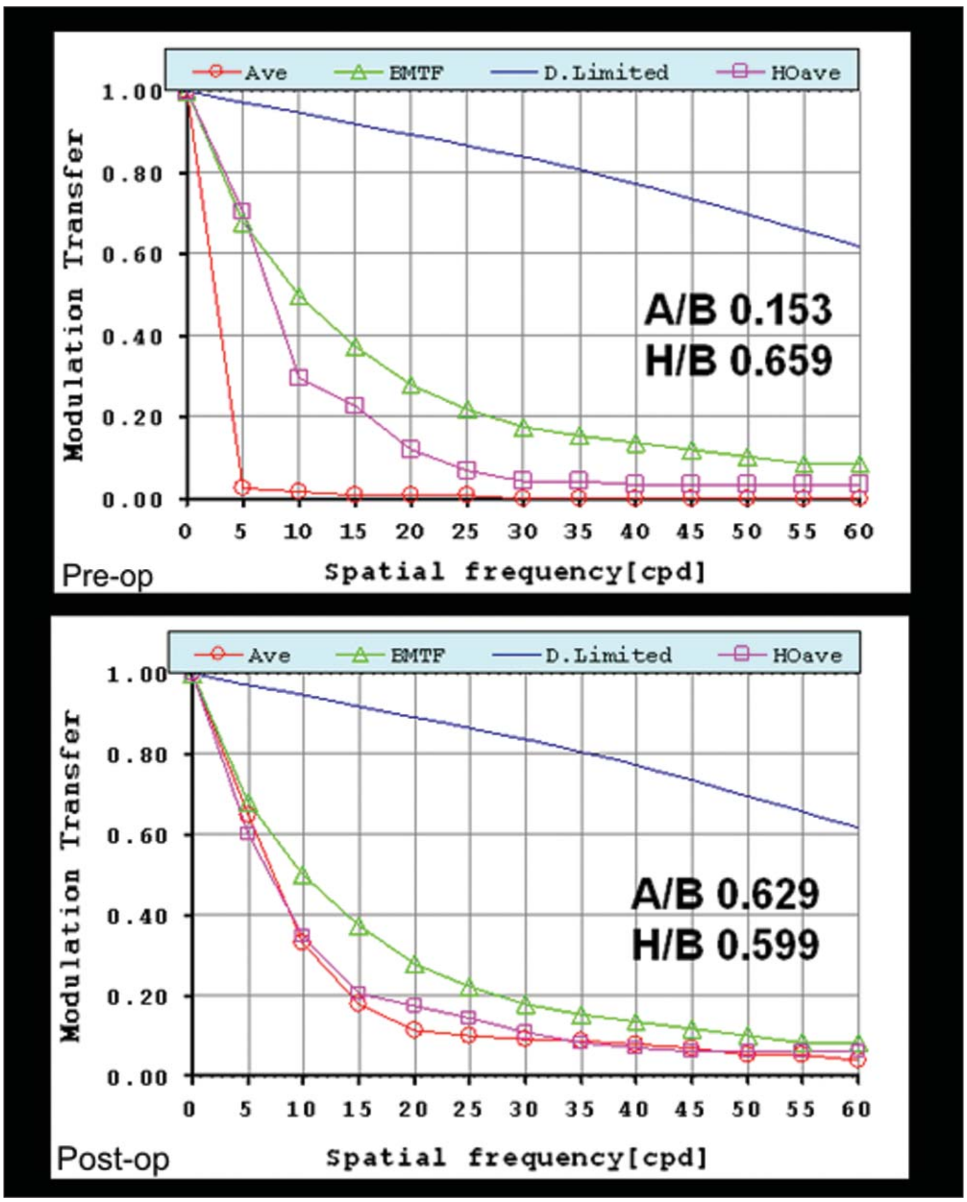

Figure 11. Pre- and postoperative mean modulation transfer functions (MTF) of eyes that underwent optical path difference custom aspheric treatment (OPDCAT). The red line represents the mean MTF curve of all 120 eyes with lower and higher order aberrations, the purple line represents the mean higher order MTF curve of all 120 eyes, the green line represents the best possible MTF curve of the human eye, and the blue line represents the limit of MTF. A/B denotes the ratio of the mean MTF of all eyes (A) with lower and higher order aberration to the best MTF of a human eye (B). H/B denotes the ratio of the mean MTF of all eyes with only higher order aberration (H) included to the best MTF of the human eye (B). Mean postoperative time was 10 months. Ave = curve of the eye, BMTF = representative curve of emmetropic human eye, D.Limited = diffraction limited curve, HOave = curve of the eye with higher order aberrations

However, spherical aberration still can be generated, albeit to a lesser extent, with custom ablation. Spherical aberration is generated after custom and conventional ablation due to laser delivery on the cornea that induces significant curvature changes in corneal topography.[4] One strategy to limit the induced spherical aberration is the use of aspheric ablation profiles such as OPDCAT that maintain the physiological prolate shape of the cornea postoperatively.

There was a mild increase of 0.053 μm in the mean higher order aberrations RMS in eyes treated with OPDCAT. On further analysis, eyes with ⩽0.3 μm higher order aberrations RMS preoperatively had an increase of 0.101 μm postoperatively; eyes with ⩾0.60 μm higher order aberrations RMS preoperatively demonstrated a decrease of 0.091 μm postoperatively (see Figs 5 and 6). From these observations, the author believes eyes with >0.30 μm of higher order aberrations preoperatively will benefit the most from custom ablation.

Analysis of coma and spherical aberrations also seem to follow this trend. For example, as the magnitude of coma increased >0.30 μm, there was less induction of coma postoperatively (see Fig 8). The induction of spherical aberration was minimal, with the majority of eyes showing <0.20 μm of induced spherical aberration postoperatively (see Fig 9). The reduced induction of spherical aberration postoperatively likely was the result of the aspheric treatment incorporated into the OPDCAT algorithm. Induction of higher order aberrations was not statistically significant regardless of the magnitude of myopic sphere treated (see Fig 10). This outcome indicates that for low to moderate myopia, the induction of higher order aberration following laser ablation likely is the result of the preoperative levels of higher order aberrations rather than the ablation itself. The greater induction of higher order aberrations in eyes with fewer higher order aberrations preoperatively might indicate flap creation itself induces a baseline amount of higher order aberration, as seen by the postoperative increase in the higher order aberrations RMS in eyes with lower values preoperatively. In contrast, in eyes with greater levels of preoperative higher order aberrations RMS, the effect of the spot ablation appears to reduce or negate the flap-related effect.

The lower induced levels of higher order aberrations, spherical aberration, and coma theoretically should lead to better visual performance compared to conventional treatments. Modulation transfer function is an objective measure of visual performance. Although the mean ratio of performance of eyes accounting for the higher order aberrations to the performance of the best human eyes (H/B in Fig 11) was slightly lower postoperatively, the mean values for the higher spatial frequencies were slightly (although not statistically significantly) higher. Based on these observations, visual performance is maintained to at least preoperative levels using LASIK with OPDCAT for myopia.

This study indicates OPDCAT treatments with NAVEX for myopia are safe and effective with excellent visual acuity and refractive surgical outcomes and the potential to maintain preoperative levels of visual quality. Eyes with >0.30 μm of higher order aberrations preoperatively will benefit more from OPDCAT treatment than eyes with <0.30 μm of higher order aberrations.

REFERENCES

1. Pop M, Aras M. Multizone/multipass photorefractive keratectomy: six month results. *J Cataract Refract Surg*. 1995;21:633-643.
2. Gimbel HV, van Westenbrugge JA, Penno EE, Ferensowicz M, Feinerman GA, Chen R. Simultaneous bilateral laser in situ keratomileusis: safety and efficacy. *Ophthalmology*. 1999;106:1461-1467.
3. Wang IJ, Sun YC, Lee YC, Hou YC, Hu FR. The relationship between anterior corneal aberrations and contrast sensitivity in conventional LASIK. *Curr Eye Res*. 2006;31:563-568.
4. Hori-Komai Y, Toda I, Asano-Kato N, Ito M, Yamamoto T, Tsubota K. Comparison of LASIK using the NIDEK EC-5000 optimized aspheric transition zone (OATz) and conventional ablation profile. *J Refract Surg*. 2006;22:546-555.
5. Caster AI, Hoff JL, Ruiz R. Conventional vs wavefront-guided LASIK using the LADARVision4000 excimer laser. *J Refract Surg*. 2005;21:S786-S791.
6. Awwad ST, Haithcock KK, Oral D, Bowman RW, Cavanagh HD, McCulley JP. A comparison of induced astigmatism in conventional and wavefront-guided myopic LASIK using LADARVision4000 and VISX S4 platforms. *J Refract Surg*. 2005;21:S792-S798.
7. Pop M, Bains HS. Clinical outcomes of CATz versus OPDCAT. *J Refract Surg*. 2005;21:S636-S639.
8. O'Doherty M, O'Keeffe M, Kelleher C. Five year follow up of laser in situ keratomileusis for all levels of myopia. *Br J Ophthalmol*. 2006;90:20-23.
9. Steinert RF, Hersh PS. Spherical and aspherical photorefractive keratectomy and laser in-situ keratomileusis for moderate to high myopia: two prospective, randomized clinical trials. Summit Technology PRK-LASIK Study Group. *Trans Am Ophthalmol Soc*. 1998;96:197-221.
10. Moreno-Barriuso E, Lloves JM, 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 surgery for myopia from total and corneal aberration measurements. *Invest Ophthalmol Vis Sci*. 2001;42:3349-3356.
12. Yoon G, MacRae S, Williams DR, Cox IG. Causes of spherical aberration induced by laser refractive surgery. *J Cataract Refract Surg*. 2005;31:127-135.