

Topographic- and Wavefront-guided Customized Ablations With the NIDEK-EC5000CXII in LASIK for Myopia

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ABSTRACT

PURPOSE: To assess refractive outcomes, changes in the total higher order root mean square (RMS) aberration, and changes in higher order wavefront aberrations after LASIK for myopia and myopic astigmatism with the NIDEK Advanced Vision Excimer Laser platform (NAVEX) using either an aspheric or topography-based or whole eye wavefront ablation algorithm.

METHODS: This was a retrospective study of 1459 eyes that underwent LASIK for myopia and myopic astigmatism. The mean preoperative spherical equivalent refraction was -4.68 diopters (D) (range: -0.50 to -9.63 D) with astigmatism up to -4.50 D. Treatments were classified into three categories depending on the type of ablation algorithm used—optimized aspheric transition zone (OATz) denoted eyes that underwent aspheric treatment zones; customized aspheric treatment zone (CATz) denoted eyes that underwent customized ablations based on corneal topography; and OPDCAT denoted eyes that underwent customized ablation based on the whole eye wavefront profile. Follow-up data are reported at 3 months (69%) and 12 months (17%) postoperatively.

RESULTS: Three months after LASIK, the predictability (± 0.5 D from target refraction) was 80% for OATz, 91% for CATz, and 76% for OPDCAT. Of all eyes, 96% were within ± 1.0 D of intended refraction 3 months postoperatively and 100% after 12 months (87% ± 0.5 D). In the aspheric and custom groups, a notable improvement of uncorrected visual acuity was noted between 3 and 12 months after LASIK. No eye lost >1 line of best spectacle-corrected visual acuity. Mean higher order RMS increased in all groups.

CONCLUSIONS: The data support that the treatment of myopia and myopic astigmatism is safe and effective with NAVEX. Customized ablation based on corneal topography rather than on total wavefront error was more predictable. [*J Refract Surg.* 2006;22:754-763.]

Laser in situ keratomileusis is currently the most popular surgical treatment for myopia and myopic astigmatism.^{1,2} As the refractive outcomes have become increasingly accurate due to nomogram, laser algorithm adjustments, and the use of larger treatment zones, the focus has shifted to maintaining, or possibly increasing, the quality of vision. This goal may be attained by addressing two major issues: 1) the reduction of induced higher order aberration, and 2) the reduction of pre-existing higher order aberrations.³⁻⁵

To attain these goals, the latest generation of wavefront-based platforms, such as NAVEX (NIDEK Co Ltd, Gamagori, Japan), need to address a number of technical obstacles. The NIDEK OPD-Scan wavefront aberrometer and topographer provides objective visual quality information such as the point spread function (PSF) and modulation transfer function (MTF). To individualize a treatment to a patient, the PSF and MTF allow the surgeon to understand the quality of vision beyond the psychophysical aspect and plan the treatment accordingly. Other challenges in meeting the aforementioned goals include laser ablation alignment. To address this, the use of one instrument to acquire all measurements ensures that the data for corneal topography and total eye wavefront are correctly aligned with respect to each other. Data alignment is fundamental when delivering a precise laser ablation based on topography, wavefront, or both. The precise alignment of laser delivery on the line of sight or visual axis is imperative when delivering a wavefront ablation that ablates minute amounts of tissue. Additionally, the prevention of cyclotorsional errors from sitting to supine position also

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need to be addressed. This information facilitates correct alignment of the corneal axis during surgery. Surgeon input via an ablation planning software would allow true customization of the treatment based on the plethora of factors related to an individual patient. For example, simulating the treatment of peripheral asphericity or the regulation of the depth of ablation specific to the higher order aberration treatment will allow the surgeon to visualize the effect on postoperative topography and wavefront maps.

In this study, we present data of a retrospective analysis of LASIK for myopia and astigmatism using either aspheric, topography-based, or whole eye wavefront-based ablation algorithms using the NAVEX platform. We report the refractive outcomes, incidence of night vision disturbances, changes in various higher order aberrations, and the induced change in total higher order aberrations root mean square (RMS).

PATIENTS AND METHODS

All LASIK procedures were performed at the Ocumax® Augenzentrum (PAN Klinik Am Neumarkt) in Cologne, Germany. All surgeries were performed with the NAVEX, which consists of the EC-5000CXII excimer laser, the NIDEK OPD-Scan ARK-10000 with FinalFit software, and NIDEK MK 2000 microkeratome.

In this retrospective study, 1459 eyes of 748 myopic (with and without astigmatism) patients who underwent LASIK from May 2003 to September 2005 were analyzed. LASIK was performed by two surgeons (O.K., G.G.). Pre- and postoperative examinations were performed by an ophthalmologist (K.S.) and two optometrists. Laser setting calculations and statistical analyses were performed by the center's laser physicist (U.O.).

Treatments were classified in one of three categories depending on the type of ablation algorithm used (Table 1):

- Optimized aspheric transition zone (OATz) (n=1310);
- Customized aspheric treatment zone (CATz) (n=71); or
- Optical path difference customized aspheric treatment zone (OPDCAT) (n=78).

Preoperative examinations included general and ophthalmic medical histories, manifest and mydriatic refractions, tear film testing using the Schirmer I/II and "break-up time" tests, applanation tonometry, slit-lamp microscopy, dilated pupil fundus examination and Orbscan (Bausch & Lomb, Rochester, NY), spatial pachymetry, and anterior as well as posterior corneal topography. The OPD-Scan was used to evaluate corneal topography and aberrometry based on spatial

TABLE 1

Abbreviations for the OPDScan, ARK-10000, and FinalFit Software (NIDEK Co Ltd, Gamagori, Japan)

OATz	Optimized Aspheric Transition Zone—ablation algorithm that creates an aspheric transition zone
CATz	Customized Aspheric Treatment Zone—ablation based on corneal topography coupled with an aspheric transition zone
OPDCAT	Optical Path Difference Customized Aspheric Treatment Zone—customized ablation based on the eye's whole wavefront profile
Segmental Ablation	Wavefront- or topography-guided irregular ablation with multiple laser spots (1.0-mm diameter)
Customized	Term used for either CATz or OPDCAT treatment using a patient-specific topographically guided or aberration-guided ablation pattern

objective refractometry for the central 6.0 mm (OPD map). Wavefront data from the OPD-Scan can be depicted both in refractive diopters and microns of elevation. The topography and aberrometry functions of the OPD-Scan allow the separation of corneal and internal aberrations of the eye. Using ray tracing calculations, this data can be converted to MTF and PSF to display objective visual quality. The OPD-Scan denotes both the visual axis and the line of sight on its maps. Iris landmarks from the acquired OPD-Scan image are compared to the live iris image in the supine position under the excimer laser accounting for any cyclotorsional error.

Exclusion criteria included patients with active systemic or ocular diseases, previous history of corneal or intraocular surgery, women who were pregnant or breast-feeding, and unstable refraction defined as change >0.50 D in the previous 12 months.

The FinalFit treatment planning software was used to individually design an optimized shape of the entire ablation area (Shot Data). Customized ablation profiles were used if two of the following three selection criteria were met:

- Significant higher order aberrations with the presence of specific Zernike polynomials such as coma and/or trefoil dominating the wavefront profile.
- Best spectacle-corrected visual acuity (BSCVA) of $\leq 20/20$.
- Large entrance pupil defined as >5.50 mm.

The decision regarding whether CATz or OPDCAT treatment was used for customization depended on the least amount of segmental ablation in the Shot Data file

and the quality of the simulated target corneal maps. The effect of all modifications could be simulated as target postoperative topography and wavefront maps. With increasing peripheral asphericity, the total ablation depth increased as well. All eyes reflected in this study were treated with a central spherical zone of 4.5 or 5.0 mm and an aspheric peripheral transition zone of 4.0 mm. Effectively, the total ablation zone was 8.5 or 9.0 mm. Ablation depth was 21 μm per diopter myopic correction for the 5.0/9.0 mm treatment zones and 17.5 μm for the 4.5/8.5 mm treatment zones.

Informed consent was obtained from all patients prior to surgery. The MK 2000 microkeratome was used for flap creation. It offers a choice between a 130- μm and 160- μm flap thickness. Corneal flap thickness varied between 110 and 160 μm . The residual corneal bed thickness was calculated to be >250 μm after laser ablation in all cases. The maximum ablation depth was 180 μm . Intraoperatively, after the flap was reflected, the eye was meticulously aligned with the laser aiming beam. Subsequently, the live iris image with the patient supine was compared to that acquired during OPD-Scan acquisition to detect torsional error based on the unique iris landmarks. If a significant torsion error (defined as $>2^\circ$) was detected, the head of the patient was repositioned to account for the torsion error. The laser delivery was aligned on the line of sight. Although relatively rare in the myopic population, if there was a significant difference between the line of sight and visual axis, laser delivery was aligned to the visual axis. The line of sight was identified by the eye tracker using the center of the pupil; the visual axis was identified by the Purkinje images.

Topical anesthesia with three drops of oxybuprocaine (Conjucain-EDO sine; Dr Mann Pharma, Berlin, Germany) within 5 minutes a suction speculum (Geuder, Heidelberg, Germany) was used to expose the globe and maintain even hydration. The flap was created with the microkeratome and lifted. After correct alignment, laser ablation was carried out with the NIDEK-EC5000CXII excimer laser. Multipoint segmental ablation, with a 1.0-mm spot size, was used for the treatment of higher order aberrations prior to the refractive correction. The refractive correction was carried out using a 0.9-mm wide and 9.0-mm long rotating slit beam with a variable energy distribution to enhance peripheral ablation.⁵ Treatment time is minimized by treating the bulk of the refractive correction with the scanning slit and using up to six spots simultaneously to deliver the higher order correction. The maximum depth of multipoint segmental ablation in customized treatments of higher order aberrations (CATz and OPDCAT) was set at 10 μm .

After laser ablation, the corneal bed was irrigated with balanced saline solution (BSS), one drop of preservative-free diclofenac (Voltaren ophtha-sine EDO; Novartis Pharma, Nuernberg, Germany) was applied, and the flap was reflected back on to the cornea. The flap edge was dried and allowed to adhere to the underlying cornea for 1 minute.

Patients were instructed to keep both eyes closed for 4 to 6 hours after surgery. Additionally, shielding glasses were provided for outdoor use for 3 days postoperatively. The patient received dexamethasone-gentamycin eyedrops (Isopto-Max; Alcon Pharma, Irvine, Calif) to be applied 5 times daily for 1 week. Hyaluronic acid-based artificial tears (Biolan; Santen GmbH, Germering, Germany) were prescribed for 6 weeks. Patients with pre-existing dry eye syndrome received punctal plugs (Odyssey, Memphis, Tenn) in the inferior puncta during surgery. Postoperatively, the patients were followed at 1 day, 1 week, and 1, 3, and 12 months. Only 3- and 12-month data are reported. All surgical and postoperative complications were recorded in the medical files. Pre- and postoperative refractive data were compared with regard to outcome and effectiveness, predictability, stability, and safety. The OPD data were used to compare pre- and postoperative higher order aberration RMS as well as coma, spherical, and trefoil values.

RESULTS

The mean preoperative spherical equivalent refraction for OATz was -4.63 ± 2.04 D, -4.65 ± 2.00 D for CATz, and -4.90 ± 2.11 D for OPDCAT. Three months postoperatively, the mean spherical equivalent refraction was -0.12 ± 0.53 D for OATz, -0.02 ± 0.43 D for CATz, and -0.13 ± 0.64 D for OPDCAT. The follow-up rate was 67.4% for OATz, 74.6% for CATz, and 80.8% for OPDCAT at 3 months. At 12 months, only 16.8% of treated eyes were available for follow-up. Retreatments were usually performed between 3 and 12 months postoperatively. We report largely on the 3-month data (Table 2). The retreatment rate (up to 12 months postoperatively) was 1.1% for all eyes.

In the OATz group, 80% of eyes were within ± 0.50 D of the intended correction. In the CATz group, 91% were within ± 0.50 D of the intended correction, whereas for OPDCAT, 76% were within ± 0.50 D of the intended correction. Statistical analysis using *t* tests showed no significant difference between OATz and OPDCAT ($P=.96$). A significant difference was noted between CATz and OPDCAT ($P=.61$) and CATz and OATz ($P=.59$).

At 3 months postoperatively, 96% of all eyes were within ± 1.0 D spherical equivalent refraction of target

TABLE 2

Characteristics of 1459 Eyes That Underwent LASIK for Myopia and Myopic Astigmatism With NAVEX

Characteristic	OATZ	CATZ	OPDCAT
Preoperative			
No. eyes	1310	71	78
Mean age (range) (y)	36 (18 to 68)	33 (18 to 51)	35 (22 to 54)
Sex (%)			
Female	812 (62)	37 (52.1)	38 (48.7)
Male	498 (38)	34 (47.9)	40 (51.3)
Eye (%)			
Left	645 (49.2)	32 (45.1)	39 (50)
Right	665 (50.8)	39 (54.9)	39 (50)
Mean Spherical Equivalent (range) (D)			
Refraction	-4.63 ± 2.04 (-9.63 to -0.50)	-4.65 ± 2.00 (-9.38 to -1.25)	-4.90 ± 2.11 (-9.25 to -0.63)
Sphere	-4.21 ± 2.01 (-9.50 to -0.50)	-4.22 ± 2.06 (-9.00 to -0.75)	-4.54 ± 2.11 (-9.00 to -0.25)
Cylinder	-0.84 ± 0.80 (-4.50 to 0.00)	-0.87 ± 0.78 (-4.25 to 0.00)	-0.72 ± 0.66 (-3.00 to 0.00)
3 Months Postoperative			
No. eyes (%)	883 (67.4)	53 (74.6)	63 (80.8)
Mean Spherical Equivalent (range) (D)			
Refraction	-0.12 ± 0.53 (-3.25 to 1.75)	-0.02 ± 0.43 (-1.00 to 1.50)	-0.13 ± 0.64 (-2.25 to 1.25)
Sphere	0.06 ± 0.53 (-3.25 to 2.00)	-0.17 ± 0.49 (-0.75 to 1.50)	0.02 ± 0.66 (-2.25 to 1.50)
Cylinder	-0.36 ± 0.38 (-2.00 to 0.00)	-0.38 ± 0.45 (-1.75 to 0.00)	-0.30 ± 0.37 (-1.50 to 0.00)

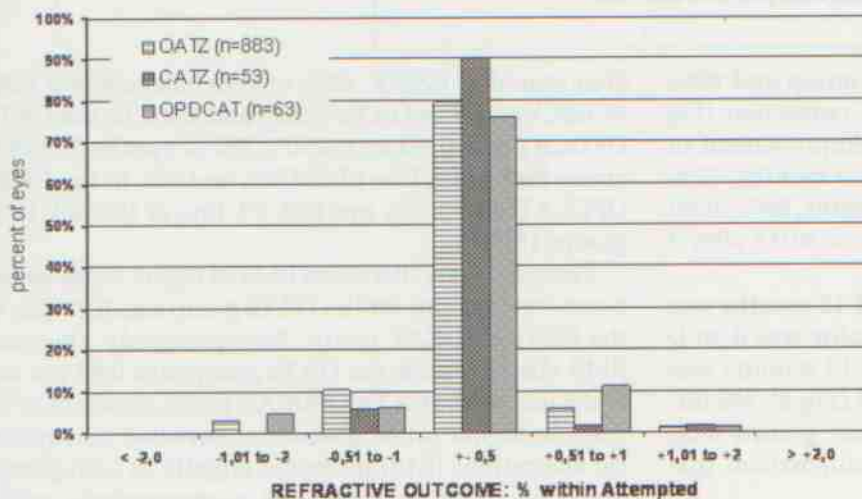


Figure 1. A refractive result of ± 0.5 D was achieved 3 months postoperatively in 80% of the OATz cases, 91% for CATz, and 76% for OPDCAT.

refraction and 100% of eyes after 12 months (Fig 1).

The efficacy of treatments was analyzed comparing the cumulative BSCVA preoperatively to the cumula-

tive UCVA postoperatively. Preoperative BSCVA was 20/20 in 96% of eyes in the OATz group and 93% in the CATz/OPDCAT group. Three months postopera-

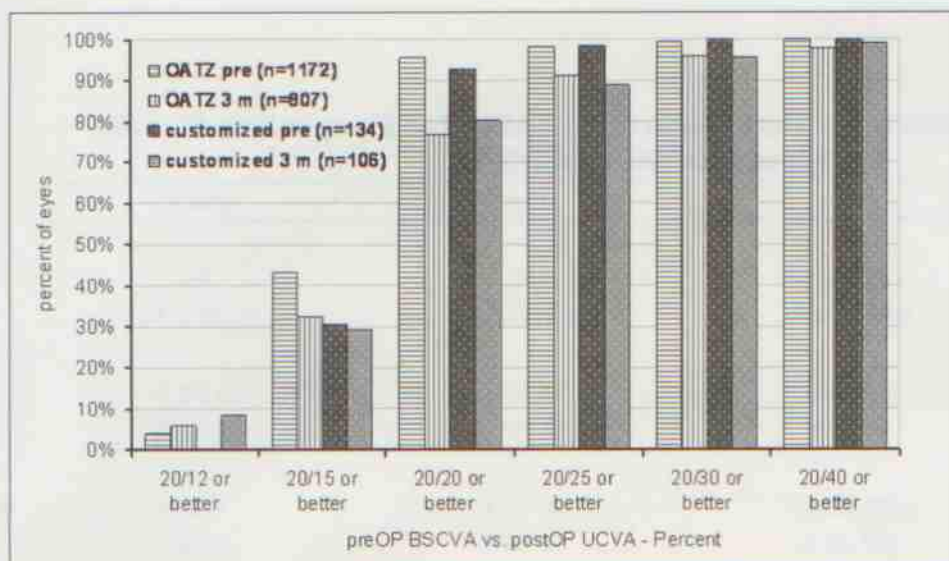


Figure 2. Efficacy. Three months postoperatively 91% of the OATz (aspheric) eyes had UCVA of $\geq 20/25$ (77% $\geq 20/20$ and 32% $\geq 20/15$). For the customized treated eyes (CATz and OPDCAT), 88% had UCVA of $\geq 20/25$ (80% $\geq 20/20$ and 30% $\geq 20/15$).

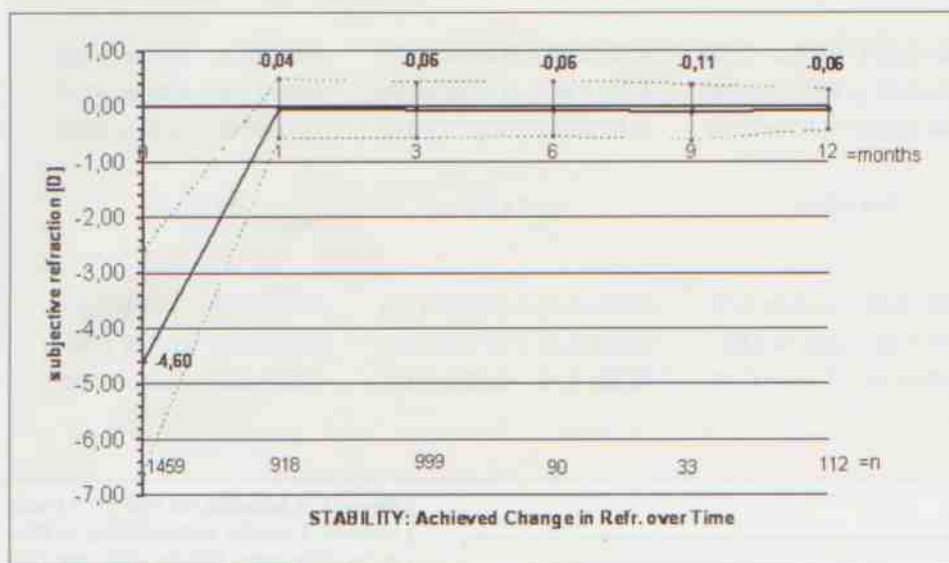


Figure 3. Stability. The refractive results show almost no regression during the first year after surgery. The error bars are the standard deviation of the mean refraction.

tively, 77% saw $\geq 20/20$ in the OATz group and 80% in the CATz/OPDCAT group without correction (Fig 2). In both groups, there was notable improvement of UCVA between 3 and 12 months. After 3 months, 77% of all eyes saw $\geq 20/20$, and after 12 months, 86% of all eyes saw $\geq 20/20$. Of all eyes, 31% saw $\geq 20/15$ after 3 months and 45% after 12 months.

Regression in all eyes between 3 and 12 months was -0.008 D (standard deviation at 3 months was 0.50 D spherical equivalent refraction and at 12 months was 0.36 D spherical equivalent refraction) (Fig 3). No difference was noted in either of the three groups with respect to the amount of myopia or astigmatism that was treated.

Safety analyses revealed 17% loss of 1 line of BSCVA in the OATz group and 16% in the CATz/OPDCAT group. There was a 28% gain of ≥ 1 line of BSCVA in the OATz group and 32% in the CATz/OPDCAT group.

One year after LASIK, 51% of eyes had gained ≥ 1 line of BSCVA in the OATz group and 60% in the CATz/OPDCAT group. At 12 months, 8% of eyes in the OATz group had lost 1 line of BSCVA and 7% in the CATz/OPDCAT group. No eye lost >1 line of BSCVA in all groups (Fig 4).

Preoperatively, the mean RMS of higher order aberrations was $0.35 \mu\text{m}$ for the OATz group and $0.43 \mu\text{m}$ for the CATz/OPDCAT group. Postoperatively, the mean RMS aberration for the OATz group was $0.48 \mu\text{m}$ and $0.465 \mu\text{m}$ for the CATz/OPDCAT group. Analysis of the specific higher order aberrations revealed that spherical aberrations (Z12) increased slightly in both groups. Coma increased in all groups postoperatively with a mean value of $0.18 \mu\text{m}$ preoperatively and $0.23 \mu\text{m}$ postoperatively in the OATz group. Coma increased from $0.21 \mu\text{m}$ preoperatively to $0.25 \mu\text{m}$ postoperatively in the CATz/OPDCAT group. Trefoil increased for

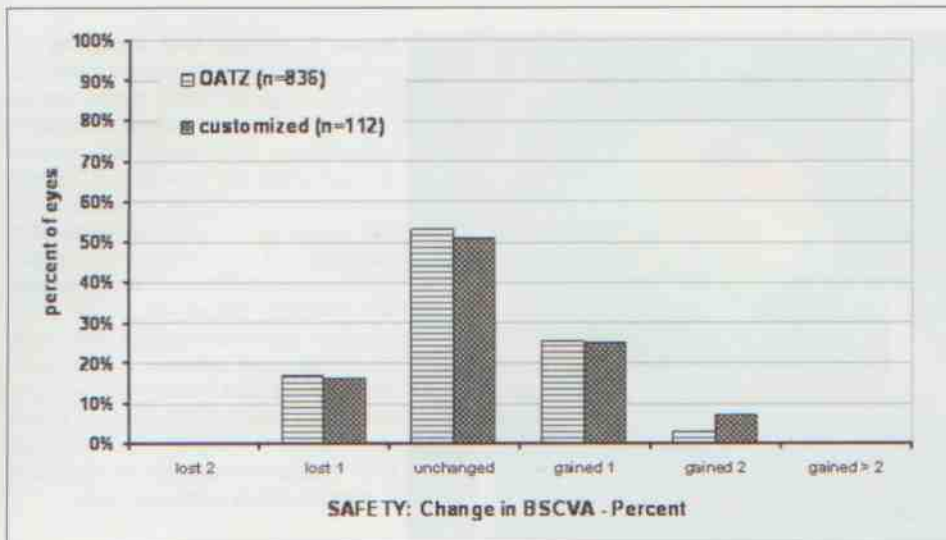


Figure 4. Safety. Three months postoperatively, 28% of the OATz (aspheric) and 32% of the customized (CATz and OPDCAT) treated eyes gained ≥ 1 line of BSCVA. None of the treated eyes lost > 1 line of BSCVA.

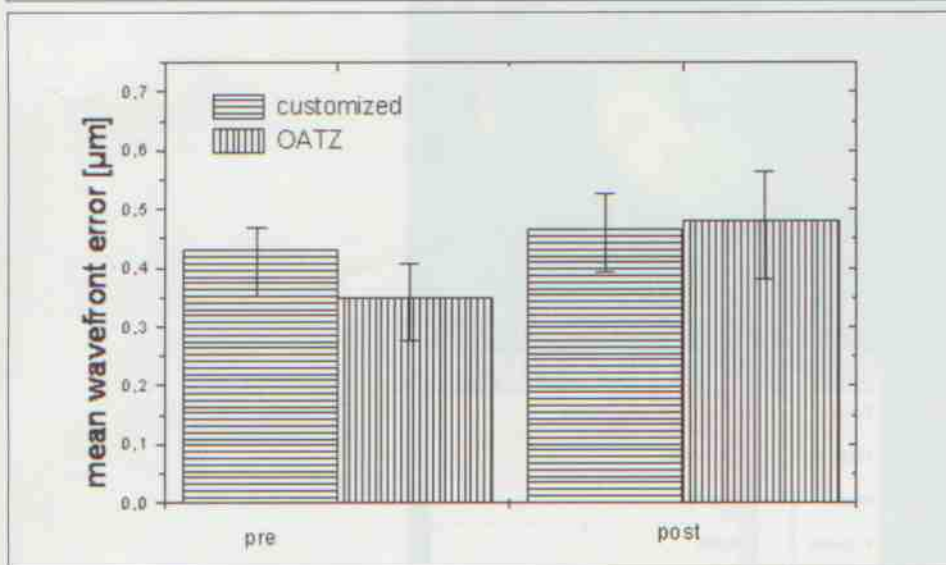


Figure 5. Comparison of higher order wavefront errors for customized (CATz and OPDCAT) ablation and standard aspheric ablation (OATz) pre- and postoperatively. The customized treatments showed a much smaller increase in RMS aberration values compared to the standard aspheric treatments. The postoperative RMS aberration values for both groups are nearly equal, although the preoperative values were much higher for the customized ablation group.

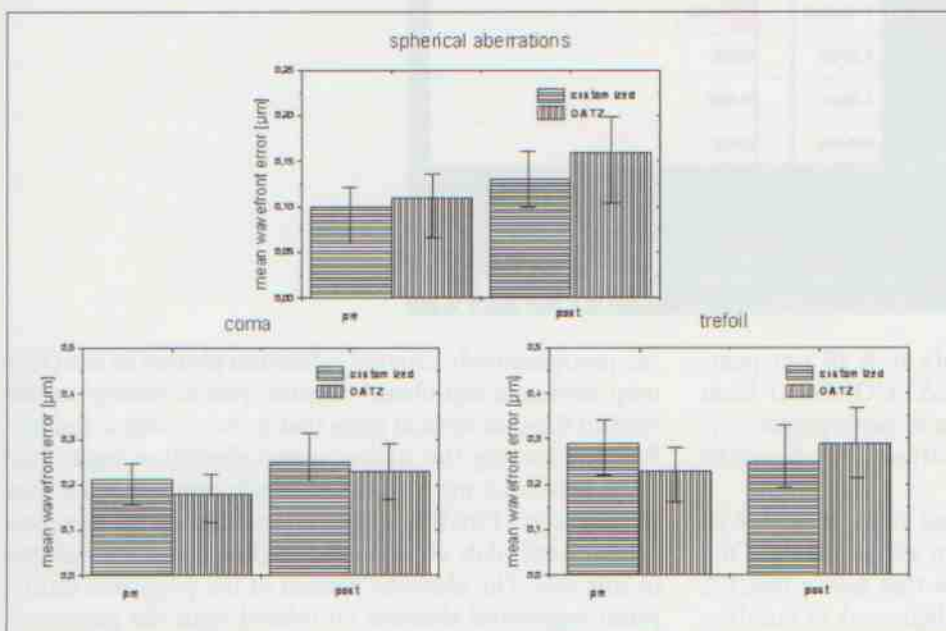


Figure 6. Comparison of spherical aberrations, coma, and trefoil for customized (CATz and OPDCAT) ablation and standard aspheric ablation (OATz) pre- and postoperatively. Both groups showed equal changes for spherical aberration and coma, whereas for trefoil, the customized treatment eyes showed a decrease for this wavefront error and the standard aspheric ablation showed an increase.

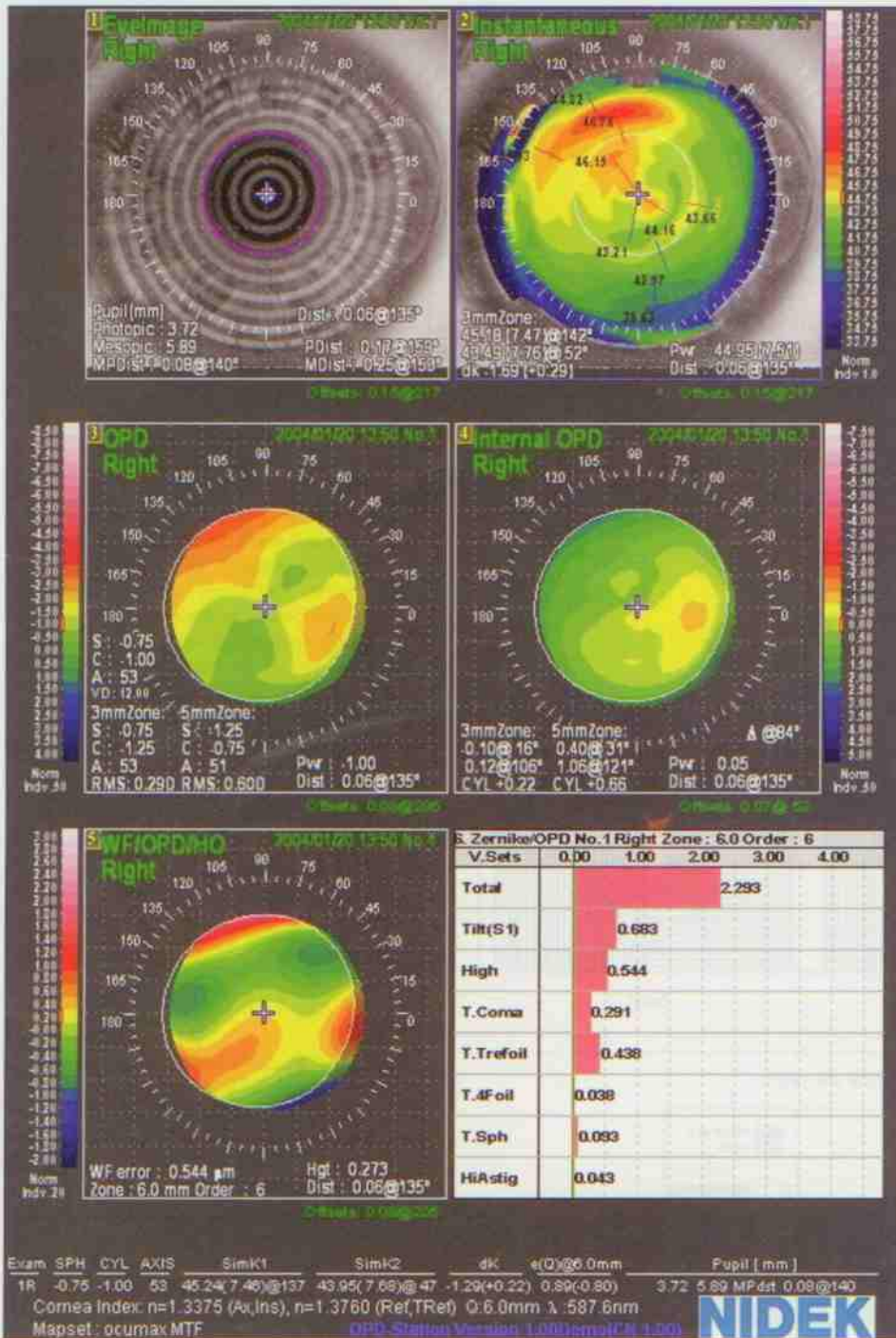


Figure 7. Standard OPD settings for the preoperative diagnostic (sample case): top left, eye image for quality control and iris registration; top right, corneal topography-instantaneous map; middle left, spatially resolved whole eye refraction (in D) from which aberrometry can be derived up to 6.0 mm; middle right, internal aberrometry after subtraction of topography (front surface power) and total OPD (including tilt, sphere, and cylinder); bottom left, higher order wavefront aberrations (without lower order, tilt, sphere, and cylinder); bottom right, Zernike coefficients. Preoperative measurement of a patient's native right eye. BSCVA was 20/32. The higher order aberration RMS (0.58 μm) is high, the wavefront error is characterized by coma and trefoil.

OATz from 0.23 μm preoperatively to 0.29 μm postoperatively. Trefoil decreased for CATz/OPDCAT from 0.29 μm preoperatively to 0.25 μm postoperatively. The changes in higher order aberrations are shown in Figures 5 and 6.

When reviewing each individual case, a subset of patients showed surprising gains in visual acuity. One case example (Fig 7) shows an eye that had a BSCVA of 20/32 preoperatively and was diagnosed as amblyo-

pic preoperatively. Spatial refraction plotted in the OPD map reveals a significant dioptric power change in the central 6.0-mm optical zone that is due to coma and trefoil dominating the higher order aberration map. The RMS was >0.5 μm and the mesopic pupil was 6.5 mm in diameter. FinalFit software enabled us to simulate a treatment plan ablating the higher order aberrations of this eye. The ablation pattern of the proposed multi-point segmental ablation correlated with the pattern of

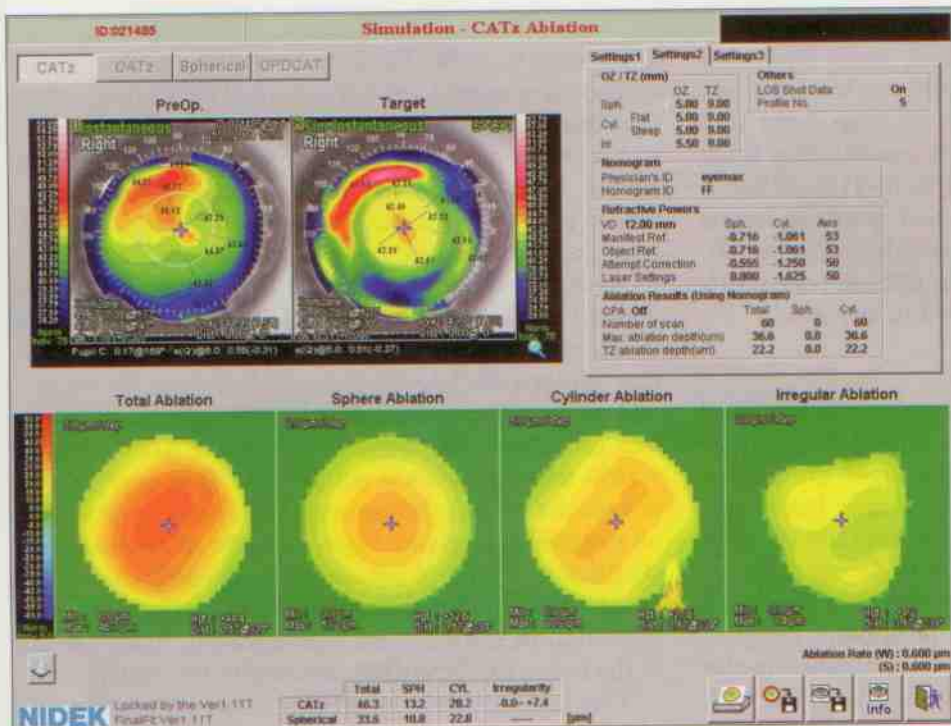
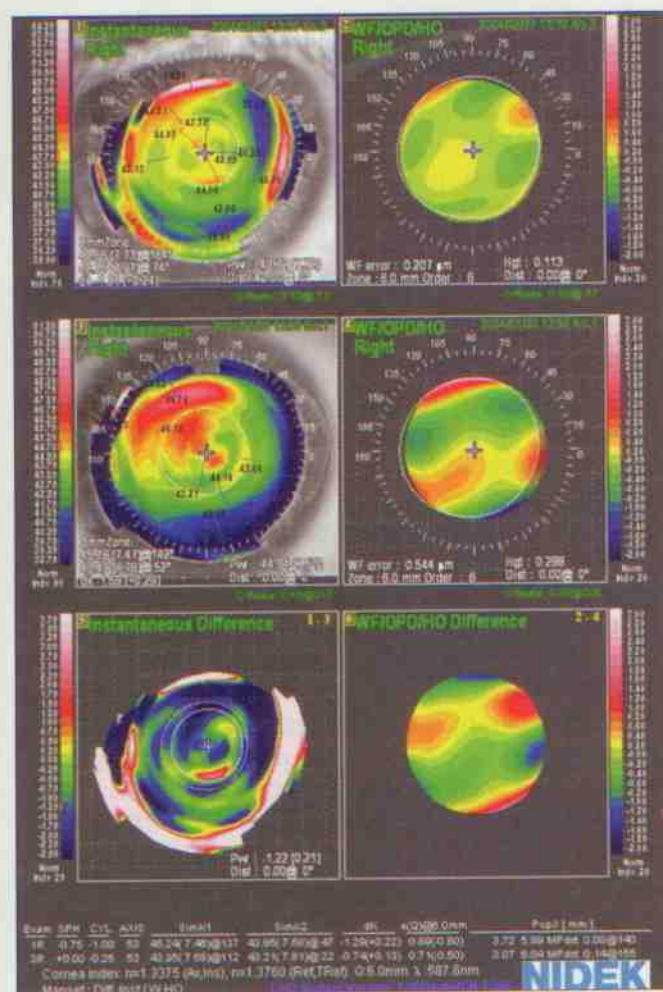


Figure 8. FinalFit shot data. CATz treatment parameters for the eye depicted in Figure 7 are shown. The interface figure showed the simulation of the treatment with segmental (multipoint) ablation (Pre-op and Target topography maps top left). The topography in the target simulation showed an improvement. The numeric data on the right side show the ablation profile parameters, which can be adjusted by the surgeon. Changing those parameters will change the shot data and the target simulation. The four bottom pictures show the total ablation profile and its separation into spherical, astigmatic, and segmental ablation components. The bottom right segmental ablation profile fits to the higher order aberration map (see Figure 7).



the wavefront higher order map. In this case, segmental laser ablation was delivered to the areas that were green and blue on the wavefront higher order map. The simulated target map showed a significantly improved refractive gradient. At 3 months after CATz, the BSCVA improved to 20/20, a gain of 2 lines (Figs 8 and 9).

Increased night vision disturbances were noted in 4.8% (70 patients) of all eyes 3 months after primary LASIK. In the first 3 months after LASIK, night vision disturbances are reported more often but seem to be correlated with tear film instabilities. The 70 patients reporting increased night vision disturbances, compared to preoperatively, showed a pronounced increase of higher order aberration RMS in the OPD map. The low follow-up rate did not allow a correlation to any of the different treatment options. Dry eye syndrome was noted in 68% of the treated patients. The high prevalence only denotes the use of artificial tears. Significant tear film problems with late recovery of visual acuity were noted in 2.4% (n=35) of patients, regardless of the laser treatment chosen.

Figure 9. Pre- and postoperative wavefront error, instantaneous topography, and PSF of the patient in Figure 7 is depicted. Top right and left maps are postoperative. Middle right and left maps are preoperative. Bottom right and left are difference maps. Segmental ablation map (see Figure 8) fits to the wavefront map. Areas where the wavefront was delayed (blue and green color code) the segmental laser ablation is higher (red color code denotes wavefront acceleration). Three months postoperatively, customized CATz-LASIK ablation of the eye has a BSCVA of 20/20. The difference maps confirm the correlation of segmental ablation and treated wavefront error. The small inserted PSF shows the improvement of the optical quality after customized LASIK.

Surgical complications included early flap displacement (0.82%, n=12), incomplete or irregular cut (0.41%, n=6), free cap (0.07%, n=1), flap folds that were treated at the slit-lamp (3.6%, n=53), flap folds that required surgical revision (2.1%, n=31), epithelial defects with the need of soft contact bandage lenses (8.1%, n=118), and epithelial ingrowth (1.5%, n=22). Central scar formation or infections did not occur. Diffuse lamellar keratitis was not noted in any eye.

DISCUSSION

The goal of improving the refractive outcomes of excimer laser refractive surgery with the NAVEX platform can be achieved by incorporating a number of technical developments. The new excimer laser (version CXII) works with a faster eye tracker (200 Hz with a latency <20 msec), has the ability to detect and correct for torsional errors between measurement and treatment, and uses an enhanced peripheral ablation to account for the increasing angle of incidence in the peripheral cornea and loss of ablation energy. In fact, aspheric ablation profiles were designed to address this issue. Addressing loss of effective energy in the periphery should result in an increase in the effective optical zone and reduce the induction of spherical aberrations after ablation. The addition of multipoint segmental ablation addresses various higher order patterns seen on the wavefront maps.

In a recent paper by Kermani,⁷ it was shown that >30% of eyes of a normal refractive population show torsional error of >5°. An investigation of the cause of cyclotorsion found it was not necessarily the change in position from sitting to supine but monofocality during surgery seemed to have a greater influence on the onset of torsional deviation.⁸ Better refractive results and less induced astigmatism can be expected when accounting for cyclotorsion. This is especially critical in the treatment of higher order aberrations that lack compensation for cyclotorsion, which may result in undercorrection and an induction of higher order aberrations.⁹ The induction of higher order aberrations would potentially result in the reduction of visual quality and increased night vision disturbances.

The ablation architecture, such as size and shape of the ablation zones, is garnering interest. A multicenter study using LADARVision (Alcon Laboratories Inc, Ft Worth, Tex) for LASIK in myopic and astigmatic eyes with a similar treatment range but using smaller ablation zones (5.5-mm optic zone/7.5-mm transition zone compared to 5.0-mm optic zone/9.0-mm transition zone in this study), spherical (not aspheric) ablations, and no torsion error correction function was published by McDonald et al.¹⁰ In their study, 75.2% of eyes

(compared to 87% of eyes at 12 months in the present study) were within ± 0.5 D spherical equivalent refraction from target refraction. Although the results were stable, with only 3% of eyes regressing 3 months after LASIK, regression in our study at the same time point was <1%, which might be due to the large, aspheric treatment zones used in our study.

Another recently published study also found decreased predictability compared to the results presented in our study. Hammer et al¹¹ reported that 75% of eyes that underwent LASIK (Bausch & Lomb) for myopia and astigmatism were within ± 0.5 D spherical equivalent refraction from targeted refraction. They reported <10% fewer eyes were within ± 0.5 D as compared to our results. Although Hammer et al's results were based on treatments applying large, aspheric ablation zones, a significant difference compared to our outcomes is still noted. One difference was the lack of cyclotorsion compensation in the study by Hammer et al, likely leading to the better predictability reported in our study.

The issue of treating higher order aberration of a virgin cornea is still a debatable point. The incidence and magnitude of higher order aberration depends on the size of the entrance pupil. Virgin eyes with small pupils (<4.5 mm) do not show significant higher order aberrations. Furthermore, eyes of younger patients rarely have RMS aberration values >0.35 μ m. Such values are within the range of natural variation due to tear film changes and represent the resolution limit of most aberrometers.¹² Kohonen and Bühren¹³ stated that customized LASIK leads to a minor induction of higher order aberrations compared to conventional treatments but that the technique has not been refined to a point that it is clinically reproducible and valid.

Treating eyes with customized ablation regardless of the specific optical profile of the eye might be one reason why no significant differences could be found in past investigations. In this study, eyes reviewed were those pre-selected for customized treatment. Generally, we offer customized treatment to our patients when a significant higher order aberration with specific Zernike polynomials such as coma and/or trefoil are detected by the OPD-Scan and when BSCVA is <20/20 or when a large entrance pupil (5.5 mm) is noted. In addition to careful patient selection, customized ablation needs to be precisely aligned and delivered. To this end, the wavefront and topography measurement should be aligned and torsional error needs to be addressed.

Between the three modalities used in this study, we found the best results with topography-based wavefront ablation using CATz. At this point the difference is statistically significant. Eyes treated with the

three treatment modalities showed little increase in spherical aberrations (Z12). This correlates with the relatively low (4.8%) number of complaints regarding night vision disturbances. Only eyes in the OATz group showed an increase of higher order aberrations other than Z12. Coma, at some level, was increased in all treatment groups, perhaps due to the keratome cut. Trefoil increased in the OATz group and decreased in the CATz and OPDCAT groups. We are at a loss to explain this observation. We believe that aspheric treatments with large transition zones, as used in the treatments reported here, prevent a significant induction of spherical aberration.

A case-by-case evaluation of the eyes that attained significant improvements in BSCVA yielded selection criteria for wavefront treatments. In these cases, we cannot attribute the increase in BSCVA to image magnification alone. Those eyes that improved dramatically after customized LASIK had large entrance pupils (≥ 5.5 mm). Furthermore, in these cases, the spatial resolution refraction map (OPD map) showed significant and often irregular power changes within the central 6.0 mm of the optical zone induced by coma or trefoil. Many of these eyes showed a reduced BSCVA before LASIK and some of the eyes were classified as partially amblyopic. Lastly, these eyes showed an RMS aberration $>0.4 \mu\text{m}$.

Approximately 10% of our LASIK treatments on primary or virgin eyes are performed as customized LASIK and most of these cases meet the following criteria: large pupil, high RMS aberration, and low BSCVA. Approximately 60% of these customized treatments lead to an improvement of BSCVA of >1 line. Customized LASIK, when applied to well-selected cases and when alignment is optimized with regard to potential torsion errors, is a successful procedure. Customization, based on topography rather than on the total wavefront error, seems to be more effective.

REFERENCES

1. Pallikaris IG, Papatzanaki ME, Stathi EZ, Frenschock O, Georgiadis A. Laser in situ keratomileusis. *Lasers Surg Med*. 1990;10:463-468.
2. Solomon KD, Holzer MP, Sandoval HP, Vargas LG, Werner L, Vroman DT, Kasper TJ, Apple DJ. Refractive surgery survey 2001. *J Cataract Refract Surg*. 2002;28:346-355.
3. Seiler T. Change of paradigms in refractive surgery [German]. *Ophthalmologie*. 2001;98:701-702.
4. 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.
5. Chalita MR, Xu M, Krueger RR. Correlation of aberrations with visual symptoms using wavefront analysis in eyes after laser in situ keratomileusis. *J Refract Surg*. 2003;19:S682-S686.
6. Lubatschowski H, Kermani O, Welling H, Ertmer W. A scanning and rotating slit ArF excimer laser delivery system for refractive surgery. *J Refract Surg*. 1998;14:S186-S191.
7. Kermani O. Alignment in customized laser in situ keratomileusis. *J Refract Surg*. 2004;20:S651-S658.
8. Tjon-Fo-Sang MJ, de Faber JT, Kingma C, Beekhuis WH. Cyclo-torsion: a possible cause of residual astigmatism in refractive surgery. *J Cataract Refract Surg*. 2002;28:599-602.
9. Guirao A, Cox IG, Williams DR. Method for optimizing the correction of the eye's higher-order aberrations in the presence of decentration. *J Opt Soc A*. 2002;19:126-128.
10. McDonald MB, Carr JD, Frantz JM, Kozarsky AM, Maguen E, Nesburn AB, Rabinowitz YS, Salz JJ, Stulting RD, Thompson KP, Waring GO III. Laser in situ keratomileusis for myopia up to -11 diopters with up to -5 diopters of astigmatism with the Summit Autonomous LADARVision excimer laser. *Ophthalmology*. 2001;108:309-316.
11. Hammer T, Duncker GI, Giessler S. Results of wavefront-guided LASIK [German]. *Ophthalmologie*. 2004;101:824-829.
12. Thibos LN, Hong X, Bradley A, Cheng X. Statistical variation of aberration structure and image quality in a normal population of healthy eyes. *J Opt Soc Am A Opt Image Sci Vis*. 2002;19:2329-2348.
13. Kohnen T, Bühren J. Current state of wavefront-guided corneal surgery to correct refraction disorders [German]. *Ophthalmologie*. 2004;101:631-647.