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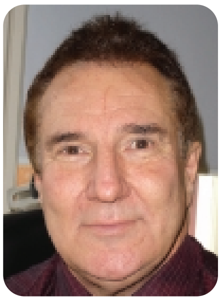
Refractive Express

In This Issue



Excellent Clinical Results Obtained Using OPDCAT Ablation Profile

Jan A. Venter, MD - Email: javenter@onetel.com

Wavefront LASIK treatments using the NIDEK OPDCAT profile can achieve excellent refractive results and greatly enhance visual quality, according to a leading surgeon who presented his clinical findings.

"I have been very impressed with the overall performance of the OPDCAT ablation profile," said Jan Venter MD. "It achieved very good results in terms of efficacy, safety, predictability and delivered consistently good outcomes in terms of quality of vision," he said.

Dr. Venter, Clinical Director of Optimax Laser Clinics in the United Kingdom, said that while conventional LASIK treatments were known to increase higher order aberrations by between 37% to 62%, custom corneal ablation with OPDCAT could treat lower order aberrations as well as decreasing or preventing an increase in higher order aberrations such as coma, trefoil and spherical aberration.

"Wavefront-guided customized treatments aim to improve optical properties of the human eye. The fact that the NAVEX platform offers an aspheric ablation that preserves the prolate shape of the cornea means a decreased risk for inducing spherical aberration," he said.

Advantages of wavefront-guided treatments

Dr. Venter said that clinical studies indicate that wavefront-guided LASIK increased higher order aberrations by just 8%, which resulted in less night vision complaints and less likelihood of patients losing lines of best-corrected visual acuity.

Dr. Venter's randomized study included 93 eyes of 60 patients treated between September 2004 and December 2004, with three months follow-up. All patients were treated on the NAVEX platform combining the NIDEK OPD-Scan topo-aberrometer, FinalFit ablation planning software, and the NIDEK EC-5000 excimer laser using the OPDCAT ablation profile.

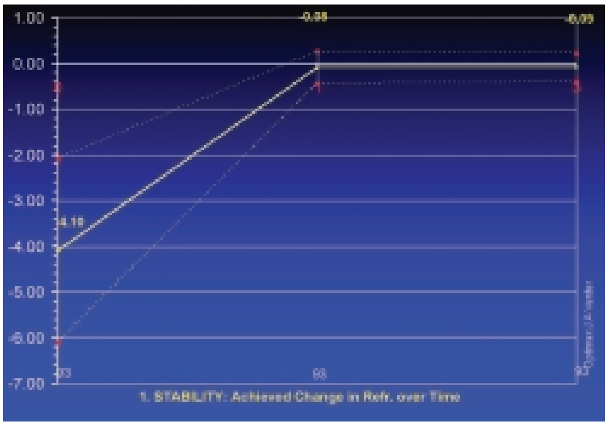


Figure 1 – Stability out to 3 months after OPDCAT ablation.

Patients had an average preoperative spherical equivalent of –4.09 D compared to –0.08 D after surgery, noted Dr Venter. Efficacy was excellent with 89% of patients recording 20/20 or better-uncorrected visual acuity (UCVA). Additionally stability was reached rather quickly with negligible change between one and three months postoperatively (Figure 1)

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NIDEK

NAVEX

continued from Page 1

Predictability was also excellent, reported Dr Venter. Over 95% of patients were within 0.5 D of emmetropia at the three-month follow-up point and 100% were within 1.0 D of emmetropia at the same period. The attempted versus achieve plot show that treatments with this laser were highly accurate (Figure 2).

The safety data were similarly encouraging, said Dr Venter. Nearly one-third of patients (29%) gained one or more lines of BCVA, no patient lost 2 or more lines, and stability was excellent three months postoperatively.

OPDCAT versus OATz

Dr Venter then compared the OPDCAT patients with a group of 48 patients who had been treated with the OATz ablation profile. In terms of UCVA, 89% of OPDCAT patients were 20/20 or better compared to 84% of OATz patients. For refractive outcomes, 92% of OATz eyes were within 0.5 D of emmetropia compared to 95% of OPDCAT eyes.

Looking at the higher order aberrations, Dr Venter said that the total RMS value increased by 19% in the OPDCAT group after surgery. Interestingly, he noted that patients with less preoperative higher order aberrations (0.3 or less) were likely to experience a greater increase in their RMS values (40%) compared to patients with higher preoperative RMS values, who experienced a decrease of 18%.

He reported similar findings for individual higher order terms such as spherical aberration and coma. Patients with less preoperative spherical aberration and coma were less likely to derive benefit from treatment compared to patients with higher preoperative values for these particular aberrations.

In conclusion, Dr Venter said the results in terms of efficacy, safety and predictability compared very favorably with other customized LASIK results from other laser manufacturers.

"It was also clear, in this study at least, that patients with higher preoperative RMS values greater than 0.3 RMS could expect to derive most benefit from this type of wavefront-guided treatment," he concluded.

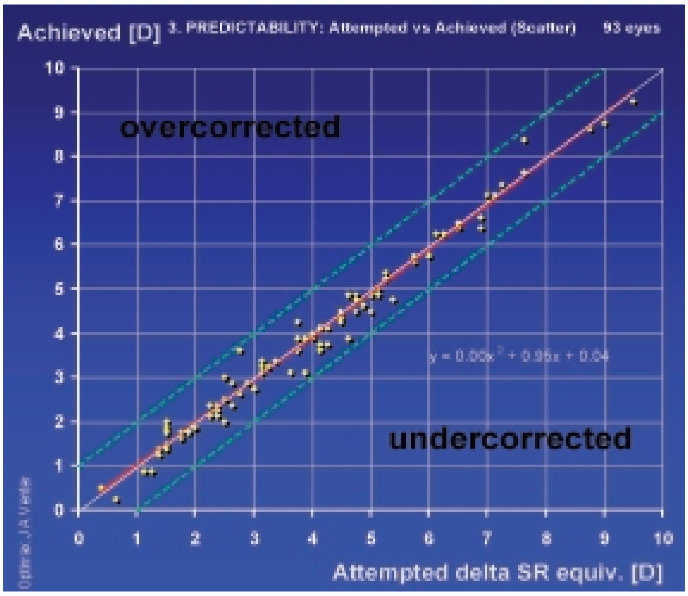

Figure 2 – Attempted versus Achieved scatter gram for OPDCAT treatments

Surgeons Corner - Clinical Pearls

Improving Hyperopic Outcomes

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LASIK and PRK are currently the most common surgical interventions for treating low to moderate hyperopes. Excimer laser treatment of hyperopia involves uses an algorithm that delivers the ablation to the midperiphery of the cornea to increase corneal curvature. This creates a prolate or hyper-prolate corneas postoperatively which is in contrast to the oblate shape induced by a myopic ablation. The correction of hyperopia using laser in-situ keratomileusis has shown inconsistent results as compared to myopia. Hyperopia treatments are generally considered less predictable than myopic treatments.

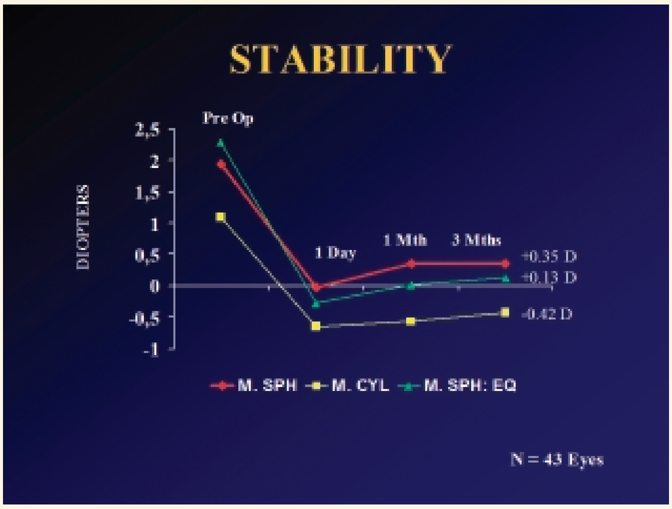

Figure 1. Change in mean sphere, mean cylinder and mean spherical equivalent over time.

As the population ages, hyperopic LASIK is increasingly becoming more prominent. In parts of the world hyperopia and mixed astigmatism treatments have steadily grown to account for approximately half of all LASIK surgeries.

As the surgical volume increases so does the potential for patient dissatisfaction with hyperopic LASIK as compared to myopic LASIK. At Instituto Zaldivar, we explored methods to improve the results obtained with hyperopic LASIK.

The aim of this study was to determine if changes, both technical and surgical, would enhance the hyperopic outcomes. All observations are based on personal experience with the treatment of hyperopia for over 20 years (RZ). Five different changes to our LASIK protocol, both surgical and technical, were identified and initiated. The five steps were consistently incorporated into all hyperopic LASIK treatments. The five steps included:

1) Hyperopic Nomogram Refinement. To incorporate the accommodative effect especially in younger patients the nomogram was refined based on age. For patients from 20-35 years old, the difference between the cycloplegic refraction (CR) and manifest refractions (MR) was divided in half and added to the manifest refraction. The final calculated result was entered into the laser. The equation is:

Laser input = MR + [0.5(CR-MR)]   Equation 1

A sample calculation is shown in Figure 2.

For patients 35 to 45 years old the following equation is used:

Laser input = MR + [0.75(CR-MR)]   Equation 2

2) The optical zone was increased from 5.50 mm to 7.00 mm along with the incorporation of a proprietary aspheric laser ablation algorithm. Both modifications involved software and hardware changes incorporated into the NIDEK CXII excimer laser system by a field service engineer.

3) We increased the flap size by changing from a 9.00mm suction ring to 10.50 mm suction ring for the NIDEK MK-2000 keratome.

4) All hyperopic laser ablations were interrupted by the surgeon (RZ) after every eight seconds of treatment.

5) During the sequential stops outlined in 4 above, a beaver blade was used to clean the stromal surface of interface debris.

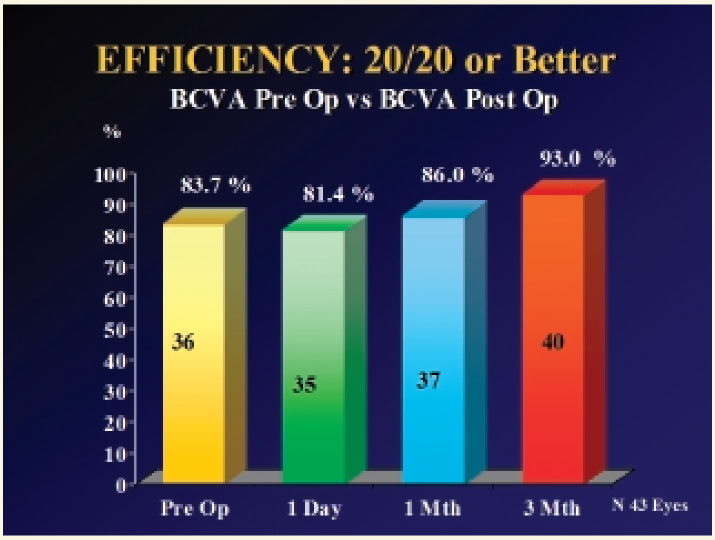

Figure 2. Number of patients with distance BCVA of 20/20 preoperatively and distance BCVA of 20/20 postoperatively

Patients with hyperopia between +0.25 to +4.50 diopters (D) with or without astigmatism upto +4.50 Diopters were treated. Forty three eyes underwent LASIK for hyperopia or hyperopic astigmatism with the NIDEK CXII excimer laser and the NIDEK MK-2000 keratome. All surgeries were performed by one surgeon (RZ). Preoperatively, the mean spherical equivalent (SE) was +2.28 D, the mean sphere was +1.93 D (range +4.25 to +0.25 D), mean cylinder was +1.10 D (range +4.50 to 0.25 D).

At one day postoperatively, the initial myopic shift was 0.27 D. At one month the SE regressed to 0.00 D and by 3 months it was +0.13 D (Figure 1). At three months postoperatively, less than 0.50 D of regression had occurred.

At three months, 28 eyes (65.11%) had a distance UCVA of 20/20 or better. Figure 2 shows comparison of the number of eyes which had a distance BCVA of 20/20 or better preoperatively and those which achieved a distance BCVA of 20/20 or better postoperatively. Postoperatively the number of patients achieving a distance BCVA of 20/20 gradually increased to 40 eyes (93%) by three months (Figure 2). Preoperatively 55.8% of the eyes had a distance BCVA of 20/15 and at 3 months postoperatively, the number of eyes that achieved 20/15 increased by 11.7 % (Figure 3). Eighty-eight percent of eyes maintained or gained lines of BCVA. Four patients lost one line of BCVA. One patient lost more than one line of vision due to visually significant microstraie.

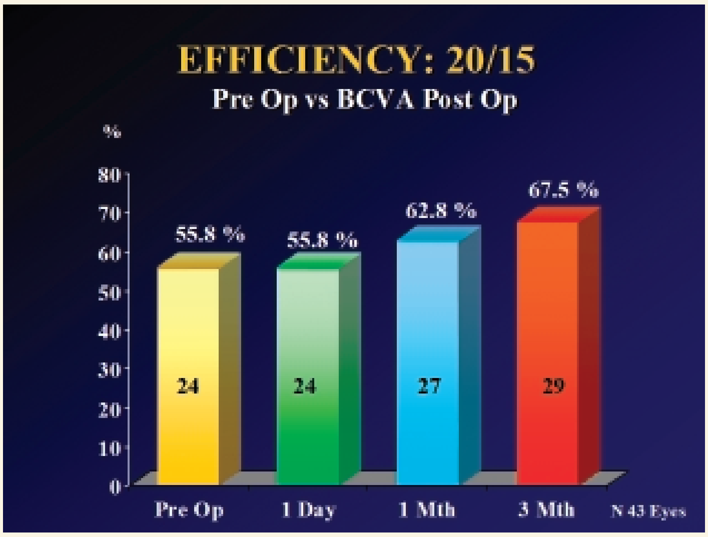

Figure 3. Number of patients with distance BCVA of 20/15 preoperatively and distance BCVA of 20/15 postoperatively.

The outcomes presented here support the observation that five surgical and technical modifications to the hyperopic LASIK procedure improves visual quality and refactive outcomes and reduces the risk of regression. The induced hyperopic shift seen after hyperopic treatments was reduced. Although we have used a number of laser platforms, this was the first time we observed an increase in BCVA with hyperopic LASIK.

Author note: The complete article is printed in Journal of Refractive Surgery 2005; 21 (Suppl), S595-S597.

Correction of the Corneal Irregularities Post Refractive Surgery

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Customized refractive surgery may be beneficial for patients with visual complications resulting from previous refractive surgery who, until recently, did not have many treatment options.

The correction of myopia with the Excimer Laser began in the early 90's. The main complications due to the laser treatment were the lack of centration, central islands, small optic zones, irregular astigmatism and others. By that time, if a patient had some of these complications, the only thing we could do was to advise the patient to wait for the development of new technology. Nowadays, more than ten years later and with the development of the customized surgery, we can say that there finally is a viable treatment option for post-refractive surgery aberrations.

...FinalFit allows the surgeon to simulate the treatment, showing the post-surgery maps for various ablation profiles that are included with the NAVEX system.

Figure 1: OPD-Scan topographer and aberrometer in the same device, used to measure corneal and entire eye aberrations.

With the development of 2nd and 3rd generation lasers using sensitive eye trackers, with better ablation profiles and larger transition zones, the laser related complications have shown a significant decrease. However, there is still a large number of patients requiring retreatments because of existing complications, due mainly to decentrations that can cause severe aberrations, with leads to complaints of glare, halos, double vision and loss of BCVA.

For the correction of corneal irregularities we use NIDEK's NAVEX platform, which consists of a combined autorefractor, topographer and wavefront analyzer called the 'OPD-Scan' (Figure 1); the interface Software FinalFit and the Excimer Laser EC-5000 equipped with multipoint and a 200 Hz Eye Tracker as well as Torsion Error Detection (Figure 2).

The measurement technique of the OPD-Scan aberrometer is different from other aberrometers as it is based on dynamic skiascopy, which uses an infrared scanning slit projected on the fundus to measure the aberrations of the eye. In just 0.4 second, it analyses 1,440 points by scanning rapidly in every meridian. It provides various maps such as axial map, instantaneous map, OPD Aberration map, internal OPD map (to detect crystalline astigmatism), HO WF map (which may be a criteria for the indication of custom ablation if HO RMS > 0.3 µm), Zernike's group with numeric interpretation of the main

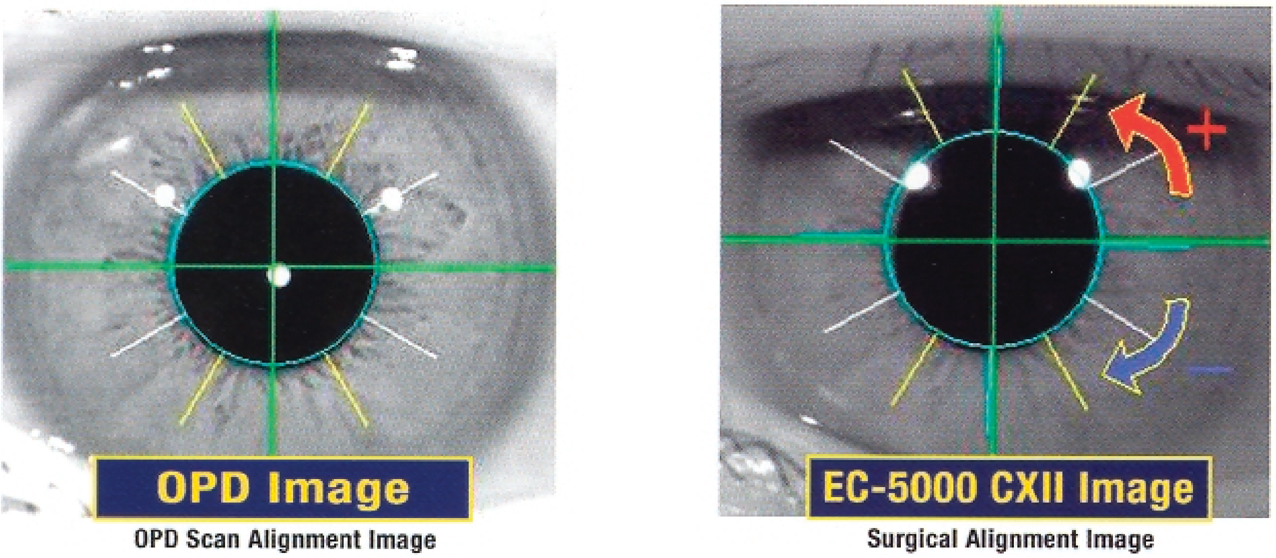

Figure 2: 200 Hz Eye-Tracker with TED (Torsion Error Detection).

aberrations like spherical aberration, coma, trefoil, PSF (point spread function), Strehl index and more. It also provides the patient's objective refraction and diameters of the photopic and mesopic pupil including angle kappa.

After the data has been collected it is transferred to the FinalFit software. FinalFit allows the surgeon to simulate the treatment, showing the post-surgery maps for various ablation profiles that are included with the NAVEX system.

Depending on the patients needs, FinalFit allows the selection of three different types of personalized ablations:

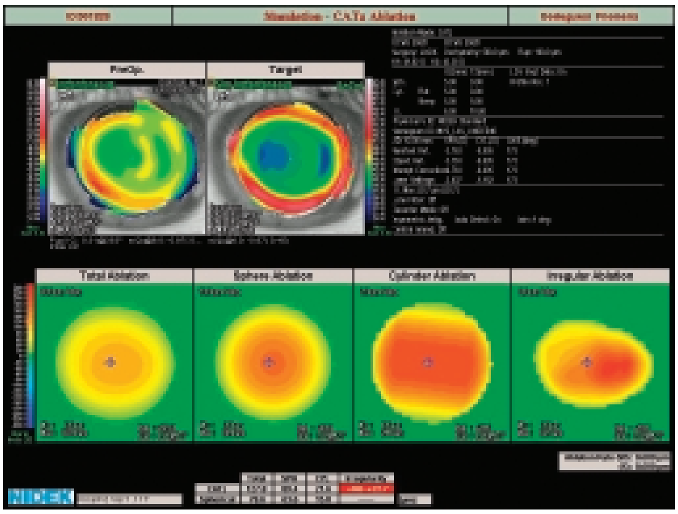

Figure 3: CATz ablation, used to correct the irregularity component smaller than 40 µm, astigmatism and myopia. Above, pre Retreatment and simulated Post-Op.

1) OATz (Optimized Aspheric Treatment Zone): is a treatment algorithm that delivers an aspheric ablation in the periphery of the cornea. Its main indication is for virgin eyes with larger pupil diameters > 6 mm, a low amount of irregularity ≤ 5 µm irregularity component and is preferred for moderate to high myopia.

2) OPDCAT (Aberrometer Based Customized Aspheric Treatment): indicated for virgin eyes, with an irregularity component of up to 10 µm, asymmetric astigmatism. All data should be evaluated in a 6 mm of pupil area.

3) CATz (Topography Based Customized Aspheric Treatment Zone) (Figure 3): ablation based on topography in eyes with vision lower than 20/20. Usually it is used for retreatments. The limit of the irregularity component is a maximum of 40 µm.

In all types of ablation, we used a central OZ (optical zone) of 5 mm with TZ (transition zone) up to 9 mm and had the choice between seven different types of ablation profiles. Profile #3 corresponds to the conventional ablation algorithm. The increase of the number enhances the peripheral ablation, but consumes more corneal tissue. An individual profile is created based on pachymetry, pupil size and refractive error.

For retreatments we use the CATz mode (topography based custom ablation) in combination with the Eye Tracking and TED (Torsion Error Detection). This allows

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the surgeon to deliver the ablation to the pupil center or the visual axis depending on the magnitude of angle kappa. The following examples show the results of retreatments on patients complaining about bad quality of vision after previous refractive surgery using the CATz mode:

Case 1

ABB, a 26-year-old female, who underwent LASIK elsewhere in 1996 to correct –6.50 D of myopia bilaterally. In June 2003, she visited our center complaining of reduced visual acuity, halos, glare and double vision.

The ophthalmic evaluation showed –1.50 –0.75 x 75° V.A.: 20/30 in the right eye and: –2.00 -0.50 x 19° AV: 20/25 in the left eye. Cornea thickness of 500 µm in both eyes and central cornea curvature of 39.20 x 39.90 @ 145° in the right eye and 38.84 x 40.51 @ 90° in the left eye.

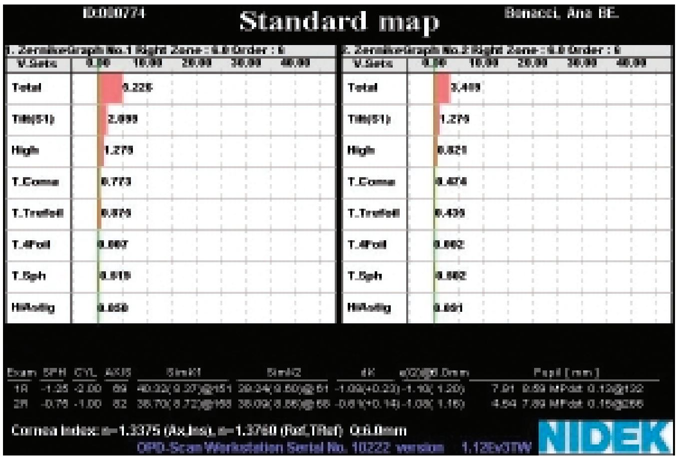

Figure 4: Pre (left) and Post (right) correction of LASIK decentralization, with decrease of the irregularities, mainly of high order, coma and trefoil.

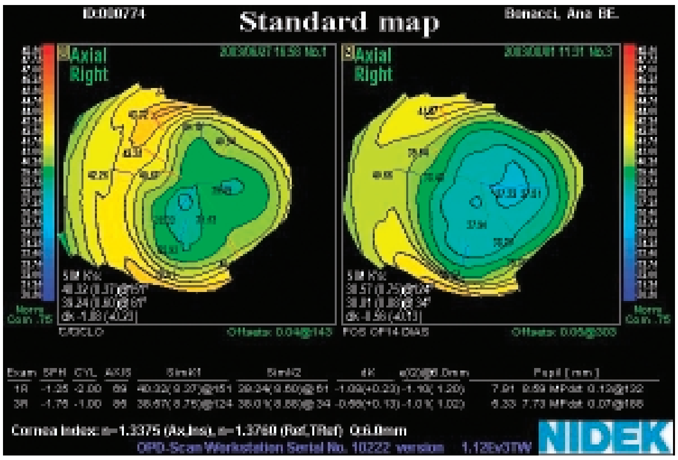

Figure 5: Axial Map, pre retreatment (Left) and post correction of decentration. (Right)

Biomicroscopy showed small flap diameter and light scar inferiorly in both eyes.

After a full workup including OPD-Scan evaluation, retreatment of the primary surgery was scheduled. The retreatment plan involved LASIK surgery with a cut of 9.5 mm diameter and custom ablation with the CATz mode to correct the irregularities, myopia and astigmatism. Post CATz treatment the patients subjective complaints were reduced and the patient remarked that the visual quality was appreciably better. UCVA post-CATz was RE: 20/25 and LE: 20/20 (Figures 4 and 5).

Case 2

T.S., a 32 year old male, who underwent LASIK FOR myopia. He complained of reduced visual acuity in both eyes, with double vision and great difficulty in the night, with glare and increased visual blur. Corneal topography evaluation and wavefront maps, it showed a significant amount of decentration. We performed custom ablation with CATz in order to correct the decentration (see pre and post maps). His visual acuity improved from 20/50 with correction to 20/25 without correction and great improvement in the night vision and a resolution of the blur and glare (Figures 6 and 7).

Case 3

PF, a 25-year-old female, was treatment for myopia of –7.50 D in both eyes. After the primary surgery, left eye had the following refraction: –4.25 -2.59 x 170° with VA: 20/40. After OPD-Scan evaluation, we opted for custom ablation to correct the irregular decentration and the myopia and astigmatism (Figures 8 and 9). Post treatment her vision improved to 20/20 without correction and there was also an improvement of contrast sensitivity.

Currently we retreated 154 post refractive surgery eyes that showed irregularities, decentrations and central islands, with the NAVEX platform. The majority of these cases showed an improvement in the visual acuity and decrease in the complaints of halos, glare and double vision.

In summary our experience shows that a detailed evaluation of the data supplied by the aberrometer and customized surgery can help patients who need retreatment because of severe visual problems after previous refractive surgery. Prior to the advent of a robust measurement and treatment technologies such as NAVEX, patients had few options for retreatments.

Contributed: Dr. Marivaldo de Oliveira, MD and Dr. Kozo Nakano

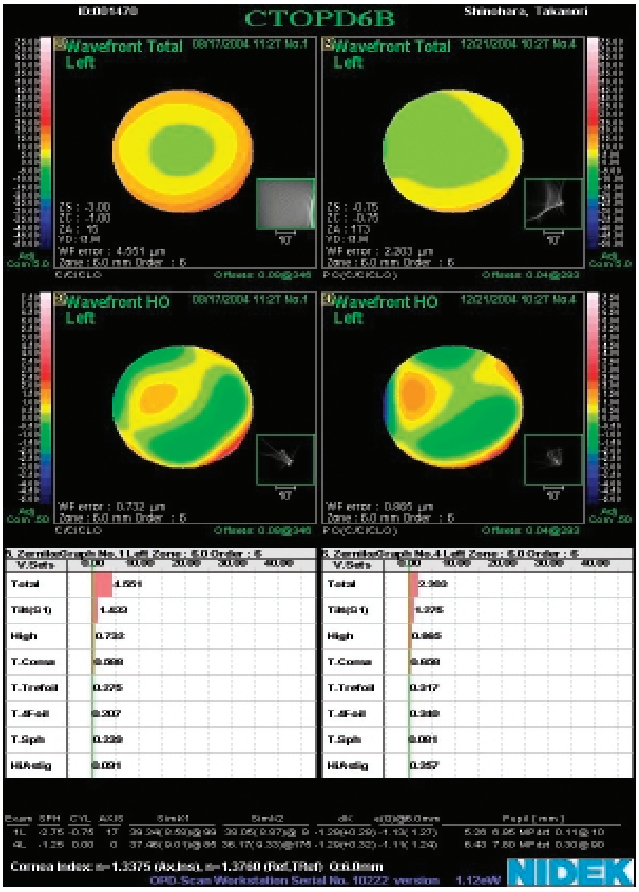

Figure 6: Pre (left) and post (right) cornea aberration correction, showing maps of total wavefront, higher order wavefront and numerical display of certain Zernike groups.

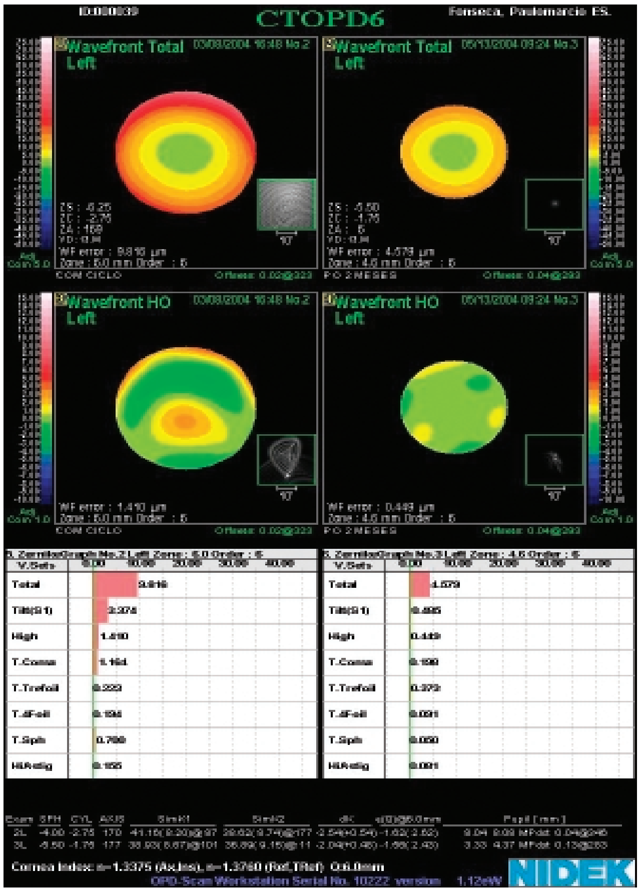

Figure 8: Pre (left) and Post-Op (right) aberrometry maps |showing the change in aberrations .

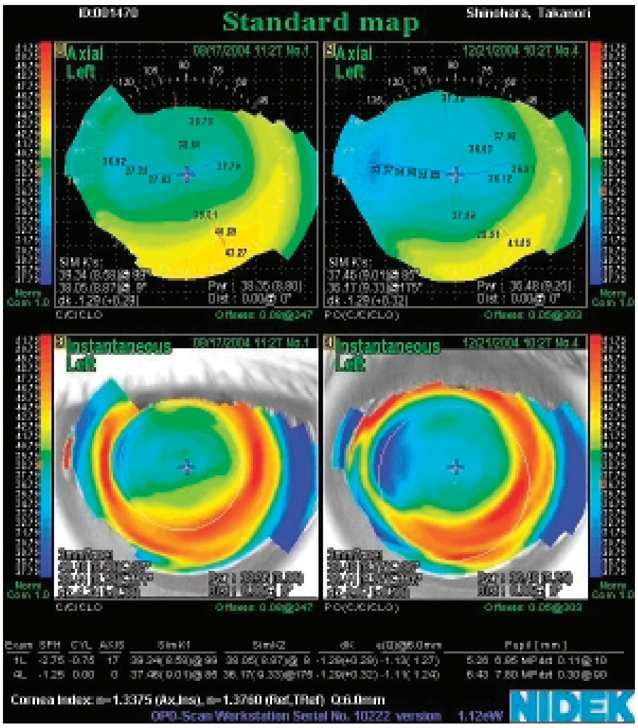

Figure 7: Pre (left) and Post-Op (right) images of axial and tangential maps.

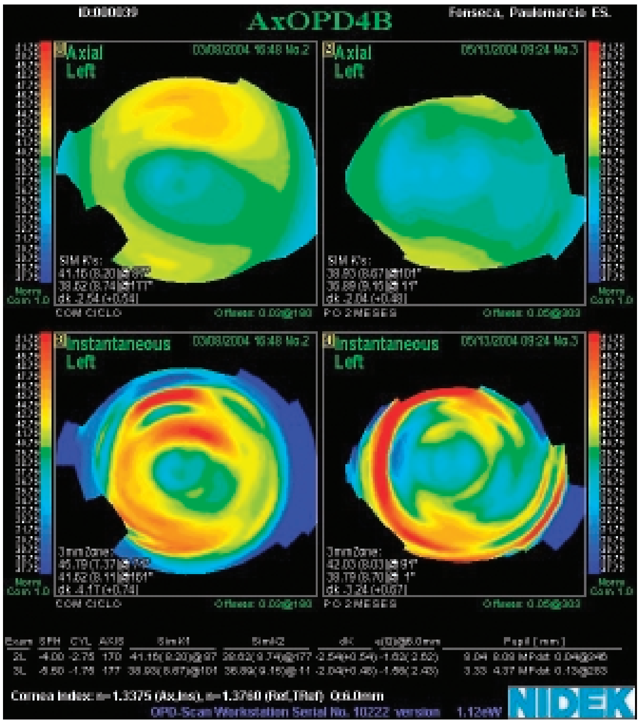

Figure 9: Case 3 – Pre-Op (left) and Post-Op (right) retreatment because of decenteration

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Congress Schedule

Taiwan Ophthalmology Congress
December 17-18,2005
Taipei, Taiwan
Booth Nos. A14 & A15

OPTI (International Optics and Eyewear Exhibition)
January 13-15, 2006
Munchen, Germany

7th International Congress of Wavefront Sensing & Optimized Refractive Corrections
January 26-29, 2006
Atlantis Resort,
Paradise Island, Bahamas

10th ESCRS Winter Refractive Surgery meeting
February 10-12, 2006
Monte Carlo, Monaco

WOC (World Ophthalmology Congress)
February 19-24, 2006
Sao Paulo, Brazil
Booth Nos. 37 & 39

ASCRS (American Society of Cataract & Refractive Surgery)
March 17-22, 2006
San Francisco, USA

Vision Expo East
March 31 - April 2, 2006
New York, USA

Annual AIOS (All India Ophthalmological Society) Conference
April 1-2, 2006
New Delhi, India

Congress of Ophthalmology & Optometry China
April 14-16, 2006
Shanghai, China

CSCRS (Canadian Society of Cataract & Refractive Surgery)
April 21-23, 2006
Montreal, Canada

ARVO (Association for Research in Vision and Ophthalmology)
April 30 - May 4, 2006
Fort Lauderdale, USA

LE Summit Meeting
May 4, 2006
Milano, Italy

MIDO (Mostra Internazionale di Optica, Optometria e Oftalmologia)
May 5-8, 2006
Milano, Italy

SFO (Société Française d'Ophtalmologie)
May 6-10, 2006
Paris, France

SOI (Italian Society of Ophthalmology) International Congress
May 17-20, 2006
Rome, Italy

Congress of German Ophthalmic Surgeons
May 25-28, 2006
Nuremberg, Germany

International Congress on Glaucoma Surgery
May 25-28, 2006
Toronto, Canada