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.

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).
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.
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:

\[ \text{Laser input} = \text{MR} + [0.5(\text{CR-MR})] \]  
\[ \text{Equation 1} \]

A sample calculation is shown in Figure 2.

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

\[ \text{Laser input} = \text{MR} + [0.75(\text{CR-MR})] \]  
\[ \text{Equation 2} \]

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.

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 microstriae.

The outcomes presented here support the observation that five surgical and technical modifications to the hyperopic LASIK procedure improves visual quality and refractive 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.

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

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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.

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...
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:

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
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.

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 V A:
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.

Figure 4: Pre (left) and Post (right) correction of LASIK
decentration, 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)
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 7: Pre (left) and Post-Op (right) images of axial and tangential maps.

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

Figure 9: Case 3 – Pre-Op (left) and Post-Op (right) retreatment because of decentration.
Taiwan Ophthalmology Congress  
December 17-18,2005  
Taipei, Taiwan  
Booth Nos. A14 & A15  

OPTI (International Optics and Eyewear Exhibition)  
January 13-15, 2005  
Munich, 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  
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SFO (Société Française d’Ophthalmologie)  
May 6-10, 2006  
Paris, France  

SOI (Italian Society of Ophthalmology) International Congress  
May 17-20, 2006  
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Congress of German Ophthalmic Surgeons  
May 25-28, 2006  
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International Congress on Glaucoma Surgery  
May 25-28, 2006  
Toronto, Canada