Volume 3, Number 1

Summer 2005

Refractive Express

In This Issue

NIDEK

NAVEX

2005 NIDEK Regional Refractive Surgery Symposiums - Dubai, UAE & Beijing, China

For 2005, NIDEK sponsored two separate regional focused Refractive Surgery Symposia for the advancement of refractive surgery around the world using the NIDEK Refractive Surgery and Diagnostic Platforms. With a focused initiative in Europe / Middle East and Asia, NIDEK hosted two outstanding events that brought together surgeons from around the world. On April 6th, 2005 – some 400 delegates from 35 countries gathered in Dubai, UAE to discuss and share clinical results, surgical techniques and technical advancements in Refractive Surgery. Similarly, on June 2nd, 2005 some 250 refractive surgeons came together in Beijing, China, where NIDEK sponsored an educational event with a specific focus on Asia and specifically China and the emerging refractive markets of Asia.

Both events focused on clinical applications and the sharing of results and surgical techniques. George O. Waring, III, MD served as program chair for both symposia and other distinguished faculty presided as Program Faculty at the two events. Faculty and session chairs included Arturo Chayet, MD, M. Alaa El-Danasoury, MD, Jack T. Holladay, MD, Omid Kermani, MD, Steven Klyce, PhD, and Roberto Zaldivar, MD.

NIDEK has long sponsored these types of educational symposia and in 2005 the focus was on establishing a strong educational and training forum in the Middle East, Europe and the Asian markets. Surgeons and product users gathered at these two events to share, collaborate and discuss in a scientific forum advancements in corneal and clinical diagnostics, wavefront diagnostics using the NIDEK OPD-Scan and clinical results using the NIDEK Refractive Surgery platform. Papers and presentations included discussion on NIDEK's various excimer treatment algorithms – OATz, CATz, OPDCAT and the new developing technology of OPA – Optimized Prolate Ablations. Other papers presented include topics related to the advanced NAVEX platform with the OPD-Scan, Final-Fit and the newly introduced NAVEX Quest – EC-5000 CXIII Platform.

NIDEK Asia - Pacific Refractive Surgery Symposium - Bejing, China

Dr. Arturo Chayet presented on his clinical experiences and findings using the newly developed EC-5000 CXIII Laser Platform and the new treatment algorithm of OPDCAT. The program also included special interest lectures and workshops on NIDEK's OPD-Scan, Final-Fit and the various advanced treatment algorithms of OATz, CATz and OPDCAT. Dr. Jack T. Holladay presented a keynote address on the newly developed OPA Treatment algorithm – focused on optimizing the corneal surface using excimer laser technology. The lecture was very well received and created the "buzz" at the two conferences.

Both conferences were great successes for NIDEK and its attendees from around the world. NIDEK will continue to host these symposia at a more local / regional level in 2006 and the comings.

We look forward to having you join us at the next meeting in 2006. Keep an eye on www.nidek.com for further information on next year's venue and program.

Alignment in Customized LASIK Using the NAVEX Platform

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The importance of correct alignment should not be underestimated if clinicians want to consistently deliver the best possible results from customized LASIK procedures using the NIDEK Advanced Excimer Laser System (NAVEX),

The fundamentals of proper alignment include factors such as lateral alignment, Z-plane focusing, tilt control, torsion error detection and eye movement tracking during the ablation procedure. If any or all of these are not rigorously controlled, they can have a serious impact on the final visual outcome.

The importance of lateral centration (X/Y-axis) is best illustrated with reference to an eye with an eccentric pupil. (Fig.1)

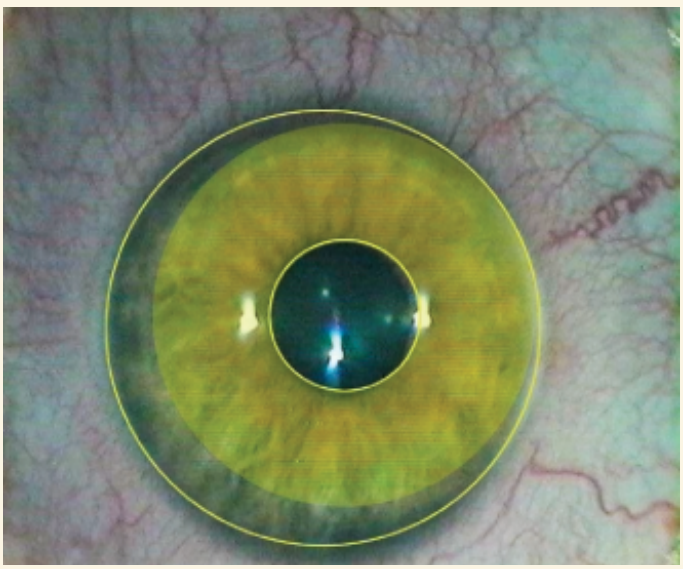

Fig. 1: Eye with eccentric pupil. The flap should be centered on the pupil, not on the cornea.

It is important to consider lateral centration when starting to operate on such an eye to ensure that an equidistant area of refracted light hits the fovea. Therefore the flap is centered on the pupil and not on the cornea.

Line of sight or visual axis?

Once the flap is well centered on the pupil, the next point of decision for the surgeon is either to center the treatment on the line of sight or on the visual axis. The line of sight is defined as the line between the center of the entrance pupil and a fixation object, and the visual axis as the line between the fovea and the fixation object. (see Fig. 2)

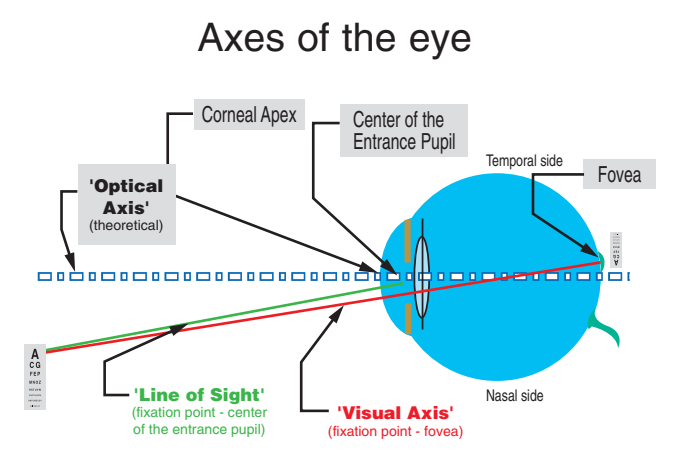

Figure 2: Line of Sight (LOS) and Visual Axis

The default for the FinalFit programme in customized multipoint ablation is to align the laser beam with reference to the line of sight (LOS). However, in cases with significant offset between the LOS and the visual axis it is possible to manually align the beam toward the visual axis. A surgeon can, for example, treat sphere and cylinder on the visual axis, using the eye-tracker's off-set function. In this case the "LOS Shot Data" function needs to be switched off to ensure that the multipoint ablation profile is centered on the visual axis. In Hyperopic LASIK it is emphasized to center on the visual axis or a point half way between the LOS and the visual axis. Usually in Hyperopic LASIK no segmental ablation is performed.

Focusing of the laser is also critical. The Z-plane is usually defined by cross-centering the two slit lamp projections on the cornea with the first Purkinje image of the fixation light, which is red.

For hyperopic laser ablation some surgeons recommend focusing a little bit further downwards because the main interaction area is in the periphery of the cornea, just below the Z-plane apex of the cornea.

In terms of the ablation rate there is no difference whether we focus on exactly the apex or slightly below as one might consider for hyperopic ablations. It is advised, however, to maintain the focus on the apex of the cornea even for hyperopic eyes, since manually changing the focus has the potential to interfere with the proper functioning of the eye-tracker, resulting in a decentration.

Tilt control is another issue. Many highly myopic eyes are affected by 'tilt' – a repeating, upward movement of the eye. The result is that even though the eye-tracker remains on the center of the pupil, the ablation is distorted because of the tilt effect.

In these cases, the eye-tracker cannot help because it continues tracking on the pupil center. The only way to prevent a distorted ablation is to ensure co-axial alignment by using the slit lamp projections on the cornea.. (See Fig. 3)

Figure 3: Only the slitlamp projections reveal the tilted position of the eye since the eyetracker is focused on the pupil.

The problem of cyclotorsion

The impact of cyclotorsion error should be minimized as it may affect the refractive outcome. This is mainly due to the change from the binocular view of the sitting position to the monocular viewing conditions under the surgical microscope. The effect on the astigmatism is significant and is even greater for the higher order aberrations especially higher terms. A misalignment of even 5 degrees can lead to 15% under-correction in the astigmatic error.

The NAVEX platform makes it relatively easy to minimize the impact of cyclotorsion. (See Fig. 4)

The OPD-Scan gives an image of the iris. The biometric data can be compared with the actual position of the eye under the operating microscope. By simple rotation of the patients head one can ensure that the torsional error is deleted. Once the flap is lifted, there is not very much rotation any more and one can continue with ablation as normal.

A closer look at the eye-tracker

Any form of eye-tracking introduces a lot of extraneous factors that also need to be considered. The phenomenon of parallax, which transforms a round pupil into an oval shape if there is movement of the eye, is not an issue for the NAVEX system since the entire delivery system moves rather than only the last mirror as in most other laser systems.

It is wise to leave the illumination unchanged during the surgery, especially in hyperopic eyes with eccentric pupils. The line of sight at the centre of the pupil is not stable with regard to the position of the cornea. If there is an eccentric pupil and a difference of illumination is present, the position of the LOS on the cornea will change also.

Summary

Correct alignment requires identification of the important axes of the eye: the line of sight, the visual axis and torsion-corrected astigmatic axis. Furthermore, tracking and stabilizing the ablation procedure has to be accomplished by both the surgeon and the machine and can be influenced by a variety of factors.

Correct alignment is vital not only for customized ablation of higher order aberrations but also for standard treatments of corneal laser ablation.

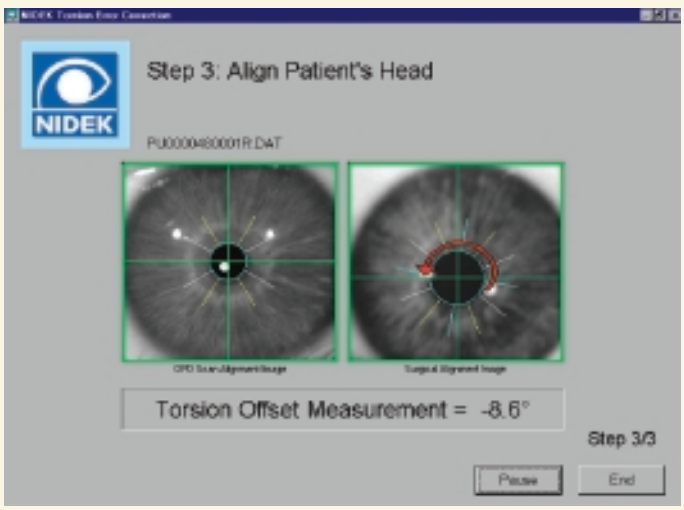

Figure 4: Torsion Error Detection (TED)

The Theory and Benefits of Optimized Prolate Ablation (OPA) Treatments

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For many years Jack T. Holladay, MD, MSEE, FACS, has been advocating the need for a laser technology that is capable of maintaining the natural prolate shape of the cornea.

His reasoning was clear: LASIK procedures typically change the natural shape of the cornea from prolate to oblate, shifting the normal pinpoint focus of the cornea to a lens with multiple points of focus. The upshot for the patient is more induction of spherical aberration and a reduction in quality of vision, particularly under scotopic conditions.

Now with the advent of the Optimized Prolate Ablation (OPA) profile, developed by NIDEK in collaboration with Dr. Holladay, the possibility of maintaining prolate corneas has finally made the transition from theoretical aspiration to clinical reality. And patients are the ones who will benefit from the breakthrough, maintains Dr Holladay, clinical professor of ophthalmology, Baylor College of Medicine, Houston, Texas.

"The fact is that every study that has ever been done on refractive procedures - whether PRK, LASEK or LASIK – show that they all end up inducing aberrations that reduce the scotopic vision primarily due to the induction of this oblate shape and spherical aberration. After treatment we are left with a cornea that is flatter in the centre and steeper in the periphery and this inevitably leads to a reduction in quality of vision with complaints of glare and halos," he said.

Taking his cue from nature, Dr Holladay remarked that the eagle, noted for its superior visual acuity, has a prolate cornea and the same is true for other predatory animals with good acuity and binocular vision. He then discussed the impact of the ageing process on quality of vision, noting that spherical aberration increases in the eye, as we get older.

The normal cornea is prolate with an average Q-value in the population of -0.26. The Q-value necessary to have no corneal aberration is -0.52, so the cornea is half way between a sphere and the perfect prolate shape. "When we are young the crystalline lens has negative spherical aberration which is almost exactly equal and opposite to the cornea yielding a very good point image on the retina. By the time we are 40, the cornea has not changed and is still prolate but the crystalline lens has changed from negative to nearly zero spherical aberration resulting in the entire eye exhibiting all of the corneal spherical aberration. This means that the crystalline lens gets harder in the periphery faster than in the centre, and by the age of 60 the spherical aberration of the crystalline lens is positive and combined with the cornea yields significant ocular spherical aberration and severe halos and glare at night or in low light conditions." he said.

Treatments for the long term

Dr Holladay said that taking due account of this natural ageing process was the best means of delivering truly optimized treatments that would stand the test of time.

"This is why we need to know the age of the patient in order to give a truly optimized treatment or better yet, measure that total ocular spherical aberration in a specific patient and the topography of the patient and then design a new prolate shape that matches or slightly over-corrects the existing cornea and crystalline lens so the patient will continue to improve for several years ," he said.

Explaining why laser treatments induce spherical aberrations, Dr Holladay said that the principal reason is that the lasers are calibrated on flat surfaces where energy distribution is always perpendicular to the surface, whereas, the cornea is dome-shaped and the effective energy drops off as we leave the center of the treatment resulting in an oblate shape and induced spherical aberrations. By changing the ablation profile, and applying more laser power to the corneal periphery, every cornea will be prolate, and the size of the optical zone will remain the same regardless of the amount of treatment," he said.

More tissue - a price worth paying

Such optimized prolate treatments, however, will result in more tissue removal than non-prolate ablations, said Dr Holladay.

"Nothing comes without a price. There is no question but that we are going to have to ~ 10 to 25% more tissue to restore the cornea to the same shape or better than it was before the surgery,, but all of this is in the periphery. We are simply doing what we had planned to do in the first place, instead of removing less than planned in the periphery" he said.

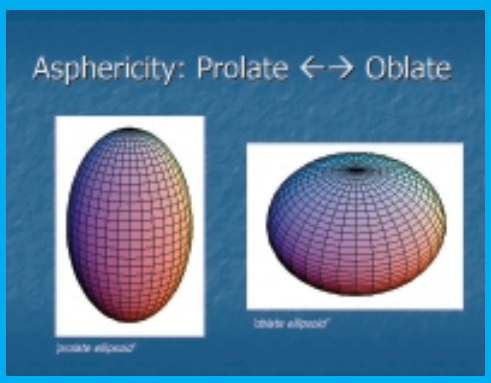
Dr Holladay said that the ultimate goal is to deliver optimized treatments that anticipate and take account of eventual changes in the crystalline lens and cornea of each patient over time.

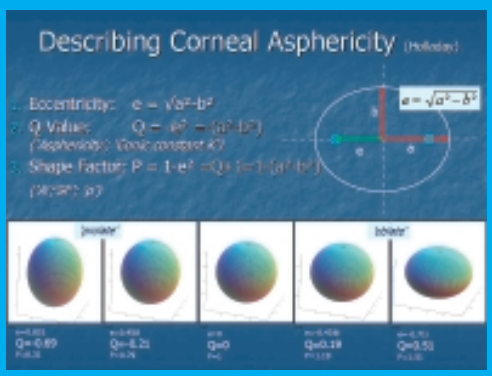
"The cornea does not change shape significantly throughout our lifetime and it keeps more or less the same Q value, unless there is some corneal pathology or dry eye. At around 40, our crystalline lens has zero spherical aberration but the cornea still has positive spherical aberration, and from then on both the lens gets more positive and the vision gets worse and results in visual symptoms such as haloes around lights. This is why prolate aspheric IOLs will dominate the IOL market in cataract surgery in the next few years because the elimination of halos and increased retinal image contrast of a 20 year old is such a big step forward in our rehabilitation of patients with cataracts … if there retina is good, they will see like they did when they were 20 years old.

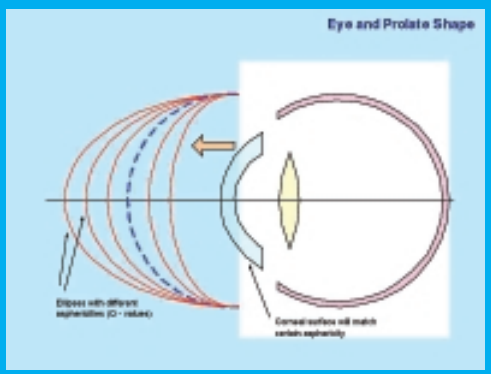
The answer for corneal surgery, he suggested, is to perform an optimized prolate ablation based on the refractive wavefront and topography, taking account of the expected increase in spherical aberration, as the patient gets older.

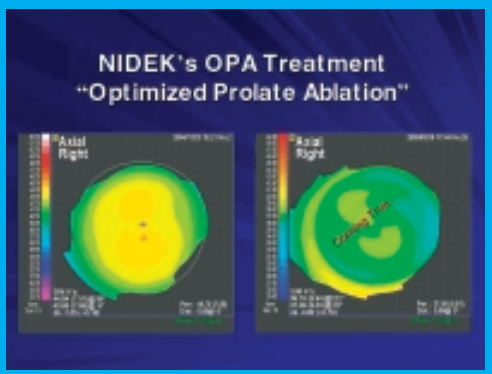
"So ideally we want to anticipate the increase in spherical aberration, which is fairly linear, and make the cornea slightly more prolate than necessary for that patient at this particularly point in their life. So a 20-year-old patient won't be quite as prolate as we would make a 40- or 50-year-old," he said.

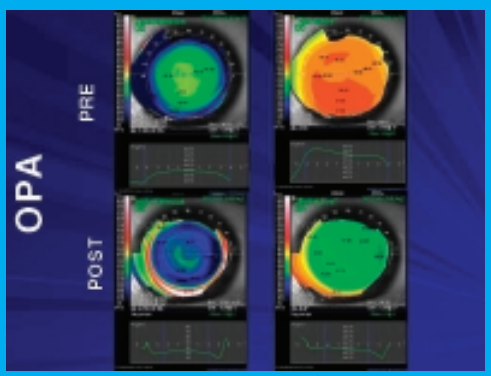
Dr Holladay said that he expected the Optimized Prolate Ablation profile to be available as a software upgrade on the NIDEK laser system before long.

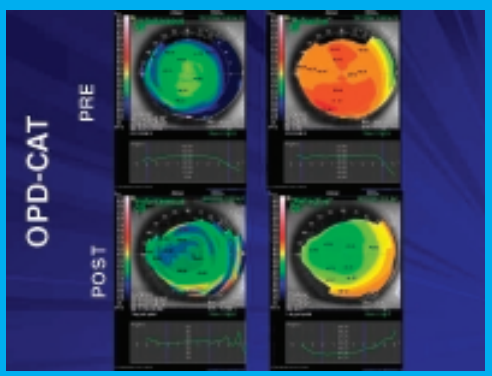












NIDEK Receives CE Mark Approval for Optical Path Difference Customized Aspheric Treatment (OPDCAT) for NIDEK EC-5000 Excimer Laser System

On June 28th, 2005, NIDEK Co. Ltd. announced that it had received CE Mark approval for its proprietary Optical Path Difference Customized Aspheric Treatment (OPDCAT) algorithm and software for the NIDEK EC-5000 Excimer Laser System. This regulatory milestone cleared the way for NIDEK to market its laser and custom treatment algorithm, known as OPDCAT, throughout the world, especially in Europe and the Middle East for the correction of myopia and myopia with astigmatism with aberrations of the entire optical system.

"This is a major milestone for NIDEK and our refractive surgery business in Asia, Europe, the Middle East and South America. With this approval, NIDEK takes an advanced step forward in providing our customers around the world and their patients with the best possible clinical outcomes in the market today for laser vision correction," said Hideo Ozawa, President and Founder of NIDEK Co., Ltd. "NIDEK can now provide an innovative system designed to improve refractive outcomes for patients and treat aberrations of the entire optical system, with wide ranges of myopia and astigmatism." Added Mr. Hideo Ozawa.

OPDCAT uses a proprietary and revolutionary ablation algorithm based on topography and wavefront data generated by the NIDEK OPD-Scan. With a combination of slit scan and multi-point ablation, OPDCAT is intended to correct refractive errors as well as optical aberrations of the entire eye. Aberrations based on corneal and entire eye irregularities can result in visual blur and other undesired visual phenomena are reduced with this new ablation algorithm. This results in a shorter visual recovery period and better post-operative visual acuity.

The clinical data submitted to gain CE mark approval showed excellent clinical outcomes with 97 percent of patients having an uncorrected visual acuity of 20/20 or better. In addition, 86 percent of patients gained at least one line of best-corrected visual acuity. 86 percent of patients were within 0.50 diopters of the targeted refractive correction. Average contrast sensitivity was maintained three months post-operatively, indicating the potential of excellent quality of vision after the procedure.

"The use of OPDCAT software algorithm with NIDEK's excimer laser technology potentially increases the visual acuity and quality of vision while addressing two major issues in refractive surgery: treatment of aberrations of the entire optical system and reducing higher order aberrations that can occur post-ablation. NIDEK's excimer platform now offers a full suite of treatment algorithms that use wavefront and topography data from the NIDEK OPD-Scan to treat a patient's refraction needs. We expect an unsurpassed level of patient and physician satisfaction with this improvement in refractive surgery," noted Mr. Hideo Ozawa

The CE Mark is an indication that a company has met essential health, safety and environmental protection requirements detailed in 22 European Directives covering an array of products including medical devices. The CE Mark allows products to gain access to the EU market, assuring physicians and patients of the safety of the product.

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NIDEK-U.S. Hyperopia Clinical Study Update

NIDEK continues to make excellent progress in its US FDA Hyperopia Clinical Study. July 2005 will mark a critically important milestone, as NIDEK prepares to submit its hyperopia study to the FDA for review and approval – Pre Market Approval (PMA) Filing. With 12-month follow-up data being received from the various clinical sites, NIDEK will submit data to the FDA showing excellent safety, stability and refractive outcomes from the 293 eyes treated in the clinical study.

NIDEK continues to work closely with the FDA and plans on having a pre-PMA meeting with the FDA at the end of July 2005, prior to its formal PMA submission to the FDA targeted for September 2005. NIDEK will report 6-12 month follow-up on all the study eyes to the FDA as part of their PMA submission and approval process.

"We continue to make outstanding progress and remain on track with the clinical study, the follow-up data collection and the PMA submission process. The results we have generated to date all exceed FDA benchmarks for hyperopia approval and we look forward to our meetings with the FDA and submitting our PMA in short-order. Our patient follow-up at 6-months is 99.3%, which is outstanding for any clinical trial. Data collection for the 12-month follow-up is currently ongoing, but results attest to the accuracy of the NIDEK EC-5000 Excimer Laser", commented George Waring, III, MD, Medical Monitor for the NIDEK US Hyperopia Study and Chairman of NIDEK's Medical Advisory Group.

Dr. Waring also added, "Outcomes for the treatment of hyperopia and hyperopic astigmatism in NIDEK's FDA trial indicate excellent refractive outcomes. Although follow-up of all patients is not completed at this point, the 9 & 12-month follow up data seem to indicate refractive stability that rivals myopia treatment and correction." (Figure 1).

Of the 98 patients available for 12-months follow up, 62% were with +/- 0.50 D of the intended MRSE. Eighty seven percent were within one diopter of the intended MRSE at 12 months. For the treatment of astigmatism, 73% of eyes were within a half diopter of the intended correction and 92% were within a diopter of the intended correction

Below is a current summary of the visual acuity data at the various post-operative visit time points for the 293 eyes enrolled in the FDA clinical trial.

Based on the current timelines and follow-up discussions with the FDA, NIDEK looks to submit the PMA filing to the FDA in September 2005. Hoping to get an expedited review with the FDA, approval for hyperopia should be in the early part of 2006. With a keen eye on the future of the NIDEK EC-5000 Excimer Laser Platform, NIDEK continues to plan and execute on its custom ablation trial in the United States and brining additional approval for its refractive platform. NIDEK recently received CE Mark approval for its advanced software algorithm, the NIDEK OPDCAT software, which utilizes topography and wavefront data from the NIDEK OPD-Scan for correcting myopia and myopia with astigmatism with aberrations of the entire optical system.

NIDEK's EC-5000 Excimer Laser System is currently approved for the reduction and elimination of myopia in the low, moderate and high ranges from -0.75 to -14.00 diopters (D) and moderate myopia with astigmatism ranging in severity from -1.00 to -8.00 D, with a refractive astigmatism from -0.50 to -4.00 D cylinder by manifest refraction, using LASIK (Laser in-situ Keratomileusis) or PRK (Photorefractive Keratectomy).

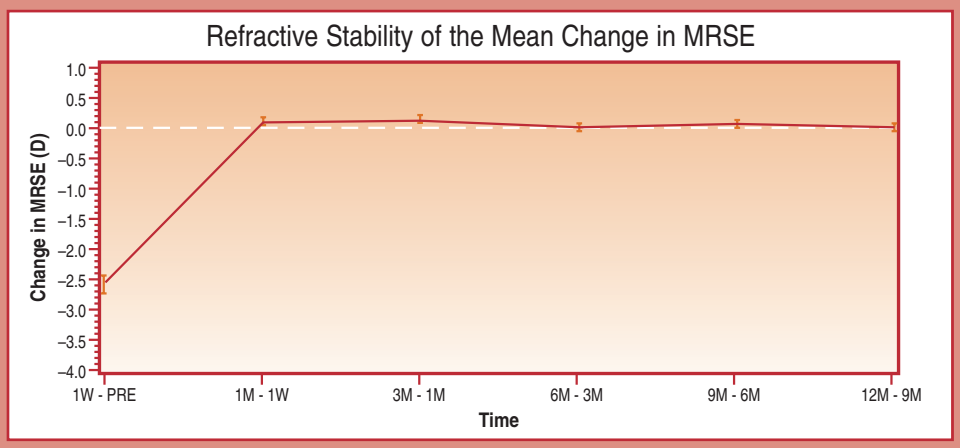

Figure 1 - This graph plots the mean change in MRSE that occurred during each specified interval (ie Screening to Week 1, Month 1 to Month 3, etc.). As expected, the largest difference in MRSE (-2.6 D) occurs in the interval from the screening visit (before LASIK) to the 1 week postoperative visit (after LASIK). Thereafter, the manifest refraction is relatively stable, with no more than a 0.02 D/month difference in MRSE occurring at any of the postoperative visit intervals after 3 months.

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
EFFICACY VARIABLES							
MRSE +/- 0.50 D	**n/N**	226/291	225/287	210/289	200/289	136/202	61/ 98
	(%)	(77.66%)	(78.40%)	(72.66%)	(69.20%)	(67.33%)	(62.24%)
MRSE +/- 1.00 D	**n/N**	279/291	276/287	272/289	272/289	187/202	86/ 98
	(%)	(95.88%)	(96.17%)	(94.12%)	(94.12%)	(92.57%)	(87.76%)
MRSE +/- 2.00 D	**n/N**	290/291	287/287	289/289	289/289	202/202	98/ 98
	(%)	(99.66%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
UCVA 20/20 or better	**n/N**	154/291	172/287	163/289	174/289	119/202	60/ 98
	(%)	(52.92%)	(59.93%)	(56.40%)	(60.21%)	(58.91%)	(61.22%)
UCVA 20/40 or better	**n/N**	281/291	284/287	285/289	285/289	201/202	98/ 98
	(%)	(96.56%)	(98.95%)	(98.62%)	(98.62%)	(99.50%)	(100.0%)

Although FDA does not have set criteria for hyperopia approvals, the US Hyperopia UCVA data exceed the FDA benchmarks that are used for its myopia approvals of at least 85% of the eyes seeing 20/40 or better and at least 50% of the eyes seeing 20/20 or better at all time points in the clinical trial

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NAVEX

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(International Division)

NAVEX, Custom Ablation & Hyperopia have not been cleared by the FDA for distribution in the United States

#205-008

NIDEK Refractive Express published by:

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Chiyoda-ku, Tokyo 101-0051 JAPAN

Congress Schedule

SAO - Sociedad Argentina de Oftalmologia
July 23-27, 2005
Buenos Aires, Argentina

AUSCRS - Australasian Society of Cataract & Refractive Surgery
August 18-22, 2005
Queenstown, New Zealand

SNEC - Singapore National Eye Center Congress
September 3-5, 2005
Singapore

China Ophthalmology Congress
September 9-13, 2005
Tenjin, China

ESCRS - European Society of Cataract & Refractive Surgeons
September 10-14, 2005
Lisbon, Portugal
Booth No. 227

Refractive Online
September 15-17, 2005
Milano, Italy

Beijing Optical Show
September 21-23, 2005
Beijing, China

SOE (European Society of Ophthalmology) / DOG (Deutsche Ophthalmologische Gesellshaft)
September 25-29, 2005
Berlin, Germany

AAO - American Academy of Ophthalmology
October 15-18, 2005
Chicago, USA

SILMO - Salon international de l'optique-lunetterie
October 21-24, 2005
Paris, France

Bascom Palmer
November 1-4, 2005
Miami, USA

RANZCO - Royal Australian & New Zealand College of Ophthalmologists
November 6-9, 2005
Hobart, Australia

Philippine Academy of Ophthalmology Annual Convention
November 18-20, 2005
Manila, Philippine

Thai Royal Ophthalmology Congress
November 25-26, 2005
Bangkok, Thailand