

Refractive Express

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NIDEK Unveils Pioneering Refractive Surgery Platform – NAVEX *Quest*

At the ESCRS 2004 meeting in Paris, France and AAO 2004 meeting in New Orleans, Louisiana; NIDEK unveiled and launched its new and advanced refractive surgery excimer laser platform – the NIDEK EC-5000 CXIII – part of the technologically advanced and integrated NAVEX Quest Platform.

The NIDEK EC-5000 CXIII, brings together many years of research and development, clinical experiences and advanced technologies in laser delivery, eye tracking, torsion error detection and compensation and advanced software algorithms to deliver to the surgeon, an advanced, highly integrated and innovative refractive surgery platform for customized and personalized refractive surgery.

The new laser, part of the NAVEX Quest platform from NIDEK, includes the following new and advanced features:

- MultiPoint Customized Ablation Platform
- Advanced Ergonomics & User Friendly Interface
- Innovative Energy Delivery Systems – Super Flex Scan
- State-Of-The-Art eye tracking systems – NAVTracker
- Detection & Compensation For Cyclo Torsion (TED)
- Automated Magnification Controls
- Integrated PC & Hardware Modules
- Superior Laser Algorithms For Optimized Treatments

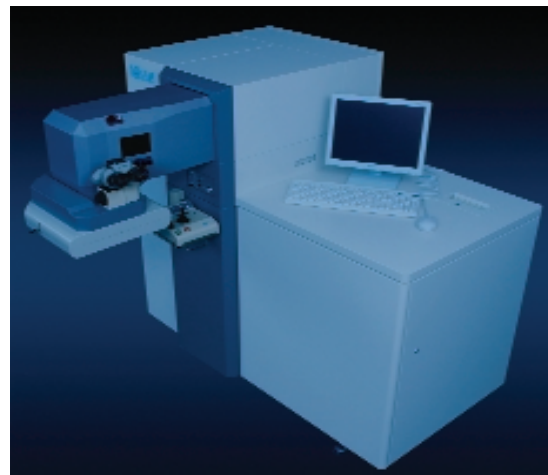
The new excimer laser is currently undergoing extensive technical evaluations and clinical trials with NIDEK's Medical Advisory Group around the world and preliminary results show that the new platform delivers outstanding results for both conventional and customized refractive surgery.

The new excimer laser will incorporate patient data from the NIDEK OPD-Scan and utilize NIDEK's propriety software – Final Fit to generate and deliver the finest laser delivery for superior and outstanding clinical results and outcomes.

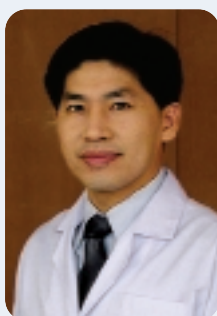
NIDEK will soon make available new clinical results and comparative data, showcasing the outstanding results generated with the new and advanced – NIDEK EC-5000 CXIII, part of the NAVEX Quest Platform.

Begin & End Your Voyage with NAVEX Quest – Delivering To You The Ability To Achieve Your Quest with NAVEX Quest.

NIDEK – Delivering Ultimate Solutions Today!



NIDEK EC-5000 CXIII Excimer Laser - Part of NAVEX Quest



Excellent Results Using Small OZ NAVEX Treatment For High Myopia

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Laser in-situ keratomileusis (LASIK) has been used to treat refractive surgery for approximately two decades. Conventional thinking for those with older ablation algorithms has been to use larger optical zones (OZ) to prevent halos and glare at night. The wider the OZ, the deeper the ablation depth. However with the limited corneal thickness of high myopes this can be a problem. Additionally corneal light scatter due to the higher ablation depth may itself produce unwanted visual phenomenon. The solution for the highly myopic patients has been to perform LASIK with smaller optical zones. However, this alternative often results in symptomatic patients with glare and night vision problems. With the introduction of newer ablation algorithms and as used in the NAVEX excimer laser system employing customized ablation (OPDCAT, OATz and CATz) and Final Fit software, small use of optical zones for treating highly myopic eyes produce much better results than conventional algorithms. This is due to aspheric ablation profiles that results in more physiologic cornea and reduces the spherical aberration induced by conventional ablation algorithms that employ spherical ablation profiles.

We conducted a prospective study assessing the accuracy, predictability and safety of LASIK treatment with a small optical zone for highly myopic eyes using NAVEX excimer laser system with an aspheric profile.

Twenty-three highly myopic eyes of 18 patients underwent LASIK using a small optical zone (OZ). A questionnaire was administered inquiring about subjective evaluation of post-LASIK glare and night vision. Three grades were determined as Grade 0 – none; Grade 1 – mild

Vinciguerra et al proposed the new method of reduction of postoperative spherical aberration, which is one of the most important induced aberrations causing night vision problems after laser refractive surgery.

symptoms (do not interfere with routine daily activities); Grade 2 – Interfere (The patients cannot drive at night). Informed consent was obtained from all patients after giving

them the details of the procedure and the risks.

The mean preoperative spherical equivalent (SE) correction was -10.3 ± 2.39 D (range, -5.5 to -15.5D). All eyes had a manifest refraction greater than -5.5 D. (SE > -6D = 91.3%, 21/23E; SE -6D or less = 8.67%, 2/23E) The preoperative best-spectacle corrected visual acuity (BCVA) was 20/20 or better 43.48%(10/23E); 20/40 or better 95.65%(22/23E) and less than 20/40 4.35%(1/23E). Preoperative BCVA in all eyes was in range of 20/20 to 20/63 using the log MAR chart.

LASIK was performed by using the NAVEX excimer laser system. Custom ablation using OPDCAT, OATz or CATz was used in all treatment. The final fit software version 1.11T imported the data from OPD scan and created the ablation algorithms for the NAVEX excimer laser system. Small optical zones were used in all cases. The range of OZ/TZ was from 3/7mm to 3.8/7.8mm. (Average 3.5/7.5mm OZ/TZ). Profiles no. 5 to no. 7 were

	Pre Op BCVA	Post Op BCVA	Post Op UCVA
≥ 20/20	43.48 %	78.26 %	47.83 %
≥ 20/25	82.61 %	100 %	95.65 %
≥ 20/40	95.65 %	100 %	100 %
< 20/40	4.35 %	0	0
Gain ≥ 1 line	-	52.17 %	30.40 %
Gain ≥ 2 line	-	13.04%	13.04 %
Loss ≥ 1 line	-	0 %	-
within ± 1 D	-	100 %	-
within ± 0.5 D	-	91.3 %	-

Table I: Preoperative and postoperative patient's results of BCVA and UCVA

applied for this study. Intraoperative pachymetry was done in all cases to verify that residual stromal bed thickness would be at least 250 micron after ablation. The mean follow-up period was 3 months or more.

All eyes were anesthetized topically before LASIK surgery. The MK-2000 microkeratome was used to create the corneal flap. The laser ablation was then performed. Antibiotic eye drops were used postoperatively for first 1 week. Postoperative examinations including uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BCVA), manifest refraction, corneal topography and high-order aberration by OPD scan were performed.

Results

Twenty-three eyes of eighteen patients, 11 male and 7 female were enrolled in this study. Mean age of the patients was 29.89 years (range, 22-45 years). Postoperative uncorrected visual acuity (UCVA) 20/20 or better in 47.83% (11/23 E) and 20/25 or better in 95.65%(20/23 E) of the patients. Postoperative best spectacle corrected visual acuity 20/20 or better in 78.26% and 20/25 or better in 100% of the patients. 52.17%(12/23 E) gained 1 or more lines of BCVA and 13.04%(3/23 E) gained 2 or more lines BCVA postoperatively. No eye lost any lines of BCVA postoperatively. Postoperative manifest refraction was within ± 0.5 D for 91.3%(2/23 E) and ± 1 D for 100% of the patients.

The results from the patient questionnaire about subjective evaluation of postoperative glare and night vision, found that most eyes 86.9% (20/23 E) were in grade 0 and 13.1%(3/23 E) were in grade 1. None reported grade 2.

Discussion

Earlier studies have reported the statistically increased high order aberrations following the LASIK procedure with both conventional ablation and wavefront-guided ablation. However, there was a greater increase after LASIK with conventional ablation. Our previous studies also confirmed these observations.

Wavefront guided customized ablation has shown to be a method of reducing postoperative higher order aberrations. However, this is not been the only factor that provides the best visual quality after laser refractive surgery. Vinciguerra et al proposed the new method of reduction of postoperative spherical aberration,

which is one of the most important induced aberrations causing night vision problems after laser refractive surgery. He introduced a method of maintaining physiologic corneal shape by increasing the transition zone and with a concomitant change in the laser profile so that it is aspheric. This results in creating the wider effective optical zone seen clearly in instantaneous or tangential topography map

By using this method the ablation can be as low as 4.5 to 5 millimeter optical zone and using a 4-millimeter or wider transitional zone combined with aspheric profile from No1 to No7. As shown in example Figure 1 the higher the aspheric profile, the wider the effective optical zone we can get postoperatively.

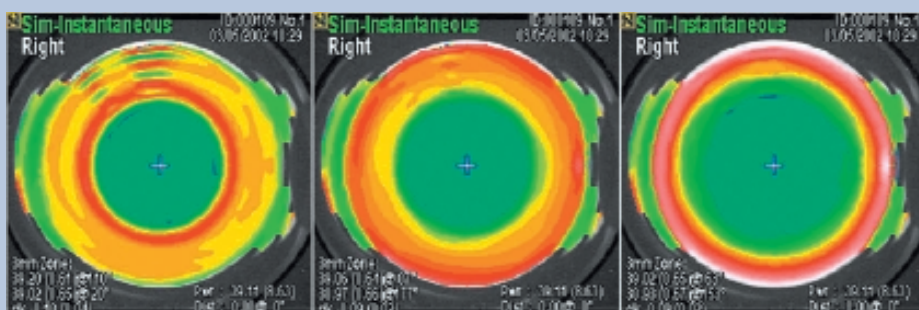


Fig 1: Changing of Aspheric profile from No1 to No4 to No7 in -5.00 D myopia with 5/9 OZ/TZ setting can create much wider effective optical zone.

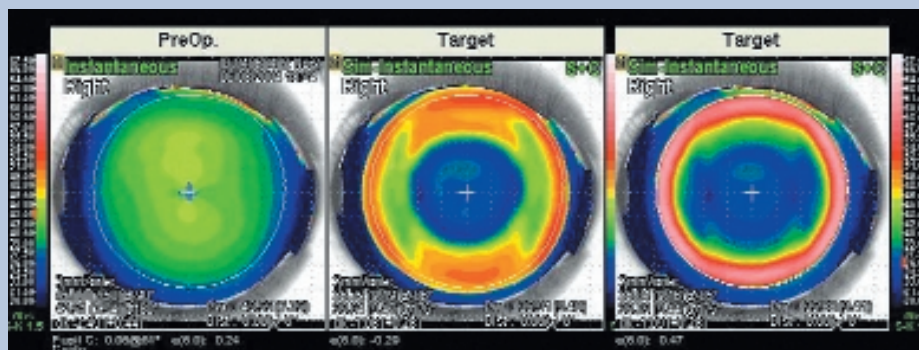


Figure2: Preoperative (left) of -8.75 -1.75 x 180 degree myopia and target results comparing 4.5/8.5 OZ/TZ with aspheric profile 4 (middle) with 3.7/7.7 OZ/TZ with aspheric profile 7 (right)

continued on Page 4

continued from Page 3

However if we increase the profile No. (from 1 to 7) to get a wider optical zone, more tissue is needed. This would not pose a problem in low myopes, but clearly in highly myopic eyes there can be an issue. The question for us was: should we decrease the aspheric profile to reduce the tissue we needed for ablation or should we decrease the optical zone setting? Which one will give better results and how far can we go? Looking at the practical example of Figure 2 which we often find in our practice we can see that even if we use a nearly 1 mm smaller optical zone setting with the higher profile we get a wider effective optical zone. (These two different settings require the same ablation depth)

Figure 3a to 3c show the simulation of target maps of varying OZ/TZ setting and Aspheric profile for different degrees of myopia. We can see clearly from these myopic eyes that in very low myopia (Fig 3a) the effective optical zone is very large and may have very little night vision problems no matter which setting is used. Surprisingly from this example of -2.25 myopic eyes we may use only 15 micron of tissue to get the target result without much compromise of visual quality (the 3/7 OZ/TZ with profile No1). Even though this low an amount of tissue removal may not normally be needed, it still gives us insight in to the tissue savings employed using the plethora of options in the NAVEX system.

In Figure 3b and 3c we can see clearly that with the higher degrees of myopia even if the larger OZ/TZ (such as 5/9) setting and higher Aspheric Profiles (such as profile No7) are used, they will create the largest and smoothest effective optical zone but at the cost of greater tissue removal. For a -9.00 D myopia, with these setting there is greater tissue removal. But in fig 3b and 3c if we simulate other options we can see that from the top to bottom and from left to right of this figure, that the effective optical zone decreases much faster from the top to the bottom. Hence decreasing the OZ/TZ settings and using the correct aspheric profile we can still get large effective optical zone postoperatively. Additionally if we look at the ablation depth we also can see that the depth from top to bottom decrease faster than from left to right. Hence, by using a higher Aspheric Profile there will be a wider effective optical zone at the same time saving the corneal tissue.

With the NAVEX platform, the concept of optical zones has to be revisited. From this example we can see that optical zone setting tell us nothing except the diameter the laser ablation will begin with. The results of same optical zone setting can be varied, creating effective optical zone results of 3 to 10 millimeter or more. It may be erroneous to think that using a larger optical zone is more advantageous. We have seen that the results of using the 3 millimeter optical zone setting sometimes come out better than 5 millimeter optical zone setting (also saving corneal tissue) because one has to keep in mind that transition zone and Aspheric profile also play a vital role in determining the postoperative outcome.

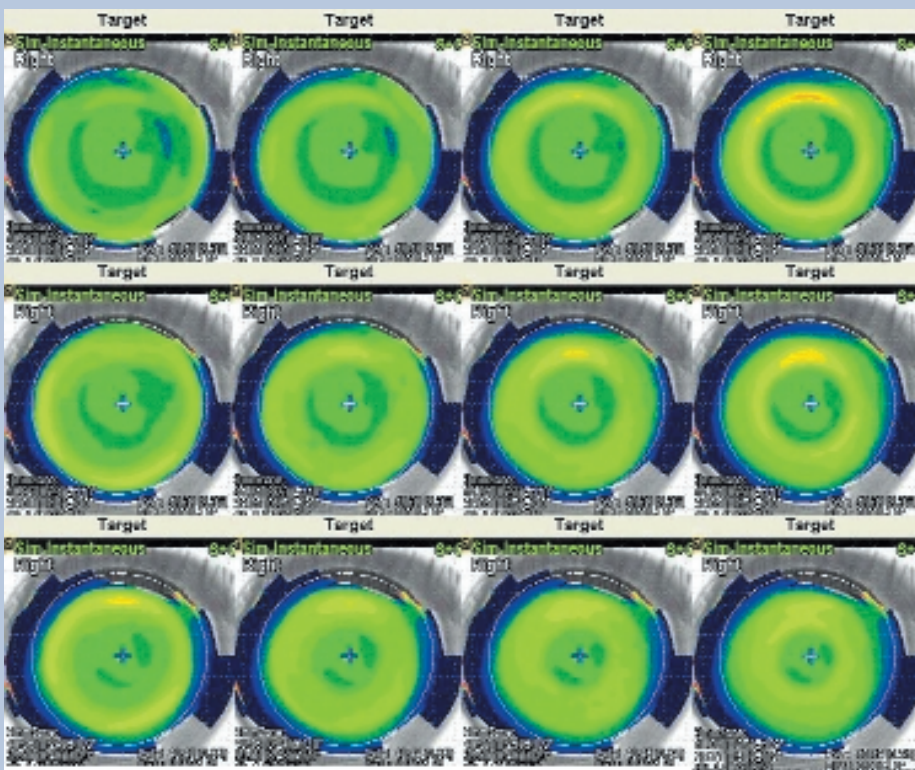



Fig 3a: Simulation target map of -2.25 -0.25 x 49 degree myopic eye. The first to third row is 5/9, 4/8, 3/7 OZ/TZ respectively. The first to fourth column is Aspheric profile No 7, 5, 3, 1 respectively. The ablation depth from left to right of 1st row are 55.2, 48.6, 40.2, 33.0 micron. For 2nd row are 40.2, 34.8, 28.2, 22.8 micron. For 3rd row are 28.8, 24.6, 19.2, 15 micron.

In addition, from the example of figure 3a to 3c we can conclude that from the Aspheric Profile provide by the NAVEX system, the profile No 1 to 3 may not be as useful as the higher profiles apart from in low myopes with extremely small Mesopic pupils and thin corneas.

By doing LASIK in high myopic groups another important factor is the accuracy and reliability of microkeratome used in creating corneal flap. In this study we did intraoperative pachymetry in every cases to verify that the residual stromal thickness left at least 250 micron after laser ablation. This was also helpful by using MK2000 microkeratome from NIDEK with 130-micron head. Our MK 2000 units always cut about 20-30 micron thinner creating 100-micron flap thicknesses. Even with this very thin flap we had no flap complications in our study. Additionally the thinner flaps left us with at least 30 microns of extra and created a safeguard against corneal ectasia.

In conclusion we found that in high myopic eyes which usually have limited corneal thickness, the NAVEX excimer laser system with the small optical zone setting and wide transition zone with highest Aspheric profile can give the promising visual outcome without compromising visual quality. 

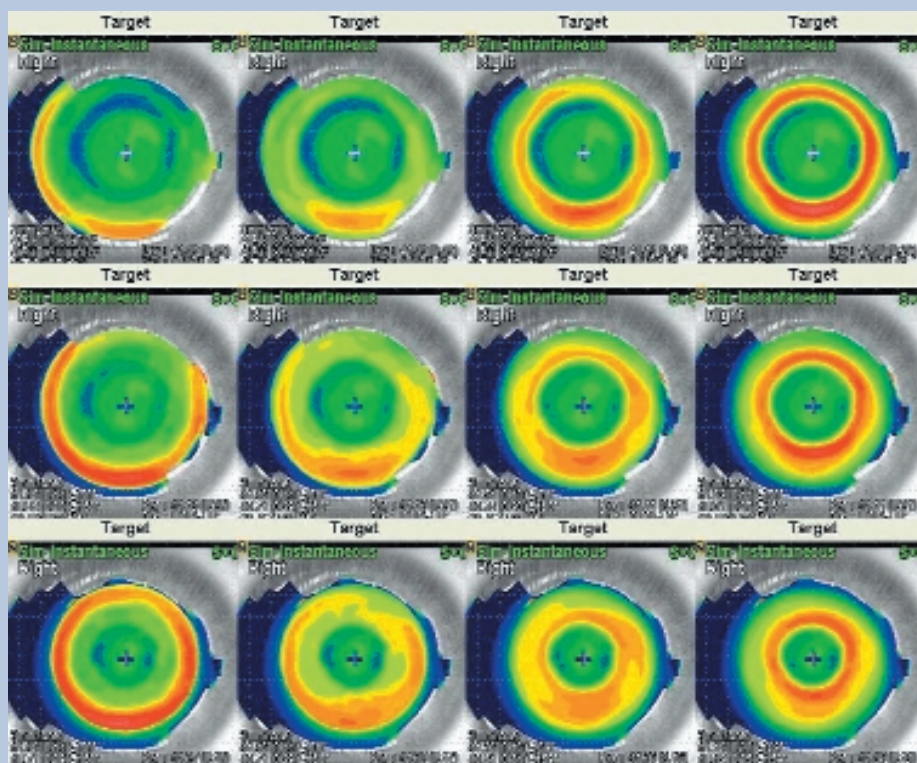


Fig3b: Simulation target map of $-5.25 -0.5 \times 4$ degree myopic eye. The first to third row is 5/9, 4/8, 3/7 OZ/ITZ respectively. The first to fourth column is Aspheric profile No 7, 5, 3, 1 respectively. The ablation depth from left to right of 1st row are 138.2, 120.2, 99.8, 82.4 micron. For 2nd row are 99.8, 86.0, 70.4, 56.6 micron. For 3rd row are 70.4, 60.2, 47.6, 36.8 micron

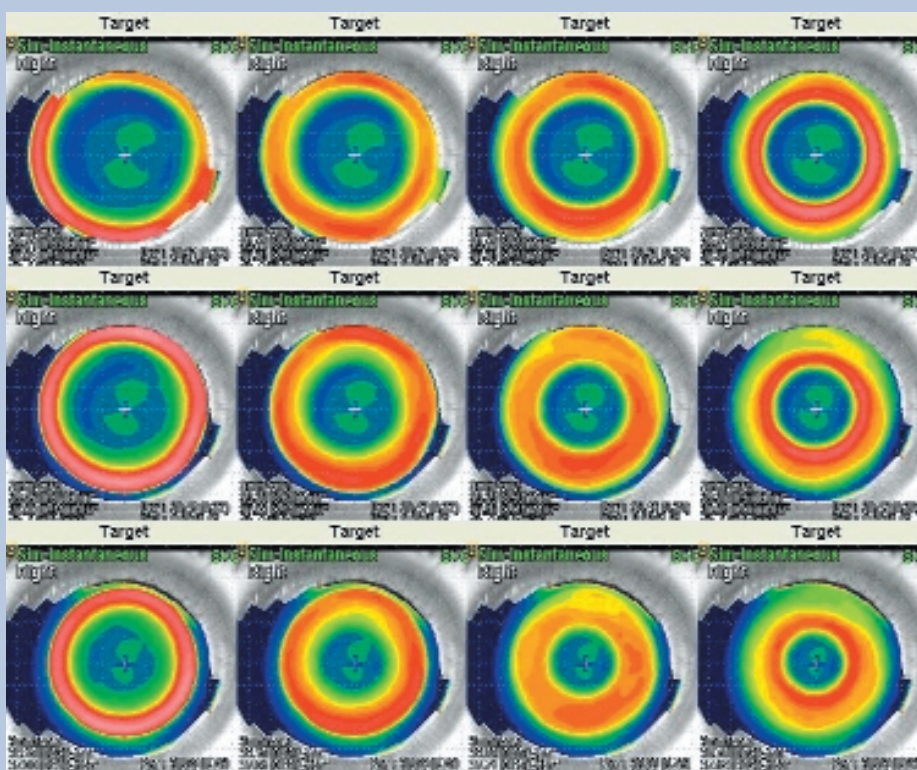


Fig3c: Simulation target map of approximately -9 D sph eqv myopic eye. The first to third row is 5/9, 4/8, 3/7 OZ/ITZ respectively. The first to fourth column is Aspheric profile No 7, 5, 3, 1 respectively. The ablation depth from left to right of 1st row are 202.9, 176.5, 145.9, 120.7 micron. For 2nd row are 147.1, 126.7, 102.7, 82.9 micron. For 3rd row are 103.3, 87.7, 69.1, 53.5 micron



Presbyopic Advanced Surface Ablation (PASA) Using The NIDEK EC-5000 Excimer Laser System

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A variety of different surgical approaches have been used to treat presbyopia these include:

- Scleral
- Intraocular
- Corneal

In terms of corneal procedures, Excimer Laser PRK has been used to correct presbyopia as described by Anschutz (1994) and Vinciguerra (1998).

Recently however, LASIK has been used to produce a multifocal cornea techniques used include:

- Sector near zone
- Central near zone
- Peripheral near zone


Advantages of laser multifocal corneal ablation include that is much less invasive than intraocular surgery, it can be used to correct both near and far vision simultaneously and with some algorithms, the contrast sensitivity can be maintained.

Here we present our preliminary results, with 3 to 6 month follow-up data using pseudo accommodative Presbyopic Advanced Surface Ablation PASA (peripheral near zone), which is a modified version of the Pseudo-Accommodative Cornea (PAC) as described by Alain Telandro MD.

Twenty-eight eyes (17 patients) with 3 – 6 months follow up are presented here. Refractive errors ranged from myopia, hyperopia, astigmatism, primary and secondary treatments, Mean age was 49.8 years (37 to 62 years), all patients had Comprehensive ophthalmologic examination, pre-op and post-op Topography (Eye Sys Premier CA,

USA), Aberrometry (OPD Scan Nidek Co. Japan) and Near visual acuity test (near modified ETDRS Lighthouse NY) 50 lux illumination (Broad Range Lux/FC Meter 840022 model Sper Scientific Taiwan) were performed on each patient.

One surgeon (RC) performed all cases using the NIDEK EC-5000: The “No Touch” technique for epithelial removal as described by Donald Johnson MD was used in all cases. Surface Ablation for distance vision correction and concentric Peripheral Near Zone Presbyopia Correction technique developed for LASIK by Dr. A. Telandro, and modified by Dr. R. Cantú termed the PASA nomogram was used (after discussion with Dr. M. Alaa El Danasoury and Huey Hiramatsu, Engineer, NIDEK Co. Ltd).

Presbyopic Advanced Surface Ablation PASA is a Promising Approach for surgical correction of Presbyopia and Potentially could be used with any type of ASA procedures (Lasek, Epi-Lasik, Advanced PRK). The increase in negative spherical aberration and asphericity/eccentricity seems to increase the depth of focus of the eye improving the near vision. 

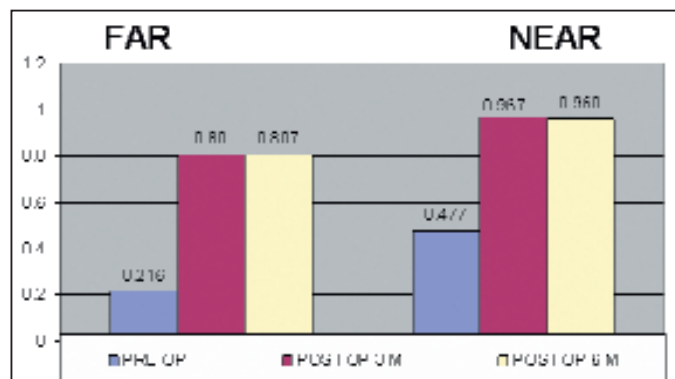


Fig. 1 (Mean pre op and post op UCVA Far and Near)

NIDEK - US Hyperopia Clinical Study Update – 9-Month Update

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During the AAO 2004 Meeting in New Orleans, Louisiana, NIDEK announced, 9-month clinical data from its US FDA Hyperopia Clinical Study for the treatment of hyperopia and hyperopic astigmatism. This marked an important milestone in the study protocol, as a total of 248 eyes had been treated, with a total number approved in the study at 300 eyes. Over the last 12 months, NIDEK worked closely with the FDA on the design, data-collection and evaluation of the clinical study.

“We are extremely excited and very pleased with these results and the 9-month follow-up data that we are getting from our 7 clinical sites for the new hyperopia software for the US EC-5000 platform. The results we have generated to date all exceed and surpass FDA criteria for hyperopia approval and we look forward to collecting all the 9-month data and thereafter working with the FDA to evaluate our submission process. With the expanded study, we look forward to completing the actual treatments in short order and doing the follow-ups necessary for submission and approval with the FDA”, commented George Waring, III, MD, Medical Monitor for the NIDEK US Hyperopia Study and Chairman of NIDEK’s Medical Advisory Group.

Below is the completed data set for all treated eyes in the US clinical trial. A total of 254 eyes have been treated out of 300 approved eyes for the study protocol.

UCVA – All Treated Eyes	1-Month		3-Month		6-Month		9-Month	
N	222		163		71		60	
	N/n	%	N/n	%	N/n	%	N/n	%
UCVA 20/20 or better	134	60.4	87	53.1	44	62.0	33	55.0
UCVA 20/25 or better	186	83.8	140	85.4	62	87.3	50	83.3
UCVA 20/32 or better	211	95.1	160	97.6	67	94.4	59	98.3
UCVA 20/40 or better	219	98.7	160	97.6	71	100.0	59	98.3

NIDEK plans to begin custom ablation clinical trials in the United States in the next few months, using its proprietary CATz (Customized Aspheric Treatment Zone) software algorithm and advanced laser hardware. The company has been in detailed discussions with the FDA for the initiation of additional studies to evaluate hardware and software for the NIDEK EC-5000 Excimer Laser System. Additionally, NIDEK and the FDA will review and perform analysis of international clinical experiences with new technologies, including CATz, OATz and OPDCAT software algorithms.

FDA criteria for hyperopia approval	
MRSE within +/- 0.5 D	50%
MRSE within +/- 1.00 D	75%
UCVA 20/40 or better	85%
Loss of 2 or more lines BCVA	5%

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 -1.0 to -14.00 diopters (D) MRSE and up to -4.00 D of astigmatism using LASIK (Laser in-situ Keratomileusis and for PRK (Photorefractive Keratectomy) treatment for 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.

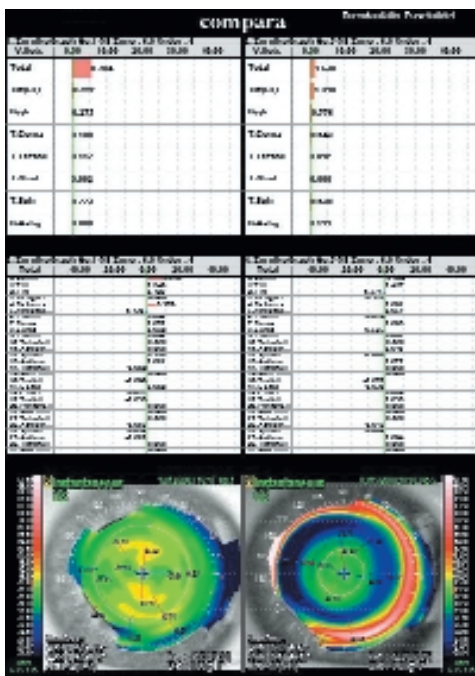
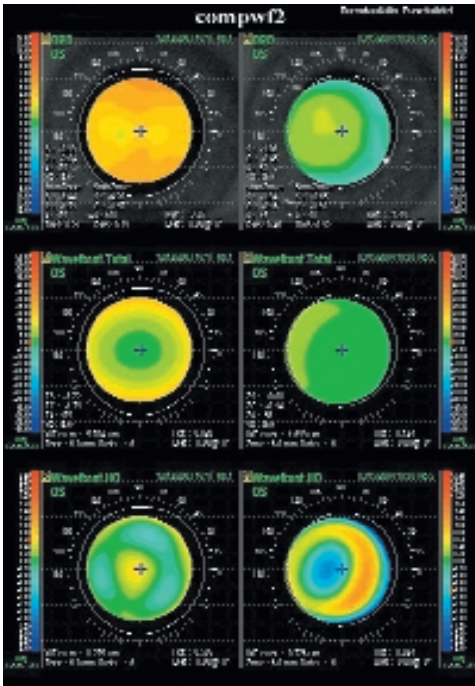


Fig. 2 - 3

Case example: female AGE 54 years OS pre op - 3.25 -1.75 X 0 20/20 FAR 20/150 NEAR ADD +1.50 20/20 (left) and PASA 3 M POST OP 20/20 UCVA FAR 20/20 UCVA NEAR VISION (right)



VISIONARY PERFORMANCE



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<http://www.nidek.com>
(English language)

<http://www.nidek.co.jp>
(Japanese language)

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

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Congress Schedule

**Hong Kong
Ophthalmology Congress**

December 3-5, 2004
Hong Kong

**The 14th Iran
Ophthalmology Congress**

December 14-17, 2004
Tehran, Iran

**Hawaii 2005 – The Royal
Hawaiian Eye Meeting**

Jan 16-21, 2005
Big Island, Hawaii, USA

**6th International Congress
of Wavefront Sensing
& Optimized Refractive
Corrections**

Feb 11-13, 2004
Athens, Greece

**The 3rd Asian Congress
of Ophthalmology**

Feb 18-21, 2005
Shanghai, China

**APAO – Asia Pacific
Academy of Ophthalmology**

March 27-31, 2005
Kuala Lumpur, Malaysia
Nooth No. 05-10

**NIDEK Refractive Surgery
Symposium Pan-Arab & Africa**

April 6, 2005
Dubai, UAE

**PAACO (Pan-Arab African
Council of Ophthalmology)**

April 7-10, 2005
Dubai, UAE
Booth No. 409

**COOC (Congress of
Ophthalmology and
Optometry China 2005)**

April 8-10, 2005
Shanghai, China

OPTRA Fair – Birmingham, UK

April 16-18, 2005
Birmingham, UK

World Cornea Congress

April 13-15, 2005
Washington, DC, USA

**ASCRS (American Society
of Cataract & Refractive
Surgery)**

April 16-20, 2005
Washington, DC, USA

**ARVO (The Association
for Research in Vision
& Ophthalmology)**

May 1-5, 2005
Fort Lauderdale, USA

**SFO (Société Française
d'Ophthalmologie)**

May 7-11, 2005
Paris, France

ISRS / AAO Asia Meeting

May 14-16, 2005
Hong Kong