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NIDEK Eye & Health Care

NAVEX

FDA CATz Outcomes

"This study confirms that LASIK using CATz is safe, predictable and results in excellent patient satisfaction for night driving and halo/glare symptoms postoperatively."

George O. Waring III. M.D.

Refactive outcomes from the first topography-guided refractive ablation study submitted to the Food and Drug Administration, have shown excellent predictability, safety, and the patient satisfaction with night vision. The study included four study sites that enrolled 135 eyes of LASIK patients with myopia and astigmatism. The Nidek EC-5000 CXIII excimer laser (CXIII) with the custom aspheric treatment zone (CATz) algorithm was used to treat myopia up to 6.00 D with astigmatism up to 2.00 D.

The CATz ablation profile uses a combination of optical and transition zones that gradually tapers the corneal curvature paracentrally and peripherally, creating what is effectively a single treatment zone. In this study all treatments used an 8mm or larger 'treatment zone' formed by the combination of 5mm optical and 8mm (or larger) transition zones. The use of aspheric profiles as used in the CATz treatment may reduce the steep curvature gradients and spherical aberration seen with conventional ablation algorithms. A recent peer review study reported larger effective optical zones and better contrast sensitivity with aspheric treatments compared to conventional treatments using the NIDEK laser. *1

Evaluation of the CATz outcomes from the FDA study 6 months postoperatively found that 93.13% of eyes were with ±0.50D of the inteded (emmetropia, figure 1).

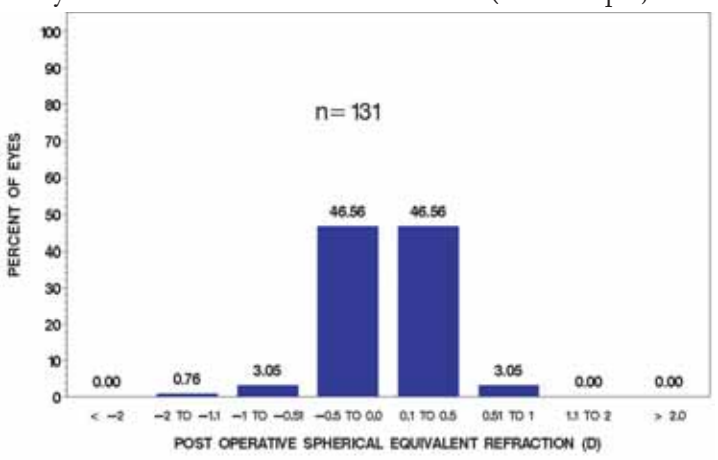
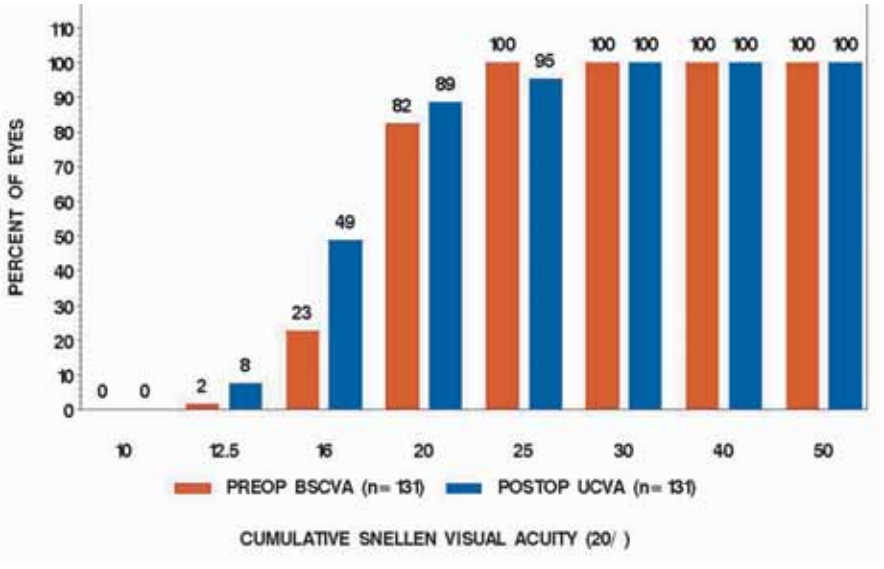


figure 1: Distribution of MRSE 6 months after myopic LASIK using the NIDEK topographically-guided custom aspheric treatment zone (CATz) algorithm.

Postoperative UCVA of 20/16 or better UCVA exceeded preoperative BSCVA in over 25% of the cases (Figure 2). A statistically significant number of eyes had better postoperative UCVA compared to preoperative BCVA. No eye lost 2 or more lines of BCVA. Six months postoperatively, total ocular higher order aberrations RMS increased by 0.04μm and spherical aberrations RMS increased by 0.053μm. The increases in aberrations were not clinically significant.

Figure 2: Preoperative best corrected visual acuity (BSCVA) compared to 6 months postoperative uncorrected visual acuity (UCVA) after myopic LASIK using the NIDEK topographically-guided custom aspheric treatment zone (CATz) algorithm. Postoperative UCVA is better than preoperative BSCVA.



Leaving little to chance, the NIDEK team elected to use 2 separate patient questionnaires to determine patient satisfaction with the CATz treatments. A custom-desined questionnaire was used for this study; the second was the validated Refractive Status and Vision Profile (RSVP) questionnaire, considered the gold standard in refractive surgery. Results from these questionnaires, indicated that patients reported statistically significantly fewer night driving and halo/glare symptoms postoperatively than preoperatively. Most strikingly, a 23% decrease in patients' reporting marked to severe difficulties in night driving, and less than three percent of the patients reporting an increase of moderate to severe mesopic/scotopic symptoms such as halos, glare or starburst postoperatively compared to preoperatively.

Validating NIDEK's approach to topography-guided ablation, this study confirms that LASIK using CATz is safe, predictable and results in excellent patient satisfaction for night driving and halo/glare symptoms postoperatively.

*1: Hori-Komai Y, Toda I, Asano-Kato N, Ito M, Yamamoto T, Tsubota K.
Comparison of LASIK using the NIDEK CXIII optimized aspheric transition zone (OATz) and conventional ablation profile.
J Refractive Surg 2006; 22: 546-55.

Active Torsion Error Correction (TEC) during Laser in Situ Keratomileusis (LASIK) or Photorefractive Keratectomy (PRK) for the correction of myopia and astigmatism.

Sudhank Bharti, M.D.

Cyclotorsion can occur during surgery when the patient is supine, and may increase under monocular conditions*1.Cyclotorsion can induce cylinder and higher order aberrations causing a decrease in visual quality.
For example a 4 degrees torsional misalignment could theoretically result in a 14% undercorrection of astigmatism*2.
With the increasing use of wavefront or custom ablations, the tolerances for misalignment become even extremely stringent to ensure accurate placement of the ablation. Hence active cyclotorsion compensation using TEC is increasingly becoming a requirement for refractive surgery.

In a prospective, bilateral, controlled clinical trial using the EC-5000 CXIII for the correction of myopia with or without astigmatism, Dr. Bharti of New Delhi, India, compared the safety and effectiveness of the NIDEK active torsion error correction system for LASIK and PRK. The torsion error correction function (TEC) now available for NIDEK's CXIII excimer laser actively compensates for cyclotorsion during laser ablation to deliver the treatment to the inteded area despite torsional eye movements.
Fifty-two eyes of 26 patients were divided in two groups; 30 eyes that underwent primary LASIK or primary PRK with TEC (TEC group) and 22 eyes that underwent LASIK or PRK without TEC (control group).
Patients with stable myopia or myopic astigmatism that met the requirements for primary LASIK or PRK were included in the study. All eyes were targeted for emmetropia and 3 months postoperatively results were reported.

In this study the scatter and predictability of manifest refractive cylinder where compared between the TEC and control groups. Postoperatively, eyes that underwent treatment using TEC had a statistically significantly lower scatter of manifest refractive cylinder than the control group (Fig. 1) (p=0.0028. F-test).
Postoperative manifest cylinder in the TEC group was also statistically significantly lower than the control group as shown (Table 1) (p<0.001, Welch's t-test).

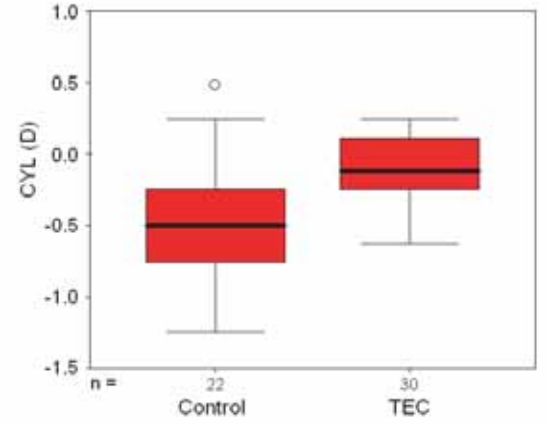


Figure 1. Manifest Refractive Cylinder at 3 months of eyes that underwent myopic LASIK or PRK with or without active torsion error compensation (TEC).

	Group	n	Mean	STD	*p* value
Manifest Cylinder (Abs. value)	TEC	30	0.210	0.155	< 0.001
	Control	22	0.555	0.340	

A *p* value < 0.01 denotes statistical significance.

Table 1. Postoperative Manifest Cylinder at 3 months of eyes that underwent mypic LASIK or PRK with (TEC) or without (control) active torsion error compensation.

The predictability was similar between groups with 90% of eyes with 0.50D in the TEC group and 64% if eyes within 0.50D in the control group (Figure 2). At 3 months postoperatively, 90% of eyes had an UCVA of 20/20 or better in the TEC group whereas 78% of eyes had an UCVA of 20/20 or better in the control group (Figure 3).

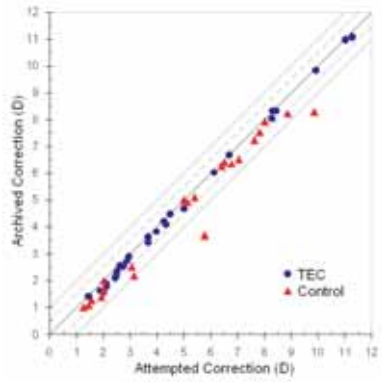


Figure 2. Attempted versus achieved MRSE 3 months postoperatively, of eyes that underwent myopic LASIK or PRK with or without active torsion error compensation (TEC).

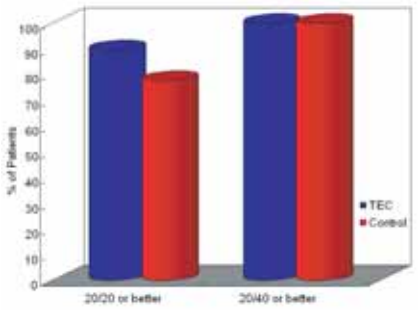


Figure 3. UCVA 3 months postoperatively, of eyes that underwent myopic LASIK or PRK with or without active torsion error compensation (TEC).

The outcomes of this study indicate that active cyclotorsional compensation using TEC results in statistically significantly better refractive outcomes. Accurate cylinder correction and the precise registration custom ablation patterns on the cornea are essential to reduce adverse outcomes. TEC uses the iris landmarks during OPD-Scan II measurement in sitting positions and continually compares these once the patient is supine. Active laser compensation is achieved by rapid changes in the position of the laser optics to continually deliver the ablation to correct position based on feedback from the TEC software module. Accurate cyclotorsion compensation using TEC with the EC-5000 CXIII excimer laser enables accurate and precise treatments that can potentially reduce enhancement rates, and achieve optimal visual outcomes. NIDEK recently achieved CE mark approval for the addition of TEC on the EC-5000 CXIII excimer laser.

References:
1) Kermani O. Alignment in customized laser in situ keratomileusis. J Refract Surg. 2004; 20: S651-8.
2) Guirao A, Williams DR, Cox IG. Effect of rotation and translation on the expected benefit of ideal method to correct the eye' s higher-order aberrations. J Opt Soc Am A 18: 1003-1015, 2001

One User's Experience with NIDEK's AFC-210

Goji Tomita, M.D.
Professor of Toho University Ohashi Medical Center

NIDEK' s AFC-210 captures highly precise 12.80 Mega-Pixel fundus images. These images are of such resolution that zooming in for detailed analysis of the optic nerve head is possible without experiencing blur. This is especially important for the diagnosis and monitoring glaucoma with fundus photography as Japan' s Glaucoma Society recommends capturing two kinds of fundus images: a magnified view for detailed recording of ONH, and a wide-angle fundus image to identify changes in the retinal nerve fiber layer. The AFC-210 can do this with just one 45 degree image due to this remarkable blur-free magnification, making the AFC-210 is highly beneficial in screening and monitoring patients with glaucoma.

Another important feature of NIDEK' s AFC-210 is its stereo imaging mode. The stereo imaging mode offers the capability of generating stereoscopic images with a consistent 2mm stereo base. In capturing a pair of images for stereoscopy, the AFC-210 presents a special target gauge each image of the pair. Therefore, by moving the camera head according to the guidance of this gauge, one can consistently capture stereoscopic images with constant visual angle. This is critical for ONH morphological observation and monitoring for changes over time. Previously, Nidek manufactured the 3DX-NM Non-Mydriatic Simultaneous Stereoscopic Fundus Camera. In my personal experience, while AFC-210' s stereoscopic photograph is not generated with "simultaneous" pair, my feeling is that the quality of image with AFC-210 is equal, if not better than 3DX-NM.

In conclusion, NIDEK' s AFC-210 is an easy to use fundus camera with high quality imaging capability, compact design, and is bundled with superior fine-tuning image software which includes various analytical features. While general limitations still exist with Non-Mydriatic fundus cameras in capturing retinal pathologies with overall fundus image including periphery, AFC-210' s ease of use helps in screening and diagnosis of pathological changes in ONH, macular area and posterior pole of fundus. Regarding these points, NIDEK' s AFC-210 is one of most suitable fundus cameras for screening, diagnosing and monitoring glaucoma.