NIDEK EC-5000 EXCIMER LASER SYSTEM

PROFESSIONAL USE INFORMATION

PHOTOREFRACTIVE KERATECTOMY (PRK)

CAUTION Restricted Device:
U. S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed physician.

U. S. Federal Law restricts this device to practitioners who have been trained in the surgical treatment and management of the cornea or refractive errors, and in the operation, maintenance and calibration of this system.

This manual is supplied to provide information on the intended clinical use of the Nidek EC-5000 Excimer Laser System. For complete information concerning laser system components, laser safety, installation, maintenance, and troubleshooting refer to the NIDEK Excimer Laser Operator's Manual.

WARNING:
The user is responsible to read all instructions before use of this system. Pay attention to all warnings, contraindications, and precautions noted in these instructions, the Operator's Manual, and other related materials. Failure to do so may result in harm to a patient or user of the system.

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1. BRIEF DEVICE DESCRIPTION

The 193 nm Nidek EC-5000 Excimer Laser System is intended to perform keratectomy on exposed corneal tissue to modify corneal curvature for vision correction. The Nidek EC-5000 laser performs optical correction by recontouring the anterior surface of the cornea with a process referred to as photoablative decomposition. By controlling the shape and depth of the ablation, the EC-5000 changes the corneal curvature to correct refractive errors.

The excimer laser output is produced by electronically exciting a mixed molecular gas combination of argon and fluorine. This produces radiation in a far-ultraviolet wavelength, which causes photodecomposition of molecular bonds. This process permanently removes tissue from the cornea without thermal injury to adjacent tissue structures.

2. INTENDED USE

The Nidek EC-5000 Excimer Laser System is intended for use:

- In Photorefractive Keratectomy (PRK) treatments for the reduction or elimination of myopia in the low, moderate, or high ranges (–0.75 to –13.00 D), spherical equivalent at the spectacle plane, uncomplicated by refractive astigmatism (i.e., $\leq$ 0.75 D in any meridian).
- In patients who have a stable history of pretreatment myopia, that is a change of $\leq$ 0.50 D in sphere or cylinder in the 12 month period preceding treatment for correction of myopia $\leq$ –7.00 D S.E. or a change of $\leq$ 1.00 D in sphere or cylinder for correction of myopia $>$ –7.00 D S.E.
- In patients who are over 21 years of age.

3. CONTRAINDICATIONS

The Nidek EC-5000 Excimer Laser System should ***NOT*** be used to perform laser surgery:

- In patients who have a systemic disease that would influence corneal wound healing, particularly autoimmune or immunodeficiency diseases and collagen vascular diseases, including rheumatoid arthritis, systemic lupus, and Sjögren's syndrome.
- In patients who have current signs, early signs, or clinical indications of keratoconus.
- In patients who are pregnant or nursing.
- In patients with systemic conditions which would stimulate excessive scar tissue (keloid formation).
- In patients whose current medications include ocular or systemic steroid regimen that would affect their refractive correction.

4. WARNINGS

Laser Eye Surgery should ***NOT*** be performed on patients with an unstable refraction, that is, refractive change of > 0.50 D in sphere or cylinder per year for correction of myopia ≤ -7.00 D S.E. or refractive change of > 1.00 D in sphere or cylinder per year for correction of myopia > -7.00 D S.E., since an under- or over-correction of treatment could result.

Caution should be exercised if the physician is considering performing laser eye surgery on patients with systemic disease likely to adversely affect wound healing. The safety and effectiveness of performing laser eye surgery on these patients has not been determined using the Nidek EC-5000 Excimer Laser System.

Laser surgery is ***NOT*** recommended for patients with a history of ocular *Herpes simplex* or ocular *Herpes zoster*. Reactivation of the virus may be a complication if these patients are treated with an excimer laser.

5. PRECAUTIONS

5.1 General

The safety and effectiveness of the Nidek EC-5000 Excimer Laser System has not been determined for use:

- In patients with active ocular disease, including but not limited to, uveitis, uncontrolled blepharitis, iritis, or severe dry eye.
- In patients with glaucoma and/or ocular hypertension (IOP >21 mm Hg).
- In patients who have insulin-dependent diabetes or clinically significant atopic disease.
- In patients currently taking medications which may affect corneal wound healing, including but not limited to, antimetabolites, retinoids, and sumatriptan succinate.
- In patients who have corneal epithelial, stromal, or endothelial dystrophy.
- In patients who have had previous penetrating ocular or corneal surgery.
- In patients who have previous corneal scarring in the treatment zone.
- In patients who demonstrate irregular astigmatism as seen in topographical analysis.
- In long term studies (over 2 years follow-up after surgery).

Because of the relatively small (n=21) sample size of myopia treatments exceeding -10.00 diopters, the clinical study may have been unable to detect other complications and/or adverse effects in this high refractive error range.

5.2 Applicable to Patient Selection/Pre-Procedure

Caution should be exercised when selecting or treating patients with the Nidek EC-5000 Excimer Laser System based on the following criteria:

- A complete baseline ocular evaluation is essential, including cycloplegic evaluation, especially in older patients, to ensure that no opacities exist prior to treatment. Indirect ophthalmoscopy through a dilated pupil is required on myopic patients, for these patients tend to have a higher incidence of retinal pathology.
- Refractive stability must be demonstrated in patients. For this purpose, stability of refractive correction will be a change of ≤ 0.50 D in sphere or cylinder in the 12 month period preceding treatment for correction of myopia ≤ -7.00 D S.E. or a change of ≤ 1.00 D in sphere or cylinder for correction of myopia > -7.00 D S.E. Contact lens wearers must refrain from wearing their soft contact lenses for at least two weeks, three weeks for hard lenses. Stable refraction must be established at two examinations, one of which may be based upon documented refraction prescription history. If the examinations are less than three weeks apart, patients may wear only spectacles during this interim period. If refractive stability is not established at the screening examination due to lack of prescription history, another examination, two or three weeks later, may be used to determine stability if not evident by the prior examination.
- Assessment of the optic nerves and intraocular pressures to screen for glaucoma must be performed prior to laser surgery. If patients demonstrate raised intraocular pressure or other signs of glaucoma, caution should be exercised when prescribing topical steroids post-operatively, or patients should not undergo laser refractive procedures.
- Pre-operative corneal topography is necessary on all patients to screen for potential topographical abnormalities. Corneal mapping may illustrate the presence of keratoconus or corneal warpage.
- Laser surgery is generally performed using a topical anaesthetic. Patients should be able to tolerate topical or local anesthesia.
- Patients should be able to lie in a supine position without difficulty.
- Patients should be able to demonstrate a steady gaze.
- Patients must be able to understand and give an informed consent for the surgery. All other alternatives to the correction, reduction, or potential elimination of their condition must be clearly communicated to patients.
- Patients who are 50 years of age or older have a higher chance of over-correction and, therefore, a slightly myopic target outcome (e.g., –0.50 D to –1.00 D) should be considered.

- Patients who have higher pre-operative MRSE (i.e., attempted correction) have a higher chance of over- and under-correction (i.e., higher variability). Therefore, since patients tend to tolerate slight myopia better than slight hyperopia, a slightly myopic target outcome should be considered.

5.3 Applicable to Procedure

As with all laser output devices, the Nidek EC-5000 Excimer Laser System presents a potential hazard to patients and operators. Avoid inadvertent direct exposure of skin and eyes to the laser. Healthcare personnel who may approach the path of the primary beam should wear protective eyewear.

If surgery is paused or terminated, the input parameter values remain in system memory for use or reference. Confirm the data input for each procedure, so previously stored or default values are used only where indicated.

Before Laser Surgery:

- Remove the corneal epithelium from the treatment area to approximately 1 mm beyond the intended zone diameter.
- Take care to clean the de-epithelialized surface without damaging Bowman's membrane.
- To avoid drying, minimize time from epithelial removal to laser treatment initiation.
- The use of any blowing gas on or across the cornea during epithelium removal or laser retreatment is not recommended.

Additional detailed procedures are described in the Operator's Manual. Follow the procedures described in the manual to ensure safe and proper operation.

6. ADVERSE EVENTS

Adverse effects of ophthalmologic laser surgery can occur at any time during the recovery period. During the Nidek clinical study, a small number of adverse events were observed through 6 months as noted in Table 6-1.

Some adverse effects are reported every time they occur during the recovery period; others resolve themselves during the recovery period and are reported only if the condition is present 6 months post-operatively.

Adverse effects were reported for the consistent follow-up cohort only if present 6 months or more post-operatively included loss of more than 2 lines in best spectacle corrected visual acuity (1.2% [7 of 585 eyes]), moderate or marked haze (0.5% [3 of 587 eyes]), induced astigmatism of greater than 2.00 D (0.2% [1 of 585 eyes]), over-correction > +2.00 D (2.0% [13 of 585 eyes]), under-correction < -2.00 D (3.0% [15 of 585 eyes]). The distribution of over- and under-correction at 6 months was closely balanced around 0.0 D.

Table 6-1 summarizes the incidence of adverse effects reported in this study for all treated eyes (n=940).

TABLE 6-1. ADVERSE EVENTS

Adverse Event	1 month	3 months	6 months
Corneal or stromal infiltrate or ulcer (2+ or above)	3/940 (0.3%)	0/940	0/940
Persistent central corneal epithelial defect at 1 month or later (2+ or above)	4/940 (0.4%)	0/940	0/940
Uncontrolled IOP with increase of >10 mm Hg above baseline	1/940 (0.1%)	5/940 (0.5%)	3/940 (0.3%)
IOP reading above 25 mm Hg	1/940 (0.1%)	5/940 (0.5%)	4/940 (0.4%)
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BsCVA			0/940 beyond 6 months
Decrease in BsCVA of >10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later			11/940 (1.2%)
Retinal detachment	0/940	0/940	0/940
Retinal vascular accidents	0/940	0/940	0/940

Table 6-2 below summarizes the incidence of complications reported in this study for all treated eyes.

TABLE 6-2. COMPLICATIONS

Complications	Immediate Post-Op	1 month	3 months	6 months
Corneal edema between 1 week and 1 month after the procedure	4/940 (0.4%)	0	0	0
Recurrent corneal erosion at 1 month or later		0	0	0
Foreign body sensation (including itching and scratchiness)	140/940 (14.9%)	0	0	0
Pain (including discomfort, pressure, etc.)	566/940 (60.2%)	0	1/940 (0.2%)	0
Ghost or double images in the operative eye	11/940 (1.2%)	0	0	0
Decrease in BsCVA > 2 lines		25/940 (2.7%)	24/940 (2.6%)	11/940 (1.2%)

An analysis to evaluate the chance of over- or under-correction was also performed using three pre-operative MRSE ranges. Over-correction of more than +2.00 D at 6 months occurred in 0.6% (2/363) of eyes with a pre-operative MRSE < –6.00 D, 4.0% (8/201) of eyes with a pre-operative MRSE from –6.00 D to –9.99 D, and 14.3% (3/21) of eyes with a pre-operative MRSE ≥ –10.00 D. Under-correction of more than –2.00 D at 6 months occurred in 0.8% (3/363) of eyes with a pre-operative MRSE < –6.00 D, 4.5% (9/201) of eyes with a pre-operative MRSE from –6.00 D to –9.99 D, and 14.3% (3/21) of eyes with a pre-operative MRSE ≥ –10.00 D. As a

result of this analysis, there appears to be a significant relationship between pre-operative dioptric (MRSE) group and the occurrence of over- and under-correction.

The following complications were reported by the subjects in the study: an increase in fluctuation of vision (34.1% pre-operatively vs. 48.1% post-operatively); glare (26.9% pre-operatively vs. 34.4% post-operatively); and difficulty in night driving (23.5% pre-operatively vs. 48.0% post-operatively).

7. CLINICAL RESULTS

7.1 Introduction

Nidek Technologies, Inc. designed and implemented a clinical trial to assess the safety and efficacy of the EC-5000 Excimer Laser System for spherical correction of myopia. The study was an open, prospective, stratified, multi-center study conducted in two phases. Subject inclusion into the study was based upon criteria that targeted participants with stable myopia and overall good health. All subjects entering the study met a common selection criteria including: over 21 years of age; low to high myopia (–0.75 to –13.0 D) in one or both eyes, uncomplicated by refractive astigmatism (*i.e.*, ≤ 0.75 D in any meridian); stable history of pretreatment myopia including documented test and prescription history (i.e., for ≤ –7.00 D S.E., a change of ≤ 0.50 D in sphere or cylinder in the 12 month period preceding treatment or for > –7.00 D S.E., a change of ≤ 1.0 D in sphere or cylinder in the 12 month period preceding treatment); stable history of pretreatment astigmatism of 0.75 D as determined by manifest refraction (≤ 0.75 D change in cylinder correction in the 12 month period preceding treatment); clear cornea in the area to receive laser energy; where applicable, discontinuation of contact lens use prior to final enrollment evaluation where soft contact lenses were removed for at least two (2) weeks, and hard contact lenses for at least three (3) weeks; best spectacle corrected visual acuity of 20/40 or better.

Patients were excluded if they had any of the following conditions:

- systemic disease that would influence corneal wound healing;
- active ocular disease;
- current significant medications including steroids (ocular or systemic) that would adversely affect their refractive correction;
- keratoconus (current, early signs, or clinical indications);
- corneal epithelial, stromal, or endothelial dystrophy;
- pregnant or nursing;
- previous penetrating ocular or corneal surgery;
- previous corneal scarring in the treatment zone;

- irregular astigmatism as seen in topographical analysis;
- nystagmus or any other condition which would prevent a steady gaze.

7.2 Patients Studied

A total of 611 subjects had a primary eye or both eyes treated (N=940 total eyes consisting of 611 primary eyes and 329 secondary eyes) at eight clinical centers (Table 7-1) during the two phases of the Nidek EC-5000 excimer laser study for PRK therapy for myopia under an FDA Investigational Device Exemption (IDE). These subjects were treated between December 1994 and April 1997 and had at least six months of follow-up.

TABLE 7-1. EC-5000 CLINICAL STUDY POPULATION DEMOGRAPHICS

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Total
# Males	45	110	31	42	31	20	9	17	305
Median Age	*39*	*43*	*41*	*41*	*36*	*44*	*41*	*44*	*41*
# Females	53	88	49	52	38	11	3	9	303
Median Age	*38*	*42*	*39*	*40*	*36*	*41*	*43*	*41*	*40*
Sex Not Given	--	1	--	--	--	1	--	1	3
Total *(by Site)*	98	199	80	94	69	32	12	27	611

49.9%

49.6%

During this study, data was collected pre-operatively and post-operatively every two to three days until re-epithelialization and then at 1, 3, 6, 12, 18, and 24 months. The "point of stability" was found to be between 3 and 6 months (i.e., by the 6 month visit). Of the 940 total treated eyes, 587 eyes were evaluated at each of the following visits: pre-operative, 1 month, 3 months, and 6 months. These 587 eyes are considered the "consistent cohort" for the following clinical study results, unless otherwise stated.

The data elements and requirements for the follow-up periods remained consistent throughout the study. In addition to having a primary eye treated, under the protocol a subject could have the contralateral eye treated, provided that the primary (or first eye) had a certain improved visual outcome and that sufficient time had elapsed between the time of the surgery on the primary eye and the time of surgery for the second eye. Both effectiveness and safety results were evaluated on the "consistent cohort" of 587 eyes that were examined at a pre-operative visit and at post-operative visits at 1, 3, and 6 months. In addition to the main protocol for both phases of this study, three sub-studies were conducted at selected sites. These sub-studies examined pachymetry, endothelial cell counts, and topography.

7.3 Patient Accountability

Accountability was determined for the primary (first treated) eyes of the 611 subjects through 6 months.

Table 7-2 summarizes patient accountability:

TABLE 7-2. PATIENT ACCOUNTABILITY—PRIMARY EYES

	1 month	3 months	6 months
Available for Analysis (Consistent Cohort)	556/611 (90.1%)	556/611 (90.1%)	556/611 (90.1%)
Discontinued	0	2/611 (0.3%)	0
Not yet Eligible for the Interval	0	0	0
Lost to Follow-up	0	1/611 (0.2%)	0
Missed Visit	7/611 (1.1%)	16/611 (2.6%)	39/611 (6.4%)
Visits Available but not in Consistent Cohort	48/611 (7.9%)	36/611 (5.9%)	16/611 (2.6%)

* N = total eyes enrolled

7.4 Methods

The efficacy data on the Nidek EC-5000 Excimer Laser System for surface ocular treatment was gathered by analyzing the predictability of the manifest refraction outcome (attempted outcome compared to achieved outcome) and the improvement of uncorrected visual acuity.

Safety data was gathered by analyzing potentially detrimental effects on expected outcome variables, combined with acceptable levels of other adverse events associated with laser refractive surgery.

7.5 Principal Effectiveness and Safety Results

A total of 611 subjects had a primary eye or both eyes treated (N=940 total eyes consisting of 611 primary eyes and 329 secondary eyes). Of the 940 total treated eyes, 587 eyes were evaluated at each of the following visits: pre-operative, 1 month, 3 months and 6 months. These 587 eyes are considered the "consistent cohort." Table 7-3 summarizes key safety and efficacy variables for the consistent cohort. Note: The sub-sample of subjects treated for myopia exceeding -10.00 D (n=21) may be too low to detect other complications and/or adverse events in this refractive error range.

TABLE 7-3. KEY SAFETY AND EFFICACY VARIABLES

	1 month		3 months		6 months	
EFFICACY VARIABLES*	n / N	%	n / N	%	n / N	%
UCVA 20/20 or better	259 / 587	44.1%	324 / 585	55.4%	355 / 586	60.6%
UCVA 20/40 or better	507 / 587	86.4%	523 / 585	89.4%	535 / 586	91.3%
MRSE ± 0.50 D	289 / 587	49.2%	361 / 587	61.5%	364 / 585	62.2%
MRSE ± 1.00 D	422 / 587	71.9%	482 / 587	82.1%	496 / 585	84.8%
MRSE ± 2.00 D	537 / 587	91.5%	560 / 587	95.4%	557 / 585	95.2%
SAFETY VARIABLES**						
BsCVA worse than 20/40	6 / 587	1.0%	5 / 586	0.9%	3 / 586	0.5%
Loss of 2 lines BsCVA	21 / 586	3.6%	10 / 585	1.7%	13 / 585	2.2%
Loss of >2 lines BsCVA	20 / 586	3.4%	17 / 585	2.9%	7 / 585	1.2%
BsCVA worse than 20/25; 20/20 or better pre-op	26 / 586	4.4%	19 / 585	3.2%	12 / 585	2.1%
Increase >2 D cylinder	3 / 587	0.5%	1 / 587	0.2%	1 / 585	0.2%

N = 587 subjects in the combined consistent cohort.

* UCVA was not reported for 2 subjects at 3 months and 1 subject at 6 months. MRSE was not reported for 2 subjects at 6 months.

** BsCVA was not reported for 1 subject at 3 months and 1 subject at 6 months. In determining loss of lines of BsCVA, values were missing pre-operatively or post-operatively for 1 subject at 1 month, and 2 subjects each at 3 months and 6 months. In determining change in cylinder, values were missing pre-operatively or post-operatively for 1 subject at 6 months.

Table 7-4 summarizes key safety and efficacy variables for the consistent cohort stratified by pre-operative manifest refraction spherical equivalent (MRSE). 364 subjects were treated in the low myopia range (< –6.00 D); 202 were treated in the moderate myopia range (–6.00 D to –9.99 D), and 21 subjects were treated in the high myopia range (≥ –10.00 D).

TABLE 7-4. KEY SAFETY AND EFFICACY VARIABLES BY PRE-OPERATIVE MRSE RANGE

A: Low Myopia: Pre-Operative MRSE < –6.00 D

	1 month		3 months		6 months	
EFFICACY VARIABLES*	n / N	%	n / N	%	n / N	%
UCVA 20/20 or better	190 / 364	52.2%	232 / 362	64.1%	245 / 364	67.3%
UCVA 20/40 or better	337 / 364	92.6%	338 / 362	93.4%	345 / 364	94.8%
MRSE ± 0.50 D	201 / 364	55.2%	260 / 364	71.4%	253 / 363	69.7%
MRSE ± 1.00 D	288 / 364	79.1%	325 / 364	89.3%	330 / 363	90.9%
MRSE ± 2.00 D	354 / 364	97.3%	358 / 364	98.4%	358 / 363	98.6%
SAFETY VARIABLES**						
BsCVA worse than 20/40	1 / 364	0.3%	1 / 363	0.3%	0 / 364	0.0%
Loss of 2 lines BsCVA	12 / 364	3.3%	3 / 363	0.8%	8 / 364	2.2%
Loss of >2 lines BsCVA	6 / 364	1.6%	6 / 363	1.7%	1 / 364	0.3%
BsCVA worse than 20/25; 20/20 or better pre-op	10 / 364	2.7%	7 / 363	1.9%	3 / 364	0.8%
Increase >2 D cylinder	1 / 364	0.3%	1 / 364	0.3%	0 / 363	0.0%

N = 364 subjects with pre-operative MRSE < –6.00 D in the combined consistent cohort.

* UCVA was not reported for 2 subjects at 3 months. MRSE was not reported for 1 subject at 6 months.

** BsCVA was not reported for 1 subject at 3 months. In determining loss of lines of BsCVA, values were missing pre-operatively or post-operatively for 1 subject at 3 months. In determining change in cylinder, values were missing for 1 subject at 6 months.

B: Moderate Myopia: Pre-Operative MRSE –6.00 D to –9.99 D

	1 month		3 months		6 months	
EFFICACY VARIABLES*	n / N	%	n / N	%	n / N	%
UCVA 20/20 or better	69 / 202	34.2%	87 / 202	43.1%	102 / 201	50.7%
UCVA 20/40 or better	156 / 202	77.2%	171 / 202	84.7%	175 / 201	87.1%
MRSE ± 0.50 D	83 / 202	41.1%	96 / 202	47.5%	106 / 201	52.7%
MRSE ± 1.00 D	124 / 202	61.4%	150 / 202	74.3%	155 / 201	77.1%
MRSE ± 2.00 D	173 / 202	85.6%	188 / 202	93.1%	184 / 201	91.5%
SAFETY VARIABLES**						
BsCVA worse than 20/40	3 / 202	1.5%	2 / 202	1.0%	3 / 201	1.5%
Loss of 2 lines BsCVA	6 / 201	3.0%	6 / 201	3.0%	5 / 200	2.5%
Loss of >2 lines BsCVA	11 / 201	5.5%	9 / 201	4.5%	6 / 200	3.0%
BsCVA worse than 20/25; 20/20 or better pre-op	11 / 201	5.5%	9 / 201	4.5%	8 / 200	4.0%
Increase >2 D cylinder	1 / 202	0.5%	0 / 202	0.0%	1 / 201	0.5%

N = 202 subjects with pre-operative MRSE -6.00 D to -9.99 D in the combined consistent cohort.

* UCVA and MRSE were not reported for 1 subject at 6 months.

** BsCVA was not reported for 1 subject at 6 months. In determining loss of lines of BsCVA, values were missing pre-operatively or post-operatively for 1 subject each at 1 month and 3 months, and 2 subjects at 6 months. In determining change in cylinder, values were missing for 1 subject at 6 months.

C: High Myopia: Pre-Operative MRSE ≥ -10.00 D

	1 month		3 months		6 months	
EFFICACY VARIABLES	n / N	%	n / N	%	n / N	%
UCVA 20/20 or better	0 / 21	0.0%	5 / 21	23.8%	8 / 21	38.1%
UCVA 20/40 or better	14 / 21	66.7%	14 / 21	66.7%	15 / 21	71.4%
MRSE ± 0.50 D	5 / 21	23.8%	5 / 21	23.8%	5 / 21	23.8%
MRSE ± 1.00 D	10 / 21	47.6%	7 / 21	33.3%	11 / 21	52.4%
MRSE ± 2.00 D	10 / 21	47.6%	14 / 21	66.7%	15 / 21	71.4%
SAFETY VARIABLES						
BsCVA worse than 20/40	2 / 21	9.5%	2 / 21	9.5%	0 / 21	0.0%
Loss of 2 lines BsCVA	3 / 21	14.3%	1 / 21	4.8%	0 / 21	0.0%
Loss of >2 lines BsCVA	3 / 21	14.3%	2 / 21	9.5%	0 / 21	0.0%
BsCVA worse than 20/25; 20/20 or better pre-op	5 / 21	23.8%	3 / 21	14.3%	1 / 21	4.8%
Increase >2 D cylinder	1 / 21	4.8%	0 / 21	0.0%	0 / 21	0.0%

N = 21 subjects with pre-operative MRSE ≥ -10.00 D in the combined consistent cohort.

7.5.1 Pre-Operative Characteristics

Pre-operative characteristics are described for the 587 eyes in the consistent cohort in Tables 7-5, 7-6, and 7-7 below.

TABLE 7-5. PRE-OPERATIVE UCVA (n=587)*

20/100 or worse		20/50 to 20/80		20/25 to 20/40		20/20 or better	
n/N	%	n/N	%	n/N	%	n/N	%
552/582	94.8%	25/582	4.3%	4/582	0.7%	1/582	0.2%

* N = 587 eyes in the consistent cohort; UCVA was reported for 582 eyes and not reported for 5 eyes at the pre-operative visit.

TABLE 7-6. PRE-OPERATIVE BSCVA (n=587)*

20/40 or worse		20/25 to 20/30		20/20 or better	
n/N	%	n/N	%	n/N	%
4/586	0.7%	28/586	4.8%	554/586	94.5%

* N = 586 eyes with BsCVA reported and 1 eye with BsCVA not reported at pre-operative visit=587 eyes.

TABLE 7-7. PRE-OPERATIVE MYOPIA/SPHERICAL EQUIVALENT (n=587)*

< -6.00 D		-6.00 D to -9.99 D		> -10.00 D	
n/N	%	n/N	%	n/N	%
364/587	62.0%	202/587	34.4%	21/587	3.6%

* N = 587 eyes with MRSE reported at pre-operative visit.

7.5.2 Post-Operative Results

Efficacy Results: Efficacy data are presented for 587 eyes in the consistent cohort. Table 7-8 presents a summary of efficacy results stratified by pre-operative MRSE (i.e., < -7.00 D and ≥ -7.00 D strata).

This data is presented on initial treatment only (i.e., excluding retreatment procedures).

TABLE 7-8. SUMMARY OF KEY EFFICACY VARIABLES BY PRE-OPERATIVE MRSE STRATA

Efficacy Variables	Pre-Operative MRSE < -7.00 D*			Pre-Operative MRSE ≥ -7.00 D		
	1 month	3 months	6 months	1 month	3 months	6 months
UCVA 20/20 or better	219 / 442 (49.5%)	270 / 440 (61.4%)	289 / 441 (65.5%)	40 / 145 (27.6%)	54 / 145 (37.2%)	66 / 145 (45.5%)
UCVA 20/40 or better	405 / 442 (91.6%)	410 / 440 (93.2%)	418 / 441 (94.8%)	102 / 145 (70.3%)	113 / 145 (77.9%)	117 / 145 (80.7%)
MRSE ± 0.50 D	235 / 442 (53.2%)	299 / 442 (67.6%)	302 / 440 (68.6%)	54 / 145 (37.2%)	62 / 145 (42.8%)	62 / 145 (42.8%)
MRSE ± 1.00 D	341 / 442 (77.1%)	388 / 442 (87.8%)	397 / 440 (90.2%)	81 / 145 (55.9%)	94 / 145 (64.8%)	99 / 145 (68.3%)
MRSE ± 2.00 D	422 / 442 (95.5%)	435 / 442 (98.4%)	432 / 440 (98.2%)	115 / 145 (79.3%)	125 / 145 (86.2%)	125 / 145 (86.2%)

N = 587 subjects in the consistent cohort; 442 subjects had a pre-operative MRSE strata < -7.00 D; 145 subjects had a pre-operative strata ≥ -7.00 D.

* For subjects with pre-operative MRSE < -7.00 D, UCVA was not reported for 2 subjects at 3 months and 1 subject at 6 months; and MRSE was not reported for 2 subject at 6 months.

Uncorrected Visual Acuity (UCVA) Table 7-9 summarizes the distribution of uncorrected visual acuity pre- and post-operatively. At the point of stability (6 months after treatment), 91.3% (535/586) of patients tested at 20/40 or better; 85.8% (503/586) tested at 20/32 or

better; 78.0% (457/586) tested at 20/25 or better; and 60.6% (355/586) of patients tested at 20/20 or better.

TABLE 7-9. UNCORRECTED VISUAL ACUITY (UCVA PRE- AND POST-OPERATIVELY)

Distance UCVA	Pre-operative		1 month		3 months		6 months	
	n / N	%	n / N	%	n / N	%	n / N	%
20/20 or better	1 / 582	0.2%	259 / 587	44.1%	324 / 585	55.4%	355 / 586	60.6%
20/25 or better	2 / 582	0.3%	375 / 587	63.9%	437 / 585	74.7%	457 / 586	78.0%
20/32 or better	3 / 582	0.5%	457 / 587	77.9%	493 / 585	84.3%	503 / 586	85.8%
20/40 or better	5 / 582	0.9%	507 / 587	86.4%	523 / 585	89.4%	535 / 586	91.3%
20/80 or better	30 / 582	5.2%	574 / 587	97.8%	567 / 585	96.9%	572 / 586	97.6%
20/200 or better	275 / 582	47.3%	585 / 587	99.7%	583 / 585	99.7%	586 / 586	100.0%

* N = 587 subjects in the consistent cohort. Distance UCVA was not reported for 5 subjects pre-operatively, 2 subjects at 3 months, and 1 subject at 6 months.

Accuracy Of Manifest Refraction (Predictability Of Outcome) Table 7-10 summarizes the accuracy of manifest refraction in terms of difference from intended outcome for the combined consistent cohort.

TABLE 7-10. ACCURACY OF MANIFEST REFRACTION (PREDICTABILITY OF OUTCOME) FOR THE COMBINED CONSISTENT COHORT (n=587)

Difference from Intended Outcome	SE at 1 month		SE at 3 months		SE at 6 months	
	n / N	%	n / N	%	n / N	%
± 0.50 D	289 / 587	49%	361 / 587	61%	364 / 585	62%
± 1.00 D	422 / 587	72%	482 / 587	82%	496 / 585	85%
± 2.00 D	537 / 587	91%	560 / 587	95%	557 / 585	95%
> ± 2.00 D	50 / 587	9%	27 / 587	5%	28 / 585	5%
Under-corrected < -2.00 D	7 / 587	1%	11 / 587	2%	15 / 585	3%
Under-corrected < -1.00 D	20 / 587	3%	49 / 587	8%	42 / 585	7%
Over-corrected > +1.00 D	145 / 587	25%	56 / 587	10%	47 / 585	8%
Over-corrected > +2.00 D	43 / 587	7%	16 / 587	3%	13 / 585	2%

* N = 587 subjects in the consistent cohort. Spherical Equivalent not reported for 2 subjects at 6 months.

Table 7-11 demonstrates the predictability of outcome stratified by MRSE of < -7.00 D and ≥ -7.00 D.

TABLE 7-11. ACCURACY OF MANIFEST REFRACTION (PREDICTABILITY OF OUTCOME) (STRATIFIED BY DIOPTRIC GROUP)

Difference from Intended Outcome	Pre-Operative MRSE < -7.00 D*			Pre-Operative MRSE ≥ -7.00 D		
S.E. at Visit:	1 month	3 months	6 months	1 month	3 months	6 months
± 0.50 D	235 / 442 (53.2%)	299 / 442 (67.6%)	302 / 440 (68.6%)	54 / 145 (37.2%)	62 / 145 (42.8%)	62 / 145 (42.8%)
± 1.00 D	341 / 442 (77.1%)	388 / 442 (87.8%)	397 / 440 (90.2%)	81 / 145 (55.9%)	94 / 145 (64.8%)	99 / 145 (68.3%)
± 2.00 D	422 / 442 (95.5%)	435 / 442 (98.4%)	432 / 440 (98.2%)	115 / 145 (79.3%)	125 / 145 (86.2%)	125 / 145 (86.2%)
> ± 2.00 D	20 / 442 (4.5%)	7 / 442 (1.6%)	8 / 440 (1.8%)	30 / 145 (20.7%)	20 / 145 (13.8%)	20 / 145 (13.8%)
Under-corrected < -2.00 D	2 / 442 (0.5%)	2 / 442 (0.5%)	4 / 440 (0.9%)	5 / 145 (3.4%)	9 / 145 (6.2%)	11 / 145 (7.6%)
Under-corrected < -1.00 D	9 / 442 (2.0%)	24 / 442 (5.4%)	20 / 440 (4.5%)	11 / 145 (7.6%)	25 / 145 (17.2%)	22 / 145 (15.2%)
Over-corrected > +1.00 D	92 / 442 (20.8%)	30 / 442 (6.8%)	23 / 440 (5.2%)	53 / 145 (36.6%)	26 / 145 (17.9%)	24 / 145 (16.6%)
Over-corrected > +2.00 D	18 / 442 (4.1%)	5 / 442 (1.1%)	4 / 440 (0.9%)	25 / 145 (17.2%)	11 / 145 (7.6%)	9 / 145 (6.2%)

N = 587 subjects in the consistent cohort; 442 subjects had a pre-operative MRSE strata < -7.00 D; 145 subjects had a pre-operative strata ≥ -7.00 D.

* For subjects with pre-operative MRSE < -7.00 D, SE was not reported for 2 subjects at 6 months.

Stability of Visual Outcome - The "consistent" cohort data are divided below into the strata for comparison of MRSE changes between the two periods 3-6 months and 6-12 months (Table 7-12). The first three tables below (A, B, and C) compare these changes for each of the myopia ranges: low myopia (pre-operative MRSE < -6.00 D), moderate myopia (MRSE -6.00 D to -9.99 D), and high myopia (MRSE ≥ -10.00 D). The fourth and fifth tables (D and E) compare these changes across two myopia strata: < -7.00 D and ≥ -7.00 D. The final table (F) compares these changes for the combined consistent cohort.

Confidence intervals (CI_{95}) for proportions are calculated by exact methods according to Fisher and Yates, 1963, and the confidence

intervals for mean of MRSE change (Δ) are calculated as 1.96 times the $SD/n^{0.5}$ for the data.

TABLE 7-12. STABILITY OF MANIFEST REFRACTION AFTER PRK (BY PRE-OPERATIVE MRSE STRATA)

A: Low Myopia: Pre-Operative MRSE Stratum < –6.00 D

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	351 / 363 (97%) [94.3, 98.3]	–0.04 ± 0.47 [–0.08, +0.01]
6-12 Months	310 / 321 (97%) [94.0, 98.3]	–0.08 ± 0.49 [–0.13, –0.03]

B: Moderate Myopia: Pre-Operative MRSE Stratum –6.00 D to –9.99 D

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	175 / 201 (87%) [81.6, 91.4]	–0.08 ± 0.80 [–0.19, +0.03]
6-12 Months	158 / 180 (88%) [82.1, 92.2]	–0.16 ± 0.84 [–0.28, –0.04]

C: High Myopia: Pre-Operative MRSE Stratum ≥ –10.00 D

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	18 / 21 (86%) [63.7, 96.6]	–0.14 ± 0.89 [–0.52, +0.24]
6-12 Months	15 / 20 (75%) [50.9, 91.3]	–0.41 ± 0.95 [–0.83, +0.01]

D: Pre-Operative MRSE < –7.00 D

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	422 / 440 (96%) [93.6, 97.6]	–0.05 ± 0.51 [–0.09, +0.00]
6-12 Months	377 / 393 (96%) [93.5, 97.7]	–0.07 ± 0.52 [–0.12, –0.02]

E: Pre-Operative MRSE ≥ -7.00 D

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	**122 / 145 (84%)** [77.2, 89.7]	**-0.08 ± 0.87** [-0.22, +0.06]
6-12 Months	**106 / 128 (83%)** [75.1, 88.9]	**-0.27 ± 0.94** [-0.43, -0.10]

F: All Pre-Operative MRSE Stratum Combined (0.00 D to -15.00 D)

Period	Proportion ±1.00 [95% CI for %]	Mean Δ ± SD [95%CI for mean Δ]
3-6 Months	**544 / 585 (93%)** [90.6, 94.9]	**-0.05 ± 0.62** [-0.10, +0.00]
6-12 Months	**483 / 521 (93%)** [90.1, 94.8]	**-0.12 ± 0.65** [-0.17, +0.06]

For the n=587 "consistent" cohort, 2 eyes did not have recorded refraction data though they appeared for their 6 month visit. The 6-12 month data uses the eyes from the consistent cohort for which both 6 and 12 month data are available (n=521), even though the 12 month follow-up visit was not required for inclusion in the consistent cohort.

Figure 7-1 plots the average change in spherical equivalent for follow-up visits through 12 months for the consistent cohort. As can be seen, the average change from 3 to 6 months is nearly zero.

FIGURE 7-1. STABILITY PLOT: CHANGE IN MRSE BETWEEN PERIODS (CONSISTENT COHORT)

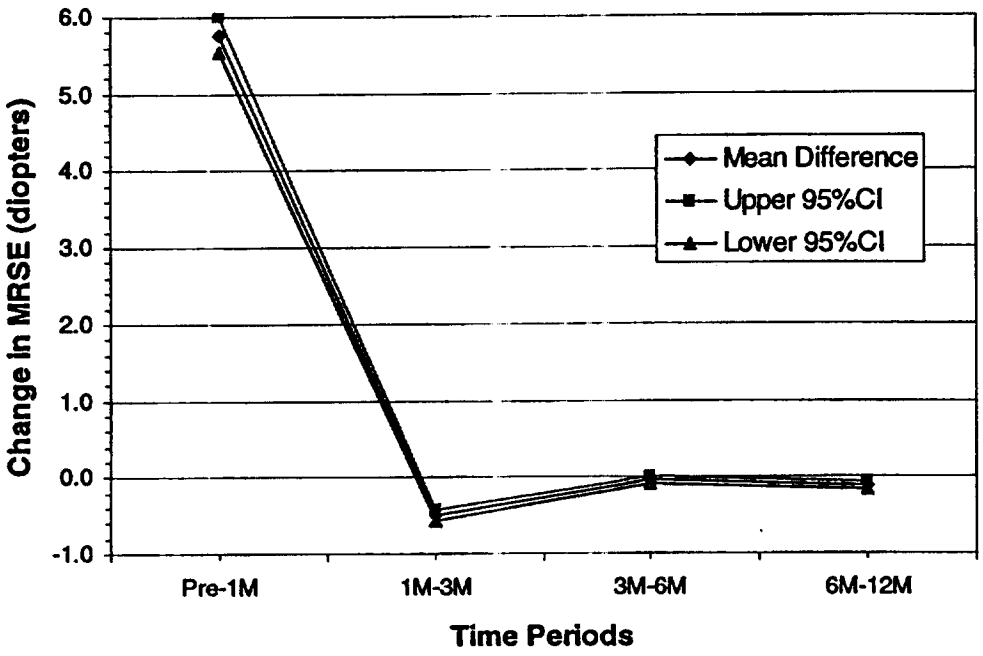
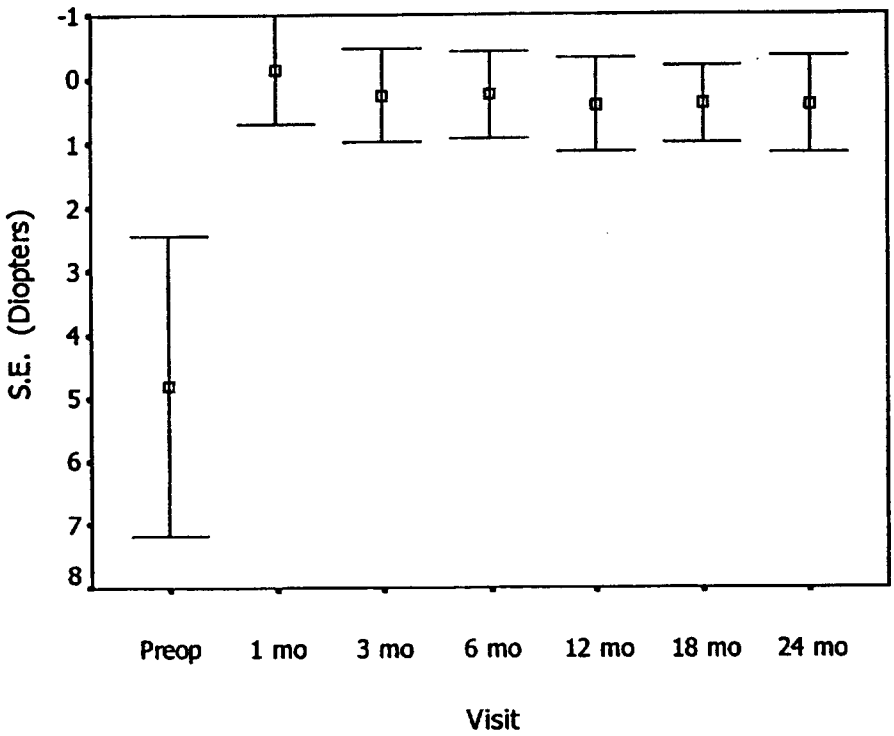


Figure 7-2 plots the average spherical equivalent (± SD) for all follow-up visits for the subgroup of treated eyes with 24 month follow-up visit data (n=165). This sub population is analyzed so that matched data for each subject is used for all follow-up visits. As can be seen, the average MRSE changes little after the 3-6 month follow-up periods.

FIGURE 7-2. AVERAGE S.E. (± SD) AT ENROLLMENT AND AT FOLLOW-UP FOR ALL TREATED SUBJECTS WITH 24 MONTH FOLLOW-UP (n=165)



7.6 Summary of Key Safety Variables and Retreatment

This summary of key safety variables includes data collected on 587 eyes in the consistent cohort. Results are summarized in Table 7-13.

TABLE 7-13. SUMMARY OF KEY SAFETY VARIABLES BY PRE-OPERATIVE MRSE STRATA

Safety Variables	Pre-Operative MRSE < -7.00 D*			Pre-Operative MRSE ≥ -7.00 D**		
	1 month	3 months	6 months	1 month	3 months	6 months
BsCVA worse than 20/40	2 / 442 (0.5%)	1 / 441 (0.2%)	1 / 441 (0.2%)	4 / 145 (2.8%)	4 / 145 (2.8%)	2 / 145 (1.4%)
Loss of 2 lines BsCVA	13 / 442 (2.9%)	5 / 441 (1.1%)	9 / 441 (2.0%)	8 / 144 (5.6%)	5 / 144 (3.5%)	4 / 144 (2.8%)
Loss of >2 lines BsCVA	8 / 442 (1.8%)	9 / 441 (2.0%)	2 / 441 (0.5%)	12 / 144 (8.3%)	8 / 144 (5.6%)	5 / 144 (3.5%)
BsCVA worse than 20/25; 20/20 or better pre-op	12 / 442 (2.7%)	9 / 441 (2.0%)	5 / 441 (1.1%)	14 / 144 (9.7%)	10 / 144 (6.9%)	7 / 144 (4.9%)
Increase >2 D Cylinder	1 / 442 (0.2%)	1 / 442 (0.2%)	0 / 440 (0.0%)	2 / 145 (1.4%)	0 / 145 (0.0%)	1 / 145 (0.7%)

N = 587 subjects in the consistent cohort; 442 subjects had a pre-operative MRSE strata < -7.00 D; 145 subjects had a pre-operative strata ≥ -7.00 D.

* For subjects with pre-operative MRSE < -7.00 D, BsCVA was not reported for 1 subject at 3 months and 1 subject at 6 months. In determining loss of lines of BsCVA, values were missing pre-operatively or post-operatively for 1 subject each at 3 months and 6 months. In determining change in cylinder, values were missing pre-operatively or post-operatively for 2 subjects at 6 months.

** For subjects with pre-operative MRSE ≥ -7.00 D, BsCVA was reported for all subjects. In determining loss of lines of BsCVA, values were missing pre-operatively or post-operatively for 1 subject each at 1 month, 3 months and 6 months.

Refer to Tables 6-1 and 6-2 for a summary of the adverse events and complications that occurred in this study.

Retreatment procedures with the EC-5000 Excimer Laser System were performed on 28 eyes under the protocol through October 15, 1997. This reflects a retreatment rate of 3.0% (28/940) for the overall study.

8. CONFORMANCE TO STANDARDS

The Nidek EC-5000 Excimer Laser System complies with internationally-recognized JIST electrical standards.

9. HOW SUPPLIED

The base unit Nidek EC-5000 Excimer Laser System includes the laser generator, excimer laser, beam delivery, optical system for observation of the patient and the procedure, gas system, and computer system control. The System requires periodic

maintenance and care, particularly for the gas system. Refer to the Operator's Manual for care instructions and precautions.

Options include a CCD color camera, TV camera adapter, color monitor, computer desk, foot controller (X, Y, Z adjustment), laser goggles, calibration unit and plates, cylinder stand (large, small) buffer tube: 5m (for outside cylinder), eye fixation and ablation plume aspirating device (factory option).

10. OPERATOR'S MANUAL

The Operator's Manual (document part number 16006-P912) is supplied separately.

PATIENT INFORMATION BOOKLET

Photorefractive Keratectomy (PRK)

for Myopia (Nearsightedness)

Nidek EC-5000 Excimer Laser System

SURGICAL LASER TREATMENT FOR NEARSIGHTED PATIENTS WITH SPHERICAL CORRECTION FROM –0.75 TO –13.0 DIOPTERS AND HAVING LESS THAN OR EQUAL TO 0.75 DIOPTERS OF ASTIGMATISM

Please read this entire booklet. Discuss its contents with your doctor so that all of your questions are answered to your satisfaction. Ask any questions you may have before you agree to the surgery.

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(510) 226-5700

Part Number 16006-P992A Version 1.5

TABLE OF CONTENTS

1. Introduction

Please read the following information if you are thinking about having Photorefrac-tive Keratectomy (PRK) laser surgery to correct nearsightedness (myopia) without treatment for any astigmatism. The options for correction of myopia now include glasses, contact lenses, and different kinds of refractive surgery such as radial keratotomy (RK), automated lamellar keratoplasty, excimer laser in situ keratomileusis (LASIK), and PRK using excimer lasers, including the Nidek EC-5000 Excimer Laser System.

This information can help you make an informed decision when selecting a method to correct your nearsightedness. If both of your eyes are nearsighted, your doctor may recommend PRK surgery for both eyes to achieve satisfactory vision. However, there are cases where it is better to reshape the cornea on only one eye.

Please read this booklet completely. Discuss any questions you may have with your doctor in order to decide if PRK is the right choice for you. Only a trained and certified practitioner can determine whether or not you are a suitable candidate for PRK. You should be aware that a small percentage of patients treated with excimer lasers experience permanent vision reduction. The goal of PRK is to reduce your need for glasses or contact lenses by changing the shape of the cornea through PRK laser surgery.

2. How the Eye Functions

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Normally, in relatively young persons (i.e., less than 50 years of age) the lens of the eye can adjust its focusing power somewhat, so you can see objects clearly both near and far away.

The eye focuses light by refracting all light rays to meet at a single point. If the focusing process works perfectly, a sharp image of the object you are looking at will be focused exactly on the retina and you will see a clear image. However, if the light focuses either in front of or behind the retina, the image on the retina (and the image you see) will be blurred, and you are said to have a refractive error. Refractive errors are not diseases, but are common variations observed in human beings across the world.

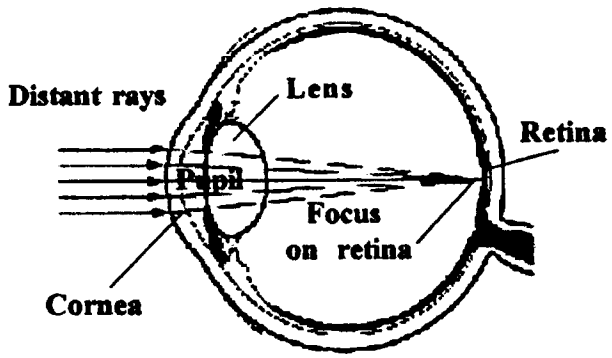
There are three main types of refractive error. They are called nearsightedness (myopia), farsightedness (hyperopia) and astigmatism. The amount of refractive error present in the eye is measured in units called "diopters." When your eye cannot focus correctly, it is said to have one of the main refractive errors: myopia or hyperopia.

Myopia usually starts in childhood and typically stabilizes in the late teens or early adulthood. The tendency to develop myopia also runs in families. Myopia can range from a very mild to a very strong nearsighted effect. The range of treatment with the Nidek EC-5000 covers a large part of that range.

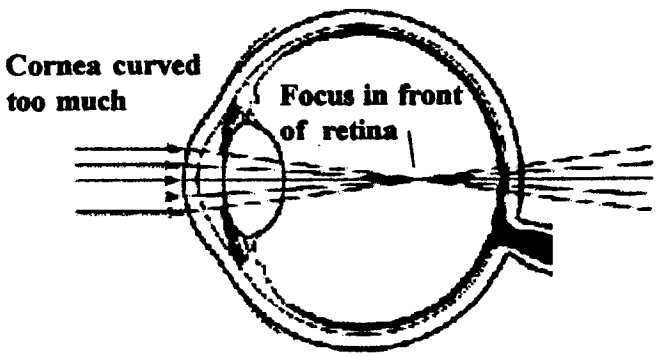
Hyperopia is also very common, and is especially problematic in older persons who have difficulty in focusing on objects up close. Astigmatism occurs when the refractive error is stronger in a p articluar direction. Astigmatism may occur with either myopia or hyperopia. The Nidek EC-5000 is not approved for treating either astigmatism or hyperopia.

The pictures below emphasize the role of the cornea in determining the focusing power of the eye. They show that the more sharply the cornea is curved, the more the light rays are bent. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. When the cornea shape is just right, the image from a distant object is focused exactly on the retina. This proper focus for distance vision is called emmetropia.

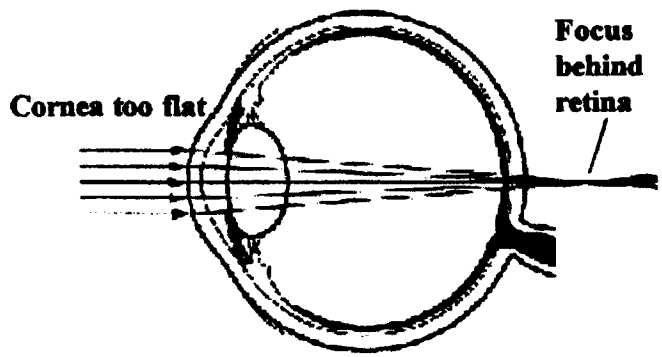
PROPER FOCUS



NEARSIGHTED EYE



FARSIGHTED EYE



Good focus depends on three factors, the overall shape and size of your eye, the shape of the cornea, and your lens power. During a regular eye examination, your doctor checks your vision to determine where the eye focuses light relative to your retina. When your doctor adjusts your vision with different lenses, he correctly focuses light on the retina.

Myopia is the most common refractive condition observed in North America and affects about 25% of the population. Myopic individuals see near objects clearly, but distant objects are blurry. Nearsightedness can be corrected by any method that reduces the total refractive power of the eye, and includes the use of glasses, contact lenses and refractive surgery. With glasses or contacts, changes in your vision that occur slowly over time can be corrected by simply adjusting the lens prescription of your glasses or contacts. Refractive surgery, on the other hand, produces changes that are permanent and cannot be undone or easily modified if your vision changes or if the initial surgery is not successful (4.8% of initial surgeries were found to be greater than 2.0 D from intended correction at 6 months after surgery).

3. What is PRK?

PRK is laser surgery to correct nearsightedness (myopia). An excimer laser beam is used to flatten the front of the cornea. The laser beam removes microscopic amounts of tissue from the front of the cornea, precisely reshaping the cornea.

The excimer laser produces a beam of ultraviolet light in a series of rapid pulses. Each pulse lasts only a few billionths of a second and removes a microscopic amount of tissue by evaporating it. Excimer laser light does not penetrate the

eye and leaves other eye structures (iris, lens, and retina) undisturbed. The laser produces very little heat and is controlled by the doctor during the operation.

Prior to PRK, some anesthetic drops are placed on the eye to numb it. Your doctor then begins the PRK procedure by gently removing the outer layer of cells from the cornea where the laser treatment will be used. These cells are usually scraped away using a scalpel or other surgical tool. This part usually takes a couple minutes. After that, your doctor uses the laser beam to complete the PRK procedure. The laser treatment usually lasts only about 15-40 seconds. This procedure is performed on one eye at a time even if both are to be treated. If all goes well with the first eye, and your vision stabilizes without complication or adverse reactions, then the second eye can be treated later. PRK laser surgery on the second eye is usually done three months after the first eye, if needed.

4. Contraindications

You should not have PRK surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease).
- You are taking prescription medications that affect corneal healing or your refraction. You should discuss all medications you take, even over-the-counter medications, with your eye doctor.

5. Warnings

Discuss with your doctor if:

- Your nearsightedness is changing. If your vision is unstable, then you should not be treated.

- You have severe allergies. Your medications may have to change before or after your eye surgery.
- You have been diagnosed with ocular *Herpes simplex* or ocular *Herpes zoster*. Herpes are viral infections. Laser treatment may reactivate the infection.
- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze. You need to be able to keep your eyes still during treatment.

6. Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser has ***NOT*** been established in:

- Eyes with disease or corneal abnormality (for example: scar, infection, corneal dystrophies, etc.).
- Eyes with previous surgery or injury to the center of the cornea where PRK will be performed.
- Patients under 21 years of age.
- Patients over the long term (more than 2 years after the surgery).

7. Risks

Laser PRK is a surgical procedure involving your eyes and has potentially serious risks. You should consider and discuss with your doctor the risks that are noted in this booklet. These are based on clinical experience with PRK cases and the possibilities that doctors believe should be considered for this kind of eye surgery.

See the information listed below for details on risks of complications and adverse events.

- ☐ Although the effects of PRK on visual performance under poor lighting conditions have not been determined, it is possible that you will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. These effects have been reported as being more common in persons with large pupils. It is possible that these may be permanent effects.

- ☐ **The first week following surgery:**

  The following complications have been reported up to several weeks following PRK treatment. They are associated with the normal healing process after treatment and include:

  - Discomfort (in 60.2% of cases, including mild to moderate pain, pressure, scratchiness, burning sensation, and dryness) may last for up to 3 days after surgery, for which your eye doctor can provide medications.
  - The feeling that something is in your eye (14.9% of cases).
  - Blurred vision (7.2% of cases) and tearing or watery eyes (5.2% of cases) may occur as the cornea heals.
  - Sensitivity to bright lights (3.5% of cases).

- ☐ **The first two to six months following surgery:**

  - Your intraocular pressure may increase due to use of steroid or anti-inflammatory medications (0.7% of eyes had a significant elevation in intraocular pressure). This is usually resolved by drug therapy or by stopping the use of steroid or anti-inflammatory medication.
  - Your cornea may become hazy or cloudy enough to affect your vision (2.2% of eyes had mild or moderate haze at 6 months after surgery, 0.5% with significant loss of vision). This haze typically disappears over time, but some patients continue to experience a small amount of haze over 1-2 years.
  - an increase in fluctuation of vision (34.1% pre-operatively vs. 48.1% post-operatively).
  - glare (26.9% pre-operatively vs. 34.4% post-operatively).
  - difficulty in night driving (23.5% pre-operatively vs. 48.0% post-operatively).
  - Increased sensitivity to bright light (0.3% at 1 month, not reported at later periods).
  - More than one diopter worsening (regression) of nearsightedness compared to their best result by 6 months (6.3%).

  Note: You should contact your doctor if you notice any pain or change or loss of vision in the eye.

- ☐ **More than one year after surgery:**

  Nidek clinical studies showed that at one or more years after PRK surgery the following vision-threatening events happened less than approximately 1% of the time:

  - Too large a correction (causing farsightedness more than +2.0 D).
  - Losing a significant amount (more than 2 lines lost) of vision even with glasses.
  - Corneal haze (that causes significant loss of vision).

  If the results of the surgery are not satisfactory, you may need to have additional PRK surgery in the same eye.

8. Benefits

- ☐ PRK surgery, as performed with the Nidek EC-5000 Excimer Laser, is effective in reducing nearsightedness between –0.75 and –13.0 diopters in patients with less than or equal to 0.75 diopters of astigmatism (84.8% of treated eyes were within 1.0 diopter of intended correction at 6 months).
- ☐ PRK may reduce overall nearsighted-ness (91.3% significantly improved uncorrected vision to the level of 20/40 or better at 6 months).
- ☐ PRK may reduce or eliminate dependency upon contact lenses or glasses (60.6% could see 20/20 or better without glasses or contacts at 6 months).
- ☐ PRK should be considered a permanent surgical procedure.

9. Are You a Good Candidate for PRK?

If you are considering PRK, you must:

- Be at least 21 years of age.
- Have healthy eyes which are free from eye disease or corneal abnormality (for example: scar, infection, etc.).
- Have nearsightedness (myopia) between –0.75 to –13.0 diopters with less than or equal to 0.75 diopters of astigmatism.
- Be sure your eye doctor has satisfactory evidence that your refraction has been stable over the past year (not changed by more than 0.5 diopters if your treatment is for less than 7.0 diopters, or by more than 1.0 diopter if your treatment is for more than 7.0 diopters).
- Be informed of PRK risks and benefits as compared to other available treatments for nearsightedness (myopia).

- Be willing to sign an informed consent form, as provided by your eye care professional.

Why PRK may not be right for you:

- *If you expect perfect results.* No surgical procedure can assure you perfect results or can guarantee that your expectations will be met.
- *If you expect perfect vision under all conditions.* At night, eyes that have been reshaped by refractive procedures such as PRK may experience haze and a variety of visual effects. The PRK procedure only reshapes the central portion of the cornea and does not reshape the entire cornea. As a result, when the pupil of the eye dilates under low light conditions it opens past the boundaries of the treated area producing unwanted changes in vision. You may find that you will need to wear corrective lenses to drive at night. In addition, PRK does not eliminate the need for reading glasses. In some patients, reading glasses may be required after treatment even if they were not worn before treatment. If the thought of occasionally wearing eye wear is uncomfortable, then PRK may not be right for you.
- *If you expect an instant change in vision.* The visual results are not instant, particularly for patients with more than 4 diopters of myopia. It may take up to three months, sometimes longer, for the shape of the cornea to stabilize following surgery. You must be patient and be willing to wait until the healing process finishes. You may also be asked to temporarily wear corrective lenses.

10. Before the Surgery

If you are interested in having PRK, you will

need to have a pre-surgical examination to determine if your eye is healthy and suitable for PRK. This will include a complete eye history, and a thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2-4 weeks before the evaluation. Failure to do this can produce poor surgical results.

Before the surgery, please tell your doctor well in advance whether you take any medications or have any allergies. Also, talk with your doctor about whether you can eat or drink immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You can resume driving only after receiving permission from your doctor.

11. The Day of Surgery

Before the surgery, anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during the surgery. For protection and comfort, a temporary shield will cover the eye not having surgery.

- Your doctor may perform a brief practice treatment so you can hear and smell what the laser will be like during the treatment.
- Using a small instrument, the surgeon begins the procedure by removing of the outermost layer of the cornea. Next, the doctor repositions your head in the

chair, and refocus the microscope on your cornea. You will then be asked to look directly at a blinking light. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. As you continue to look at the blinking light, small amounts of tissue will be removed from your cornea using the Nidek EC-5000 Excimer Laser.

PRECAUTION:

It is very important that you keep looking at the blinking light during the procedure, even if the light fades or becomes dim. Your surgical results depend upon your looking at this blinking light throughout the treatment.

- You will be using the laser less than 1 minute. However, the entire surgical procedures takes about 10 to 15 minutes.
- After the laser surgery is complete, some drops or ointment will be placed into your eye. Then it will be covered and patched for your protection and comfort. The surgery itself is painless because of the numbing actions of the anesthetic drops that were applied to your eye at the beginning of the procedure.
- After 45 to 60 minutes, the anesthetic will wear off and your eye may hurt for 1 to 3 days. Most patients describe this pain as moderate to severe. Do ***NOT*** rub your eyes for the first 3 to 5 days. Rubbing your eyes can damage the cornea and will delay healing. Your doctor can prescribe pain medication to make you more comfortable during this brief time after the surgery.

WARNING:

Your doctor will monitor you for any side-effects if topical steroids were used. The possible side-effects from prolonged use of topical steroids are ocular hypertension (an increase of pressure in the eye), glaucoma or cataract formation.

12. The First Days After Surgery

In your doctor's office, your eye patch will be removed the following day. You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

- Your vision should become stable within the first several weeks after surgery. Some patients may experience some small changes (for example, improvement or worsening of their vision). These changes may occur up to six months or more after surgery.
- A haze or cloudiness is typically seen in the cornea following surgery, but usually does not affect your vision. This haze tends to decrease over time and usually disappears completely over a 1 to 2 year period.

IMPORTANT:

Use the anti-inflammatory eye drops and lubricants as directed by your doctor. Your surgical results depend upon your following your doctor's directions.

13. Questions to Ask Your Doctor

You may want to ask the following ques-tions to help you decide if PRK is right for you:

- What other options are available for correcting my nearsightedness?

- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK for my amount of nearsightedness?
- What quality of vision can I expect in the first few months after surgery?
- If PRK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after PRK if I need them?
- How is PRK likely to affect my need to wear glasses or contact lenses as I get older?
- Is it likely I will need reading glasses sooner than later?
- Will my cornea heal differently if injured after having PRK?
- Should I have PRK surgery in my other eye?
- How long will I have to wait before I can have PRK surgery on my other eye?
- What vision problems might I experience if I have PRK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser treatment is not covered by most health insurance policies.

14. Self-Test

Are you an informed and educated patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser refractive surgery is risk free.	[ ]	[ ]
2. Excimer laser surgery use pulses of invisible light.	[ ]	[ ]
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	[ ]	[ ]
4. The laser does all the work; I just have to lie on the chair and close my eyes.	[ ]	[ ]
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	[ ]	[ ]
6. I may need reading glasses after laser surgery.	[ ]	[ ]
7. There is a risk that I may lose some vision after laser surgery.	[ ]	[ ]
8. It doesn't matter if I am pregnant.	[ ]	[ ]
9. If I have an auto-immune disease, I am still a good candidate for PRK.	[ ]	[ ]

Answers to SELF-TEST are found at the top of page 18.

15. Summary of Important Information

- ☐ PRK is a permanent operation to the cornea; it cannot be reversed.
- ☐ Alternatives to PRK include glasses, contact lenses and RK.
- ☐ PRK is not a laser version of radial keratotomy (RK); they are completely different from one another.
- ☐ Some occupations, such as pilots, do not accept applicants who have had any refractive surgery.
- ☐ Refractive error must be stable (within ± 0.5 diopters if your treatment is for less that 7.0 diopters, or within ± 1.0 diopters if more) for at least one year before surgery.
- ☐ The following risks of PRK surgery should be noted:
  - transient complications: discomfort (24-48 hours), corneal swelling, blurred vision, feeling something in the eye, shadow images, light sensitivity, tearing, and pupil enlargement. These problems are common (over 60% of cases report one or more of these complications) and may last up to several weeks.
  - adverse events beyond the first few months: night vision difficulty (48.1% at 6 months); elevation of intraocular pressure (0.7% at 6 months); cloudy cornea affecting vision (0.3% at 6 months with mild to moderate haze reducing vision); overcorrection by more than 2.0 diopters (2.0% at 6 months, 0.6% at 12 months); under correction or nearsighted by more than 2.0 diopters (2.3% at 6 months, 3.4% at 12 months); loss of best vision that can be achieved with glasses (1.2% at 6 months); ghost images (1.3% at 6 months); and, glare (34.4% at 6 months, compared to 9.2% before surgery).
- ☐ The following benefits of PRK surgery should be noted:
  - Nearsightedness may be reduced so that the amount of time contact lenses or glasses are used during the day is reduced or eliminated.

- PRK may be an alternative to glasses in some patients who are intolerant of contact lenses.
- Another alternative to correct nearsightedness.

☐ Patients considering PRK surgery should:

- Discuss fully with one or more ophthalmic surgeons the complications of PRK surgery, the risks and the time required for healing, and have a complete eye examination before making a final decision.
- Read both the Patient Information Booklet and the Informed Consent Document (ICD) provided by your doctor carefully before signing the ICD.

Answers to Self-Test Questions:

1. False (see Risks on page 6);
2. True (see What is PRK? on page 4);
3. False (see Before The Surgery on page 11);
4. False (see The Day of Surgery on page 11);
5. True (see Benefits on page 9);
6. True (see What is PRK? on page 4);
7. True (see Risks on page 6);
8. False (see Contraindications on page 5);
9. False (see Contraindications on page 5).

16. Summary Tables

Summary of Key Safety and Efficacy Variables at 6 months after Surgery	
Efficacy Variables	
Visual acuity without glasses or contacts:	
20/20 or better	60.6%
20/40 or better	91.3%
Treated eyes within range of target correction:	
± 0.50 diopters	62.2%
± 1.00 diopters	84.8%
± 2.00 diopters	95.2%
Safety Variables	
Visual acuity with glasses being worse than 20/40	0.5%
Loss of more than 2 lines on vision chart with glasses on	1.2%
Visual acuity with glasses on is worse than 20/25, when better than 20/20 before surgery	2.1%
Increase in astigmatism by more than 2.0 diopters	0.2%

Complications and Adverse Events		
Description	Immediate Post-op to 1 Month	At 6 Months
Complications—		
Discomfort	60.2%	0.0%
Haze (trace to moderate)	18.5%	10.5%
Foreign body sensation	14.9%	0.0%
Blurry/cloudy vision	7.2%*	0.0%
Tearing/watery eyes	5.2%	0.0%
Photophobia	3.5%	0.0%
Ghost/double images	1.2%	0.0%
Corneal edema	0.4%	0.0%
Recurrent erosions	0.0%	0.0%
Adverse events—		
Persistent corneal defect	0.4%	0.0%
Corneal infiltrate	0.3%	0.0%
Elevated intraocular pressure (relative or absolute)	0.2%	0.7%
Loss of visual acuity after 6 months	-----	1.2%
Late onset haze with decreased vision	-----	0.3%
Retinal accidents/detach.	0.0%	0.0%

** Percentage taken from consistent follow-up cohort (n=556); all other complications and adverse event data from all available eyes (n=940).*

Note: Because of the relatively small (n=21) sample size of myopia treatments exceeding –10.0 diopters, the clinical study may have been unable to detect other complications and/or adverse events that occurred at lower rates in patients in this high refractive error range.