PROFESSIONAL USE INFORMATION

LASER IN SITU KERATOMILEUSIS (LASIK)

NIDEK EC-5000
EXCIMER LASER SYSTEM

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Document Part Number: 16008-P822A 10.06

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CAUTION

Restricted Device:

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

U.S. Federal Law restricts the use of 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 EC-5000 Excimer Laser Operator's Manual.

WARNING:

The user is responsible for reading all instructions before use of this system. Observe all warnings, contraindications, and precautions noted in this Professional Use Information, 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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1.0 DEVICE DESCRIPTION

The Nidek EC-5000 Excimer Laser System is an ophthalmic laser system for refractive surgery of the cornea designed to correct the vision of subjects with a variety of refractive errors (myopia, myopic astigmatism, hyperopia, and hyperopic astigmatism).

The Nidek EC-5000 device consists of an argon fluoride (ArF) excimer laser and beam delivery system, a diode aiming laser; the laser optical viewing system including the microscope, fixation light, and illumination lamps; the mechanical systems used for positioning, focusing, and gas handling; and microprocessor controllers.

The Nidek EC-5000 Excimer Laser System uses a 193 nm ArF laser beam to recontour the cornea by ablation of corneal tissue. The laser system features a scanning beam delivery system in which the laser beam is dynamically rotated about the optical axis and paired with an iris diaphragm in a series of predetermined beam offset positions to produce a series of circular scan patterns for hyperopic corrections, eliminating the need for the slit aperture that is used for myopic ablations. The hyperopic treatment is a time-based treatment in which the degree of refractive treatment applied is mathematically calculated to determine the amount of time the scanning beam must spend in each beam offset position to produce the desired hyperopic treatment shape. The treatment algorithm and laser treatment parameters were empirically optimized based on international clinical results.

For hyperopia spherical corrections, the optical axis of the system is first aligned with the optical axis of the cornea. Then, the linear scanning mirror is set at a fixed position relative to the optical axis of the cornea, thereby establishing an offset for the laser beam. This offset is later increased in steps throughout the treatment, beginning with step 1 and ending with step 7. Pulses are delivered such that they are positioned 159 degrees apart and overlap by 21 degrees. After the first step is completed, the linear scanning mirror is moved to the second step. The iris diaphragm continues to open at a specified rate and the laser beam continues to rotate about the corneal axis and fire at the same constant rate as in Step 1. This sequence of events is completed for each of the seven steps. For cylindrical corrections, the laser scanning method is the same as spherical corrections, except that the angular separation of each pulse is 180 degrees rather than 159 degree angular separation used for spherical corrections.

The laser parameters used in the clinical study were as follows:

Model	EC-5000 (Model EC2B)
Pulse Repetition Rate	34 Hz
Fluence (nominal)	300 mJ/cm^2/scan (mean at the cornea)
Slit Beam	2 mm by 10 mm (FWHM)
Iris Diaphragm Diameter	10 mm (Max)
Optical Zone	6.0 mm
Ablation Zone	9.0 mm
Ablation Rate in Cornea	0.6 μm/scan
Ablation Rate in PMMA	0.315 μm/scan
PMMA/Cornea Ratio	0.89
Cyl/Sph Ratio	0.32

The software versions in the laser system used during the clinical trial were as follows:

Laser Operating System	Windows 2000 v.5.26(a)
200 Hz Eye tracker	ETC v.4.10
Dragon Eye Software	v.3.15

The software versions in the laser system at approval are:

Laser Operating System	Windows 2000 v.5.27
200 Hz Eye tracker	ETC v.4.10
Dragon Eye Software	v.3.20

The Nidek EC-5000 Excimer Laser System for hyperopia plus astigmatism ablations is locked out for spherical treatments greater than +5.0 D, cylindrical treatments greater than +2.0 D cylinder, treatments with an MRSE greater than +5.0 D, and for optical zones (OZ) different from the approved OZ of 6.0 mm or treatment zones (TZ) different from the approved TZ of 9.0 mm.

The systems of the EC-5000 Excimer Laser used in the hyperopia clinical study include:

1. Optical Transmission System

   The optical delivery system aims to deliver the laser beam oscillated from the laser head and coaxial aiming beam to the cornea. The optical delivery system consists of mirrors, attenuator controller, laser shutter, linear scanning and image control, astigmatic control unit, variable circular iris diaphragm that controls the size, shape, and position of the laser beam, aiming shutter and projection lens. The linear scanning mechanism is driven by a stepping motor and a cylinder cam feed followed by an image rotator mechanism which is also driven by a stepping motor. Both mechanisms are equipped with sensors and encoders for positional feedback.

2. Energy Monitoring and Control

The beam fluence is monitored directly by monitoring the energy of the laser beam. An energy detector, placed in the laser head, is used to monitor the energy and will shut off the laser beam if the fluence is too high or too low. It is recommended that the surgeon perform a calibration before each surgery.

3. Gas Handling System

The EC-5000 Excimer Laser System incorporates two gas supply devices. The premix ArF gas is used for laser light formation and the nitrogen gas is used to rinse the beam path and optics during treatment.

4. Eye Tracking System

The Eye Tracking System is used to measure eye movements from a digital high speed video camera at a sampling rate of 200 Hz, with a sampling interval of 5.0 ms. The eye position data are used to control the scanner position of the laser and validity flags are used to control the actual firing of the laser. The active video eye tracker can be decentered by the operator.

5. Operating Microscope

The observation system consists of an operational microscope. Observation and alignment of the cornea are performed through the operation microscope. Observation of the cornea is always possible even before, after, and during laser emission.

6. Fixation Target

The fixation lamp is positioned on the same path as the path of the excimer laser beam to make the patient's visual line coaxial with the optical path of the laser.

7. Alignment and Illumination System

The alignment and illumination system consists of alignment illumination (inner illumination which is also used for alignment), external illumination, an arm control system that varies exposure and focusing position, and the fixation lamp.

The correct eye exposure position is identified by the use of the aiming beam, which is coaxial to the excimer laser as viewed through the operational microscope. The focusing position occurs when the reflection of the optical alignment illumination lights, which shine on the cornea in two different directions, are superimposed on each other.

The initial exposure position is aligned to the center of the pupil and the focusing position is aligned to the surface of the cornea by the motorized control stick and the focusing knob.

When the eye tracker is activated, it automatically tracks the center of the patient pupil; it is not necessary to perform subsequent alignment with the control stick.

8. Patient Bed

The patient lays on his/her back on the movable and height adjustable bed, which enables the operator to position and center the patient under the laser beam.

9. Laser System Software Control

The Windows 2000 based laser control software contains a hyperopic module that controls the hyperopic and hyperopic astigmatism ablation patterns. The hyperopic treatment module is security key controlled.

2.0 INTENDED USE

The Nidek EC-5000 Excimer Laser System is indicated for Laser In-Situ Keratomileusis (LASIK) treatment:

- for the reduction or elimination of hyperopia refractive errors from +0.5 to +5.0 D of sphere with or without astigmatic refractive errors from +0.5 to +2.0 D at the spectacle plane with manifest refraction spherical equivalent (MRSE) of +5.0 D or less;
- in patients 21 years of age or older; and,
- in patients with documented stability of manifest refraction over the prior year, demonstrated by a change in manifest refraction spherical equivalent (MRSE) not greater than ±0.5 D.

3.0 CONTRAINDICATIONS

LASIK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus, keratoconus suspect, or unstable central keratometry readings with irregular mires;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane®) or amiodarone hydrochloride (Cordaron®); or,
- Eyes that have a calculated residual stromal bed thickness that is less than 250 microns.

To avoid corneal ectasia, residual corneal bed thickness remaining after laser ablation must be calculated preoperatively to be 250 microns or greater.

4.0 WARNINGS

LASIK is not recommended in patients who:

- Have diabetes with ocular involvement;
- Have 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; or,
- Have connective tissue disease with ocular involvement.

5.0 PRECAUTIONS

5.1 General

Eyes with the following conditions were not enrolled in the clinical study and the safety and effectiveness of the Nidek EC-5000 Excimer Laser System for LASIK correction of hyperopia or hyperopic astigmatism have not been determined in:

- Eyes with rapidly progressive hyperopia or hyperopic astigmatism that have a rate of change in manifest refraction spherical equivalent (MRSE) that is greater than ±0.5 D MRSE, or exceeds a rate of change of 0.04 D/month, during the 12 months prior to surgery.
- Eyes with a mesopic pupil size that is 8 mm or larger in diameter
- Eyes with a previous ocular condition that may predispose the eye to future complications, such as:
    - history of recurrent erosion syndrome
    - history of corneal dystrophy
    - penetrating ocular or corneal surgery
    - scarring in the treatment zone
- Patients who are taking medications that may affect corneal wound healing, including but not limited to, steroids, antimetabolites, and sumatriptan succinate;
- Patients who have acute or chronic diseases or conditions that could increase the operative risk, such as:
    - dry eye syndrome that is unresponsive to treatment
    - clinically significant atopic disease
    - evidence of retinal vascular disease
    - glaucoma or examination findings consistent with glaucoma suspect

The long term safety and effectiveness (more than 1 year after surgery) has not been established.

Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes after LASIK surgery, even if they do not have dry eyes preoperatively.

5.2 Patient Selection

Caution should be exercised when selecting patients for treatment with the Nidek EC-5000 Excimer Laser System. The following should be considered when evaluating patients as candidates for LASIK refractive surgery:

- Each prospective patient must be given the Patient Information Booklet and provided with the opportunity to read it thoroughly and to have all their questions answered to assure their understanding before giving consent to have LASIK performed with the Nidek EC-5000 Excimer Laser System.
- A complete baseline ocular examination must be performed, including cycloplegic evaluation. The lens must be evaluated (especially in older patients) to ensure that no lens opacities exist prior to LASIK treatment. Baseline examinations should be performed within 60 days of the laser refractive surgery.
- Refractive stability must be evaluated in patients. For this purpose, eyes to be treated should have a rate of change that is no greater ±0.5 D MRSE, or does not exceed a rate of change of 0.04 D/month, during the 12 months prior to LASIK surgery.
- Contact lens wearers must discontinue spherical soft lenses for at least 3 days, soft toric lenses for at least 2 weeks, and rigid gas permeable and hard lenses for at least 4 weeks or longer prior to the preoperative eye examination. Contact lens wearers must exhibit a stable refraction at two exams that are at least 7 days apart. A stable refraction is first determined as one in which the manifest refraction measurement and the topography (i.e., average SIM K readings from the topography) taken at the first visit do not differ by more than 0.5 D MRSE from the respective measurements taken at the second exam. Once a stable manifest refraction is confirmed, a cycloplegic refraction should be performed, which should be within 0.75 D SE of this last manifest refraction. The last manifest refraction that is used to confirm stability should be used in the surgical treatment plan calculation.
- Preoperative corneal topography is necessary on all patients to screen for potential topographical abnormalities. Corneal mapping may detect the presence of keratoconus and other corneal irregularities, including those that may be due to corneal warpage in those patients with a history of contact lens usage.
- Accurate preoperative corneal pachymetry measurements must be performed preoperatively. Eyes with a preoperative central corneal thickness that is less than 475 microns, or those in which the residual corneal bed thickness remaining after

the laser ablation is calculated preoperatively to be less than 250 microns, have a greater risk of developing postoperative corneal ectasia.

- Mesopic pupil size should be measured preoperatively. Mesopic pupil diameters that are more than 8 mm may have a higher incidence of glare and halos or associated problems with driving at night.
- Laser surgery is generally performed using a topical anesthetic. 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 and maintain a steady gaze throughout the surgical procedure.
- 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 each patient before the informed consent is obtained.

5.3 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.

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

5.4 Before Laser Surgery

The following general recommendations should be observed before performing any LASIK refractive treatment:

- Care should be taken to plan the surgery so as to preserve a residual stromal bed thickness of at least 250 microns to reduce the risk of corneal ectasia secondary to LASIK.
- If a microkeratome is used to perform the keratectomy, carefully clean and assemble the microkeratome before each procedure, following the specific instructions in the Operator's Manual provided by the microkeratome manufacturer. Only an experienced surgeon, nurse or technician who is trained on the use of the microkeratome should handle and prepare it.
- Inspect the microkeratome blade under the microscope to detect nicks or irregularities. After the microkeratome has been reassembled, check the base

plate thickness and the position of the translation stopper (if used). Test the microkeratome to verify that a smooth translation occurs in both directions.

- The use of any blowing gas on or across the cornea during laser treatment is not recommended.
- Verify the refractive astigmatism treatment axis entered into the EC-5000 against the preoperative topographic map and calculated treatment plan.
- Additional detailed procedures on the use of the Nidek EC-5000 Excimer Laser system during the laser portion of LASIK treatment are described in the Operator's Manual. Follow the procedures described in the manual to ensure safe and proper operation.

6.0 SAFETY INFORMATION FOR HYPEROPIA CLINICAL STUDY

A total of 293 eyes were treated in a clinical study to evaluate the safety and effectiveness of the Nidek EC-5000 Excimer Laser System for LASIK treatment of spherical hyperopia (144 eyes) and hyperopic astigmatism (149 eyes). All eyes treated in the study were included in the safety analyses. Follow-up through 9 months after the LASIK surgery was required during the study and the majority of eyes (n=232) were followed for at least 12 months postoperatively.

6.1 Adverse Events

The adverse events and that occurred during the clinical study are summarized in Table 1, below.

TABLE 1
Adverse Events

ADVERSE EVENTS	Intraop % (n/N)	1 Day % (n/N)	1 Wk % (n/N)	1 Mo % (n/N)	3 Mo % (n/N)	6 Mo % (n/N)	9 Mo % (n/N)	12 Mo % (n/N)
Diffuse lamellar keratitis with progressive melt		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Corneal infiltrate or ulcer		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Any corneal epithelial defect involving keratectomy site at 1 month or later				0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Corneal edema at 1 month or later				0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Epithelium in interface with loss of 2 or more lines (≥10 letters) of BSCVA		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Miscreated flap (lost, incomplete, too thin)	0.0% (0/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Melting of the flap		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
IOP on 2 consecutive exams that is increase of > 10 mm Hg above baseline or > 30 mm Hg		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Haze beyond 6 mos. with loss of ≥2 lines (≥10 letters) BSCVA							0.0% (0/285)	0.0% (0/232)
Decrease of BSCVA of 2 or more lines (≥ 10 letters) not due to irregular astigmatism as shown by hard contact lens refraction at 3 months or later[1]					1.4% (4/291)	2.4% (7/291)	2.1% (6/285)	0.4% (1/232)
Retinal detachment	0.0% (0/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Retinal vascular accidents	0.0% (0/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Any other vision threatening event	0.0% (0/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Ocular penetration	0.0% (0/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)

No adverse events occurred in the study except loss of 2 or more lines (≥10 letters) of BSCVA. Of the eyes that lost BSCVA at 6 months or later, all but 2 eyes had a preoperative BSCVA of 20/16 or better and these eyes did not have the ability to gain lines of BSCVA.

[1] The incidence of new reports of loss of 2 or more lines (≥10 letters) of BSCVA was 1.4% at Month 3, 2.4% at Month 6, 2.1% at Month 9, and 0.7% at Month 12. The overall cumulative rate was 6.5% (19/293 eyes) for the cohort, of which 1.4% (4/293 eyes) had a persistent loss of at least 2 lines (10 letters) of BSCVA; last visit BSCVA was 20/20 for 1 eye, 20/32 for 2 eyes, and 20/40 for 1 eye that had a concomitant posterior subcapsular cataract that diminished the BSCVA.

6.2 Complications

The incidence of postoperative complications is summarized in Table 2 below.

TABLE 2
Complications

COMPLICATIONS	Intraop % (n/N)	1 Day % (n/N)	1 Wk % (n/N)	1 Mo % (n/N)	3 Mo % (n/N)	6 Mo % (n/N)	9 Mo % (n/N)	12 Mo % (n/N)
Corneal edema between 1 week and 1 month after procedure			0.7% (2/293)	0.0% (0/291)				
Peripheral corneal epithelial defect at 1 month or later		0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.3% (1/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Epithelium in interface		0.7% (2/293)	0.0% (0/293)	0.0% (0/291)	0.3% (1/291)	0.0% (0/291)	0.0% (0/285)	0.4% (1/232)
Foreign body sensation at 1 month or later				1.0% (3/291)	0.0% (0/291)	0.0% (0/291)	0.4% (1/285)	0.0% (0/232)
Pain at 1 month or later				1.4% (4/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Ghost/double images in the operative eye		0.0% (0/293)	0.0% (0/293)	0.7% (2/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Flap is not of the size and shape as initially intended or microkeratome stopped mid-cut	0.3% (1/293)	0.0% (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Diffuse lamellar keratitis		3.1% (9/293)	0.7% (2/293)	0.7% (2/291)	0.3% (1/291)	0.0% (0/291)	0.0% (0/285)	0.0% (0/232)
Dry eyes requiring punctal plugs or prescribed use of ocular lubricants at 1 month or later				2.7% (8/291)	0.3% (1/291)	1.4% (4/291)	0.0% (0/285)	0.0% (0/232)

The complications with an incidence of >1% at any visit were DLK, pain, foreign body sensation (FBS), and dry eye requiring prescribed ocular lubricants (the most common complication; Month 1, 2.7%; and Month 6, 1.4%).

6.3 Other Postoperative Observations

Other postoperative observations that occurred during the study are summarized in Table 3 below.

TABLE 3
Postoperative Observations for All Eyes Treated

Observations	Intraop % (n/N)	1 Day % (n/N)	1 Wk % (n/N)	1 Mo % (n/N)	3 Mo % (n/N)	6 Mo % (n/N)	9 Mo % (n/N)	12 Mo % (n/N)
Blepharitis		0.0 % (0/293)	0.0% (0/293)	0.7% (2/291)	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Chalazion		0.0 % (0/293)	0.0% (0/293)	0.7% (2/291)	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Conjunctivitis, allergic		0.0 % (0/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.7 (2/285)	0.0 % (0/232)
Discomfort		0.0 % (0/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.7% (2/291)	0.0 % (0/285)	0.0 % (0/232)
Epithelial abrasion	0.3% (1/293)	0.0 % (0/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Epithelial basement membrane degeneration		0.0 % (0/293)	0.3% (1/293)	0.3% (1/291)	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Hordeolum		0.0 % (0/293)	0.0% (0/293)	0.3% (1/291)	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Interface blood		0.3% (1/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Laceration, lid	0.7% (2/293)	0.0 % (0/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Lens opacity		0.0 % (0/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	1.0% (3/291)	0.0 % (0/285)	0.9% (2/232)
Misaligned flap		0.3% (1/293)	0.0% (0/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
PEK 3+		0.0 % (0/293)	0.7% (2/293)	0.0% (0/291	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Photophobia		0.0 % (0/293)	0.0 % (0/293)	0.7% (2/291)	0.0% (0/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Sheen in interface		5.8% (17/293)	3.4% (10/293)	6.9% (20/291)	4.5% (13/291)	4.1% (12/291)	0.0 % (0/285)	0.0 % (0/232)
Striae		0.0 % (0/293)	0.3% (1/293)	0.7% (2/291)	0.3% (1/291)	0.0% (0/291)	0.0 % (0/285)	0.0 % (0/232)
Tearing, excessive		0.0 % (0/293)	0.0% (0/293)	0.0% (0/291)	0.0% (0/291)	0.3% (1/291)	0.4% (1/285)	0.0 % (0/232)

The most commonly occurring postoperative observation was that of sheen in interface that developed transiently (1 Day, 5.8%; 1 Week, 3.4%; 1 Month, 6.9%; 3 Months, 4.5%; 6 Months, 4.1%; and, 0% thereafter). Lamellar sheen is not unique to this study, having been observed by international Nidek users.

Lamellar sheen occurs after Nidek EC-5000 hyperopic LASIK in the lamellar bed and is randomly distributed in the central cornea. The sheen appears as a faint dusting in the interface that is spotty and grayish in color with feathered edges and an orange-peel texture. In some cases, reflective patches give the surface a slight shiny appearance, hence the term sheen.

[NOTE: The lamellar sheen observed after hyperopic LASIK is different from subepithelial stromal haze that occurs after PRK (diffuse, gray, granular confluence) and is also different from DLK (diffuse lamellar keratitis with a granular 'Sands of Sahara' appearance, associated with ocular inflammation).

All cases of lamellar sheen in the study were transient, beginning 1 day to 6 months after surgery, lasting 1 week to 6 months, and resolving without treatment. No cases were observed after the 6 month examination. Lamellar sheen did not affect visual acuity in most cases, although it likely contributed to a transient loss of 2 lines (10 letters) of BSCVA in 7 eyes in the study (each of which returned to within 1 line (5 letters) of baseline BSCVA and a final BSCVA of 20/20 or better upon resolution of the sheen). At the 6 month examination, there was no statistically significant difference in BSCVA between eyes with and without sheen.

6.4 Subjective Visual Complaints

Subjective visual complaints were obtained from each subject using a 10-point questionnaire to record symptoms. Visual complaints were recorded for each eye, and severity was classified as being either: *"none," "mild," "moderate," "marked,"* or *"severe."* "Postoperative spectacle/contact lens use" and "patient satisfaction with LASIK outcome" were not included as specific questions on the visual complaint questionnaire and, therefore, were not evaluated in the PMA clinical trial. The results of the subjective questionnaire at baseline and at the 6- and 12-month examinations are summarized by symptom in Table 4 below. Visual symptoms after hyperopic LASIK were generally mild in severity. The reduction in post-operative complaints of difficulty reading and the increase in complaints about eye dryness were both clinically significant, defined as a change of ±10% or more in the proportion of eyes reporting symptoms that were moderate to severe postoperatively compared to baseline.

TABLE 4

SUBJECTIVE COMPLAINTS

QUESTION	VISIT	NONE	MILD	MODERATE	MARKED	SEVERE
LIGHT SENSITIVITY	SCREENING	207/293 (71%)	59/293 (20%)	17/293 (6%)	6/293 (2%)	4/293 (1%)
	POSTOP MONTH 6	211/291 (73%)	66/291 (23%)	10/291 (3%)	4/291 (1%)	0/291 (0%)
	POSTOP MONTH 12	218/276 (79%)	40/276 (14%)	14/276 (5%)	2/276 (1%)	2/276 (1%)
DIFFICULTY NIGHT DRIVING	SCREENING	199/293 (68%)	57/293 (19%)	27/293 (9%)	7/293 (2%)	3/293 (1%)
	POSTOP MONTH 6	243/291 (84%)	39/291 (13%)	8/291 (3%)	1/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	221/276 (80%)	40/276 (14%)	13/276 (5%)	2/276 (1%)	0/276 (0%)
DIFFICULTY READING[2]	SCREENING	146/293 (50%)	54/293 (18%)	61/293 (21%)	22/293 (8%)	10/293 (3%)
	POSTOP MONTH 6	153/289 (53%)	86/289 (30%)	30/289 (10%)	16/289 (6%)	4/289 (1%)
	POSTOP MONTH 12	131/276 (47%)	88/276 (32%)	39/276 (14%)	16/276 (6%)	2/276 (1%)
DOUBLE VISION	SCREENING	285/293 (97%)	6/293 (2%)	1/293 (0%)	0/293 (0%)	1/293 (0%)
	POSTOP MONTH 6	278/291 (96%)	7/291 (2%)	6/291 (2%)	0/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	263/287 (92%)	20/287 (7%)	4/287 (1%)	0/287 (0%)	0/287 (0%)
FLUCTUATION IN VISION	SCREENING	254/293 (87%)	32/293 (11%)	7/293 (2%)	0/293 (0%)	0/293 (0%)
	POSTOP MONTH 6	186/291 (64%)	85/291 (29%)	14/291 (5%)	6/291 (2%)	0/291 (0%)
	POSTOP MONTH 12	204/276 (74%)	58/276 (21%)	11/276 (4%)	1/276 (0%)	2/276 (1%)
GLARE	SCREENING	232/293 (79%)	35/293 (12%)	18/293 (6%)	6/293 (2%)	2/293 (1%)
	POSTOP MONTH 6	227/291 (78%)	59/291 (20%)	5/291 (2%)	0/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	220/276 (80%)	37/276 (13%)	15/276 (5%)	4/276 (1%)	0/276 (0%)
HALOS	SCREENING	255/293 (88%)	24/293 (8%)	10/293 (3%)	2/293 (1%)	2/293 (1%)
	POSTOP MONTH 6	235/291 (81%)	42/291 (14%)	10/291 (3%)	4/291 (1%)	0/291 (0%)
	POSTOP MONTH 12	231/276 (84%)	31/276 (11%)	12/276 (4%)	2/276 (1%)	0/276 (0%)
STARBURSTS	SCREENING	271/293 (92%)	14/293 (5%)	6/293 (2%)	2/293 (1%)	0/293 (0%)
	POSTOP MONTH 6	243/291 (84%)	40/291 (14%)	7/291 (2%)	1/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	243/276 (88%)	21/276 (8%)	11/276 (4%)	1/276 (0%)	0/276 (0%)
DRYNESS[3]	SCREENING	222/293 (76%)	57/293 (19%)	8/293 (3%)	4/293 (1%)	2/293 (1%)
	POSTOP MONTH 6	134/291 (46%)	111/291 (38%)	34/291 (12%)	10/291 (3%)	2/291 (1%)
	POSTOP MONTH 12	153/276 (55%)	92/276 (33%)	18/276 (7%)	9/276 (3%)	4/276 (1%)
PAIN	SCREENING	290/293 (99%)	2/293 (1%)	1/293 (0%)	0/293 (0%)	0/293 (0%)
	POSTOP MONTH 6	277/291 (95%)	14/291 (5%)	0/291 (0%)	0/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	269/276 (97%)	4/276 (1%)	2/276 (1%)	0/276 (0%)	1/276 (0%)
FOREIGN BODY	SCREENING	278/293 (95%)	14/293 (5%)	1/293 (0%)	0/293 (0%)	0/293 (0%)
	POSTOP MONTH 6	238/291 (82%)	47/291 (16%)	6/291 (2%)	0/291 (0%)	0/291 (0%)
	POSTOP MONTH 12	233/276 (84%)	32/276 (12%)	7/276 (3%)	3/276 (1%)	1/276 (0%)

[2] Clinically significant decrease (≥ 10% change) in the proportion of eyes reporting moderate to severe difficulty reading at 6 Months (17%) and 12 Months (21%) compared to baseline (32%).
[3] Clinically significant increase (≥ 10% change) in the proportion of eyes reporting moderate to severe dry eye symptoms at 6 Months (16%) compared to baseline (5%).

Changes in patient symptoms reported via a self-administered questionnaire are summarized below in Table 5. A patient's rating of a symptom was considered to be worse if there was 2 or more grade worsening in the symptom after LASIK compared to before LASIK, better if the change from baseline was 2 or more grades better after LASIK, and unchanged if there was only a one grade change or no change in the symptom after LASIK compared to baseline. Clinically significant changes in a symptom were considered to have occurred when there was a 10% or greater proportion of the subjects that reported an improvement (2 or more grades better than baseline) or worsening (2 or more grades worse than baseline) of a symptom. Using this criterion, there was a clinically significant improvement in night driving (12.4%) and difficulty reading (25.1%), and clinically significant worsening in dryness after LASIK (13.7%), as well as worsening of reading difficulty (10.3%), although this is offset by the number of patients with an improvement in their ability to read (25.1%).

TABLE 5

Change in Subjective Complaints between Baseline and 6 Months

Symptom	Better than Baseline (2 or more grade change)	No Change from Baseline (0-1 grade change)	Worse than Baseline (2 or more grade change)
LIGHT SENSITIVITY	7.9% (23/291)	89.3% (260/291)	2.7% (8/291)
DIFFICULT NIGHT DRIVING	12.4% (36/291)	85.2% (248/291)	2.4% (7/291)
DIFFICULTY READING	25.1% (73/291)	63.0% (186/291)	10.3% (30/291)
DOUBLE VISION	0.7% (2/291)	97.3% (283/291)	2.1% (6/291)
FLUCTUATION IN VISION	1.4% (4/291)	92.1% (268/291)	6.5% (19/291)
GLARE	8.6% (25/291)	90.0% (262/291)	1.4% (4/291)
HALOS	3.4% (10/291)	93.1% (271/291)	3.4% (10/291)
STARBURSTS	2.1% (6/291)	95.9% (279/291)	2.1% (6/291)
DRYNESS	2.7% (8/291)	83.5% (243/291)	13.7% (40/291)
PAIN	0.3% (1/291)	99.7% (290/291)	0% (0/291)
FOREIGN BODY	0.3% (1/291)	97.6% (284/291)	2.1% (6/291)

7.0 CLINICAL RESULTS FOR HYPEROPIA CLINICAL STUDY

7.1 Study Design

A prospective, non-randomized, multicenter clinical study was conducted to evaluate the safety and effectiveness of the Nidek EC-5000 Excimer Laser System for performing LASIK treatments for spherical hyperopia (from +0.5 D to +6.0 D sphere) without or with astigmatism (up to +3.0 D cylinder. Eyes with astigmatism that was <0.5 D were treated for spherical hyperopia and eyes with astigmatism ≥0.5 D were treated for hyperopic astigmatism. All eyes were treated using a 6.0 mm optical zone with a 9.00 mm ablation zone with the intention of full correction to emmetropia.

The surgical treatment parameters for the treated eye were be based on the manifest refraction from the screening visit (non-contact lens wearers only) or, for contact lens wearers, the last contact lens stability confirmation visit and the manifest refraction obtained preoperatively on the operative day. To account for any differences between the two measurements, the surgical treatment plan was calculated by averaging the screening and preoperative manifest refraction as follows:

HYPEROPIC ASTIGMATISM:

Surgical sphere	=	(Screening sphere + Preop sphere)/2
Surgical cylinder	=	(Surgical cylinder + Preop cylinder)/2

SPHERICAL HYPEROPIA:

Surgical sphere	=	(Screening MRSE + Preop MRSE)/2
Surgical cylinder	=	0

Analyses of safety and efficacy results were performed on data obtained at 1, 3, 6, 9, and 12 months after LASIK surgery. Ophthalmic efficacy evaluations included slit lamp examination of the eye, corneal topography, cycloplegic refraction, manifest refraction, and measurements of corrected and uncorrected visual acuity. Safety monitoring throughout the study included observations at appropriate times for complications, adverse events, and clinically significant findings on ophthalmic examination. Primary efficacy evaluations were based on measurements of postoperative manifest refraction and uncorrected visual acuity. Primary safety analyses included changes in best spectacle corrected visual acuity (BSCVA), and tabulations of adverse events, complications, other postoperative observations, and patient ratings of subjective complaints.

7.2 Patient Accountability

A total of 293 eyes (spherical hyperopia, n=144 eyes; hyperopic astigmatism, n=149 eyes) in 148 subjects were treated at six centers in the United States and 1 international center. All eyes evaluated at each postoperative examination were included in the safety and efficacy analyses.

Table 6 presents the demographic information for the cohort of subjects enrolled in the study. Of the 148 subjects enrolled in the study, 32% (48/148) were male and 68% (100/148) were female. Racial distribution consisted of 70% Caucasian (103/148); 28% Hispanic (42/148); 1% Black (2/148); and, 1% Asian (1/148). The cohort had a mean age of 49.5 years with a range of 23 to 69 years.

TABLE 6
Subject Population Demographic Characteristics

GENDER	N	% (N=148)
Male	48	32
Female	100	68
RACE		
Caucasian	103	70
Black	2	1
Asian	1	1
Hispanic	42	28
AGE (YR)	N	148
	Mean	49.54
	Std	8.88
	Min	23
	Max	69

Accountability by eye for the 293-eye cohort is summarized in Table 7 below for the entire cohort of treated eyes. Overall accountability was greater than 99% at all visits through 6 months, with more than 99% of the cohort available for inclusion in the data analysis for determination of refractive stability at 6 months and 98% of the eyes available for confirmation of refractive stability at the 9-month examination.

TABLE 7
Accountability

Status	1 Day		1 WK		1 MO		3 MO		6 MO		9 MO		12 MO	
Enrolled (N)	293		293		293		293		293		293		293	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
Available for Analysis	293	100.0	293	100.0	291	99.3	291	99.3	291	99.3	287	98.0	279	95.2
Discontinued (Retreated)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Active (Not Eligible for Interval)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lost to Follow-up	0	0.0	0	0.0	0	0.0	2	0.7	2	0.7	2	0.7	2	0.7
Missed Visit (Accounted for)	0	0.0	0	0.0	2	0.7	0	0.0	0	0.0	4	1.4	12	4.1
Excluded from Efficacy Analysis	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
% Accountability		100.0%		100.0%		99.3%		99.3%		99.3%		98.0%		95.2%

7.3 Data Analysis and Results

7.3.1 Baseline Characteristics

The preoperative refractive errors for the entire cohort of treated eyes are summarized in Table 8 (stratified by baseline sphere and cylinder) and Table 9 (stratified by baseline MRSE) below.

TABLE 8
Preoperative Refractive Errors
Stratified by Baseline Sphere and Cylinder

Sphere	Cylinder				Total Hyperopic Astigmatism	TOTAL EYES ENROLLED
	0 - 0.49	0.50 - 1.00	1.01 - 2.00	2.01 - 3.00		
0.5 - 1.00	3	13	4	3	20	23
1.01 - 2.00	58	34	12	0	46	104
2.01 - 3.00	44	33	9	2	44	88
3.01 - 4.00	29	12	8	3	23	52
4.01 - 5.00	8	5	4	1	10	18
5.01 - 6.00	2	4	1	1	6	8
Total Treated	144	101	38	10	149	293
	Spherical Hyperopia Eyes	Hyperopic Astigmatism Eyes				TOTAL

TABLE 9 Preoperative Refractive Errors Stratified by Baseline Manifest Refraction Spherical Equivalent (MRSE)						
MRSE	Cylinder				Total Hyperopic Astigmatism	TOTAL EYES ENROLLED
	0 - 0.49	0.50 - 1.00	1.01 - 2.00	2.01 - 3.00		
0.5 - 1.00	3	7	0	0	7	10
1.01 - 2.00	57	30	9	1	40	97
2.01 - 3.00	45	35	11	2	48	93
3.01 - 4.00	29	19	10	0	29	58
4.01 - 5.00	8	3	4	5	12	20
5.01 - 6.00	2	6	3	1	10	12
> 6.00	0	1	1	1	3	3
Total Treated	144	101	38	10	149	293
	Spherical Hyperopia Eyes	Hyperopic Astigmatism Eyes				TOTAL

7.3.2 Uncorrected Visual Acuity (UCVA)

All eyes treated in the study were targeted for emmetropia. Uncorrected visual acuity was measured in the H70 study using an ETDRS visual acuity chart. Uncorrected visual acuity across time is summarized below in Table 10 for the entire cohort and for eyes treated for spherical hyperopia and for hyperopic astigmatism, respectively, in Tables 11 and 12.

TABLE 10

UCVA for All Eyes Treated

		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
20/20 or better	n/N	16/293	174/291	162/290	174/291	174/287	170/279
	(%)	(5.46%)	(59.79%)	(55.86%)	(59.79%)	(60.63%)	(60.93%)
	(CI)	(2.8, 8.1)	(54.0, 65.5)	(50.0, 61.7)	(54.0, 65.5)	(54.9, 66.4)	(55.1, 66.8)
20/25 or better	n/N	27/293	245/291	246/290	249/291	238/287	228/279
	(%)	(9.22%)	(84.19%)	(84.83%)	(85.57%)	(82.93%)	(81.72%)
	(CI)	(5.8, 12.6)	(79.9, 88.5)	(80.6, 89.0)	(81.4, 89.7)	(78.5, 87.4)	(77.1, 86.3)
20/32 or better	n/N	45/293	276/291	279/290	277/291	272/287	265/279
	(%)	(15.36%)	(94.85%)	(96.21%)	(95.19%)	(94.77%)	(94.98%)
	(CI)	(11.1, 19.6)	(92.3, 97.4)	(94.0, 98.5)	(92.7, 97.7)	(92.1, 97.4)	(92.4, 97.6)
20/40 or better	n/N	61/293	287/291	285/290	287/291	284/287	277/279
	(%)	(20.82%)	(98.63%)	(98.28%)	(98.63%)	(98.95%)	(99.28%)
	(CI)	(16.1, 25.6)	(97.3,100.0)	(96.7, 99.8)	(97.3,100.0)	(97.8,100.0)	(98.3,100.0)
20/80 or better	n/N	172/293	291/291	290/290	291/291	287/287	279/279
	(%)	(58.70%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(53.0, 64.5)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)
20/200 or better	n/N	277/293	291/291	290/290	291/291	287/287	279/279
	(%)	(94.54%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(91.9, 97.2)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)

TABLE 11

UCVA for Eyes Treated for Spherical Hyperopia

		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
20/20 or better	n/N	14/144	97/142	93/143	100/144	99/143	96/137
	(%)	(9.72%)	(68.31%)	(65.03%)	(69.44%)	(69.23%)	(70.07%)
	(CI)	(4.8, 14.7)	(60.5, 76.1)	(57.1, 73.0)	(61.8, 77.1)	(61.5, 76.9)	(62.2, 77.9)
20/25 or better	n/N	20/144	123/142	127/143	129/144	126/143	122/137
	(%)	(13.89%)	(86.62%)	(88.81%)	(89.58%)	(88.11%)	(89.05%)
	(CI)	(8.1, 19.7)	(80.9, 92.3)	(83.5, 94.1)	(84.5, 94.7)	(82.7, 93.5)	(83.7, 94.4)
20/32 or better	n/N	27/144	134/142	137/143	138/144	137/143	130/137
	(%)	(18.75%)	(94.37%)	(95.80%)	(95.83%)	(95.80%)	(94.89%)
	(CI)	(12.2, 25.3)	(90.5, 98.2)	(92.5, 99.2)	(92.5, 99.2)	(92.5, 99.2)	(91.1, 98.7)
20/40 or better	n/N	34/144	140/142	139/143	142/144	141/143	136/137
	(%)	(23.61%)	(98.59%)	(97.20%)	(98.61%)	(98.60%)	(99.27%)
	(CI)	(16.5, 30.7)	(96.6,100.0)	(94.4,100.0)	(96.7,100.0)	(96.6,100.0)	(97.8,100.0)
20/80 or better	n/N	91/144	142/142	143/143	144/144	143/143	137/137
	(%)	(63.19%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(55.2, 71.2)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)
20/200 or better	n/N	139/144	142/142	143/143	144/144	143/143	137/137
	(%)	(96.53%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(93.5, 99.6)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)

TABLE 12

UCVA for Treated for Hyperopic Astigmatism

		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
20/20 or better	n/N	2/149	77/149	69/147	74/147	75/144	74/142
	(%)	(1.34%)	(51.68%)	(46.94%)	(50.34%)	(52.08%)	(52.11%)
	(CI)	(-0.5, 3.2)	(43.5, 59.9)	(38.7, 55.2)	(42.1, 58.6)	(43.8, 60.4)	(43.7, 60.5)
20/25 or better	n/N	7/149	122/149	119/147	120/147	112/144	106/142
	(%)	(4.70%)	(81.88%)	(80.95%)	(81.63%)	(77.78%)	(74.65%)
	(CI)	(1.2, 8.2)	(75.6, 88.2)	(74.5, 87.4)	(75.2, 88.0)	(70.8, 84.7)	(67.3, 81.9)
20/32 or better	n/N	18/149	142/149	142/147	139/147	135/144	135/142
	(%)	(12.08%)	(95.30%)	(96.60%)	(94.56%)	(93.75%)	(95.07%)
	(CI)	(6.7, 17.4)	(91.8, 98.8)	(93.6, 99.6)	(90.8, 98.3)	(89.7, 97.8)	(91.4, 98.7)
20/40 or better	n/N	27/149	147/149	146/147	145/147	143/144	141/142
	(%)	(18.12%)	(98.66%)	(99.32%)	(98.64%)	(99.31%)	(99.30%)
	(CI)	(11.8, 24.4)	(96.8,100.0)	(98.0,100.0)	(96.7,100.0)	(97.9,100.0)	(97.9,100.0)
20/80 or better	n/N	81/149	149/149	147/147	147/147	144/144	142/142
	(%)	(54.36%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(46.2, 62.5)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)
20/200 or better	n/N	138/149	149/149	147/147	147/147	144/144	142/142
	(%)	(92.62%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
	(CI)	(88.3, 96.9)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)	(100.0,100.0)

Good uncorrected visual acuity results were achieved in each of the individual cohorts, as well as the combined cohorts, with 60% of all the eyes achieving UCVA of 20/20 or better and 86% of the eyes achieving an UCVA of 20/25 or better at the 6 month examination. Eyes treated in the study also showed good improvement in functional vision. As shown in Table 13 below, 76% of the eyes achieved an uncorrected visual acuity (UCVA) postoperatively that was no worse than 1 line (5 letters) below the baseline best spectacle-corrected visual acuity (BSCVA) at Month 6.

TABLE 13

UCVA compared to Baseline BSCVA

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
UCVA ≥ 2 lines (≥10 letters) better than Baseline BSCVA	n/N	5/293	9/291	3/291	3/291	4/287	3/279
	(%)	(1.71%)	(3.09%)	(1.03%)	(1.03%)	(1.39%)	(1.08%)
	(CI)	(0.2, 3.2)	(1.1, 5.1)	(-0.2, 2.2)	(-0.2, 2.2)	(0.0, 2.8)	(-0.2, 2.3)
UCVA within 1 line (5 letters) of Baseline BSCVA	n/N	205/293	224/291	227/291	219/291	214/287	220/279
	(%)	(69.97%)	(76.98%)	(78.01%)	(75.26%)	(74.56%)	(78.85%)
	(CI)	(64.6, 75.3)	(72.0, 81.9)	(73.2, 82.9)	(70.2, 80.3)	(69.4, 79.7)	(74.0, 83.7)
UCVA ≥ 2 lines (≥10 letters) worse than Baseline BSCVA	n/N	83/293	58/291	61/291	69/291	69/287	56/279
	(%)	(28.33%)	(19.93%)	(20.96%)	(23.71%)	(24.04%)	(20.07%)
	(CI)	(23.1, 33.6)	(15.2, 24.6)	(16.2, 25.7)	(18.7, 28.7)	(19.0, 29.1)	(15.3, 24.9)

7.3.3 Accuracy of MRSE over Time

The number of eyes that are within ±0.5 D, ±1.0 D, and ±2.0 D of attempted versus achieved manifest refraction spherical equivalent (MRSE) and the proportion of eyes that were overcorrected or undercorrected at each of the postoperative examinations are summarized in Tables 14 through 16 below, respectively, for all eyes treated and for eyes treated for spherical hyperopia and for hyperopic astigmatism

Overall at 6 months postoperatively, 68.7% (200/291) of all the eyes treated (Table 14 below) were within ± 0.5 D of the attempted refraction and 93.5% (272/291) of the eyes were within ± 1.0 D of the attempted refraction. Similar results were observed in the individual cohorts, with 95.1% (135/144) of the eyes treated for spherical hyperopia (Table 16) and 91.8% (135/147) of the hyperopic astigmatic eyes (Table 16) within ±1.0 D of attempted MRSE. None of the eyes (0/291; 0.0%) in the study were undercorrected by more than 2.0 D MRSE and only one spherical hyperopia eye (1/291; 0.3%) was overcorrected by more than 2.0 D MRSE at 6 months postoperatively. The subject with the overcorrected eye developed bilateral posterior subcapsular cataracts, which became evident on the slit lamp examination at the 6 month examination. Obtaining a reliable and accurate manifest refraction was difficult in this subject because of the cataracts.

TABLE 14

Accuracy of Attempted vs. Achieved MRSE Refractive Correction

All Eyes Treated

		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12	MONTH 18
± 0.5 D	n/N	1/293	227/291	210/291	200/291	197/287	176/279	35/ 70
	(%)	(0.34%)	(78.01%)	(72.16%)	(68.73%)	(68.64%)	(63.08%)	(50.00%)
	(CI)	(-0.3, 1.0)	(73.2, 82.9)	(66.9, 77.4)	(63.3, 74.2)	(63.2, 74.1)	(57.3, 68.9)	(38.0, 2.0)
± 1.0 D	n/N	14/293	278/291	272/291	272/291	268/287	252/279	57/ 70
	(%)	(4.78%)	(95.53%)	(93.47%)	(93.47%)	(93.38%)	(90.32%)	(81.43%)
	(CI)	(2.3, 7.3)	(93.1, 98.0)	(90.6, 96.4)	(90.6, 96.4)	(90.4, 96.3)	(86.8, 93.9)	(72.1, 0.7)
± 2.0 D	n/N	112/293	289/291	290/291	290/291	286/287	279/279	69/ 70
	(%)	(38.23%)	(99.31%)	(99.66%)	(99.66%)	(99.65%)	(100.0%)	(98.57%)
	(CI)	(32.5, 43.9)	(98.3,100.0)	(99.0,100.0)	(99.0,100.0)	(99.0,100.0)	(100.0,100.0)	(95.7,101.4)
Undercorrected > +1.0 D	n/N	279/293	9/291	14/291	14/291	17/287	24/279	11/ 70
	(%)	(95.22%)	(3.09%)	(4.81%)	(4.81%)	(5.92%)	(8.60%)	(15.71%)
	(CI)	(92.7, 97.7)	(1.1, 5.1)	(2.3, 7.3)	(2.3, 7.3)	(3.1, 8.7)	(5.2, 12.0)	(7.0, 24.4)
Undercorrected > +2.0 D	n/N	181/293	0/291	0/291	0/291	0/287	0/279	0/ 70
	(%)	(61.77%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(56.1, 67.5)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)
Overcorrected <-1.0 D	n/N	0/293	4/291	5/291	5/291	2/287	3/279	2/ 70
	(%)	(0.00%)	(1.37%)	(1.72%)	(1.72%)	(0.70%)	(1.08%)	(2.86%)
	(CI)	(0.0, 0.0)	(0.0, 2.7)	(0.2, 3.2)	(0.2, 3.2)	(-0.3, 1.7)	(-0.2, 2.3)	(-1.1, 6.8)
Overcorrected <-2.0 D	n/N	0/293	2/291	1/291	1/291	1/287	0/279	1/ 70
	(%)	(0.00%)	(0.69%)	(0.34%)	(0.34%)	(0.35%)	(0.00%)	(1.43%)
	(CI)	(0.0, 0.0)	(-0.3, 1.7)	(-0.3, 1.0)	(-0.3, 1.0)	(-0.3, 1.0)	(0.0, 0.0)	(-1.4, 4.3)

TABLE 15
Accuracy of Attempted vs. Achieved MRSE Refractive Correction
Eyes Treated for Spherical Hyperopia

Achieved MRSE		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
± 0.5 D	n/N	1/144	116/142	115/144	111/144	108/143	94/137
	(%)	(0.69%)	(81.69%)	(79.86%)	(77.08%)	(75.52%)	(68.61%)
± 1.0 D	n/N	8/144	137/142	138/144	137/144	139/143	130/137
	(%)	(5.56%)	(96.48%)	(95.83%)	(95.14%)	(97.20%)	(94.89%)
± 2.0 D	n/N	63/144	140/142	143/144	143/144	142/143	137/137
	(%)	(43.75%)	(98.59%)	(99.31%)	(99.31%)	(99.30%)	(100.0%)
Undercorrected	n/N	136/144	1/142	1/144	2/144	2/143	4/137
> +1.0 D	(%)	(94.44%)	(0.70%)	(0.69%)	(1.39%)	(1.40%)	(2.92%)
Undercorrected	n/N	81/144	0/142	0/144	0/144	0/143	0/137
> +2.0 D	(%)	(56.25%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Overcorrected	n/N	0/144	4/142	5/144	5/144	2/143	3/137
< -1.0 D	(%)	(0.00%)	(2.82%)	(3.47%)	(3.47%)	(1.40%)	(2.19%)
Overcorrected	n/N	0/144	2/142	1/144	1/144	1/143	0/137
< -2.0 D	(%)	(0.00%)	(1.41%)	(0.69%)	(0.69%)	(0.70%)	(0.00%)

TABLE 16
Accuracy of Attempted vs. Achieved MRSE Refractive Correction
Eyes Treated for Hyperopic Astigmatism

Achieved MRSE		PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
± 0.5 D	n/N	0/149	111/149	95/147	89/147	89/144	82/142
	(%)	(0.00%)	(74.50%)	(64.63%)	(60.54%)	(61.81%)	(57.75%)
± 1.0 D	n/N	6/149	141/149	134/147	135/147	129/144	122/142
	(%)	(4.03%)	(94.63%)	(91.16%)	(91.84%)	(89.58%)	(85.92%)
± 2.0 D	n/N	49/149	149/149	147/147	147/147	144/144	142/142
	(%)	(32.89%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)	(100.0%)
Undercorrected	n/N	143/149	8/149	13/147	12/147	15/144	20/142
> +1.0 D	(%)	(95.97%)	(5.37%)	(8.84%)	(8.16%)	(10.42%)	(14.08%)
Undercorrected	n/N	100/149	0/149	0/147	0/147	0/144	0/142
> +2.0 D	(%)	(67.11%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Overcorrected	n/N	0/149	0/149	0/147	0/147	0/144	0/142
<-1.0 D	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Overcorrected	n/N	0/149	0/149	0/147	0/147	0/144	0/142
<-2.0 D	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)

7.3.4 Stability of Refractive Outcome

Refractive stability was evaluated in the eyes that completed one or more pairs of successive postoperative visits. The mean changes (paired differences) in MRSE (±Standard Deviation (S.D.) and 95% confidence interval (C.I).) between pairs of successive refractions for eyes with all consecutive visits from Month 1 through Month 9 are reported in Tables 17 through 19, respectively, for all eyes treated, eyes treated for spherical hyperopia, and for those treated for hyperopic astigmatism.

Refractive stability was achieved at 6 months and confirmed at 9 months postoperatively for all the cohorts. The time point to refractive stability was 3 months for the spherical hyperopia eyes and 6 months for the hyperopic astigmatism eyes and the entire cohort of treated eyes. At the time point of refractive stability, the mean rate of change was 0.033 D/month for the spherical hyperopia cohort (at 3 months) and 0.009 D/month for the eyes treated for hyperopic astigmatism (at 6 months).

TABLE 17

Refractive Stability for All Eyes that Underwent the 1 Week and 1, 3, 6, and 9 Month Visits

		WEEK 1 TO MONTH 1	MONTH 1 TO MONTH 3	MONTH 3 TO MONTH 6	MONTH 6 TO MONTH 9
Change of MRSE ≤ 1D	n/N	277/283	277/283	278/283	280/283
	(%)	(97.88%)	(97.88%)	(98.23%)	(98.94%)
	(CI)	(96.2, 99.6)	(96.2, 99.6)	(96.7, 99.8)	(97.7,100.0)
Change of MRSE in diopters	Mean	0.061	0.115	0.021	0.064
	Std	0.41	0.39	0.37	0.36
	(CI)	(-0.01, 0.14)	(0.04, 0.19)	(-0.05, 0.09)	(-0.01, 0.13)
Rate of Change (diopters/month)		0.061	0.058	0.007	0.021

TABLE 18

Refractive Stability for All Spherical Hyperopia Eyes that Underwent the 1 Week and 1, 3, 6, and 9 Month Visits

		WEEK 1 TO MONTH 1	MONTH 1 TO MONTH 3	MONTH 3 TO MONTH 6	MONTH 6 TO MONTH 9
Change of MRSE ≤ 1D	n/N	135/140	138/140	140/140	140/140
	(%)	(96.43%)	(98.57%)	(100.0%)	(100.0%)
	(CI)	(93.4, 99.5)	(96.6,100.0)	(97.4,100.0)	(97.4,100.0)
Change of MRSE in diopters	Mean	0.066	0.065	0.014	0.102
	Std	0.49	0.37	0.28	0.32
	(CI)	(-0.05, 0.18)	(-0.04, 0.17)	(-0.07, 0.10)	(0.01, 0.20)
Rate of Change (diopters/month)		0.066	0.033	0.005	0.034

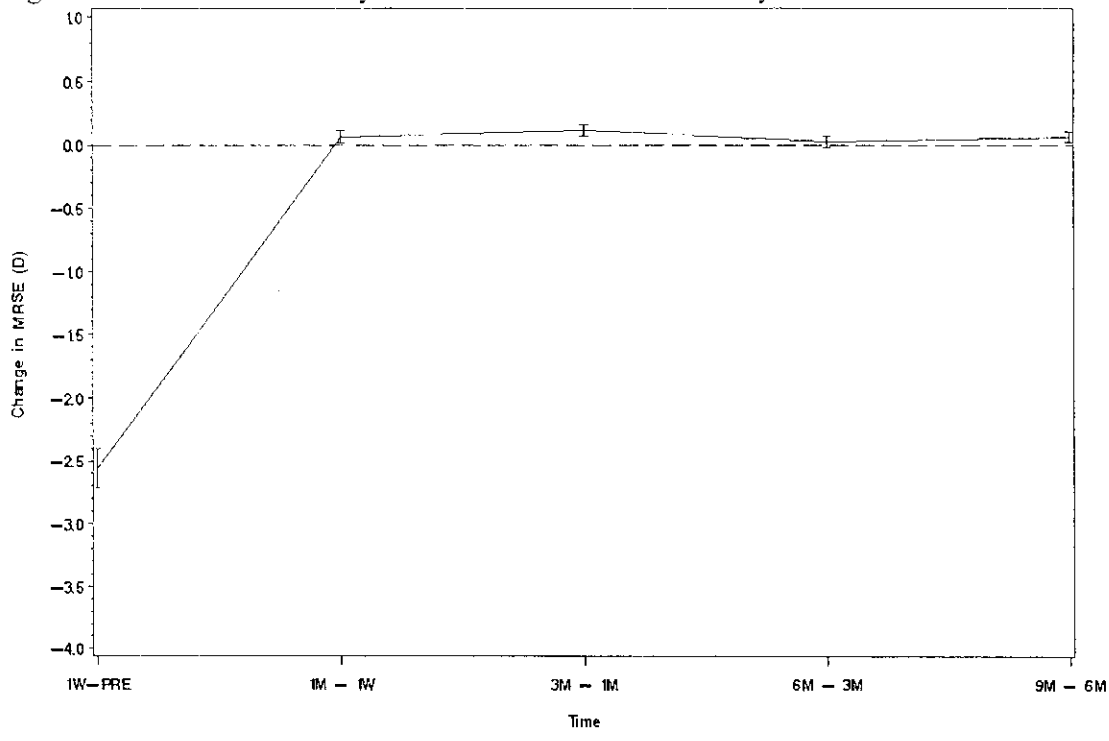
TABLE 19

Refractive Stability for All Hyperopic Astigmatism Eyes that Underwent the 1 Week and 1, 3, 6, and 9 Month Visits

		WEEK 1 TO MONTH 1	MONTH 1 TO MONTH 3	MONTH 3 TO MONTH 6	MONTH 6 TO MONTH 9
Change of MRSE ≤ 1D	n/N	142/143	139/143	138/143	140/143
	(%)	(99.30%)	(97.20%)	(96.50%)	(97.90%)
	(CI)	(97.9,100.0)	(94.5, 99.9)	(93.5, 99.5)	(95.6,100.0)
Change of MRSE in diopters	Mean	0.056	0.163	0.028	0.026
	Std	0.32	0.40	0.43	0.39
	(CI)	(-0.04, 0.15)	(0.06, 0.27)	(-0.08, 0.14)	(-0.08, 0.13)
Rate of Change		0.056	0.082	0.009	0.009

The stability of the mean MRSE plotted over time (Figure 1) illustrates the excellent refractive stability for the cohort.

Figure 1: Refractive Stability of MRSE over Time for All Eyes



7.3.5 Efficacy of Astigmatism Correction

Vector analysis was performed on the cohort of eyes treated for hyperopic astigmatism. All vector analysis is based on the vector components vertex-corrected to the corneal plane.

Cylinder stability calculated as the magnitude of cylinder vector differences is summarized in Table 20 below for each postoperative visit interval between Month 1 through Month 9.

TABLE 20

Magnitude of Cylinder Vector Differences

		MONTH 1 TO MONTH 3	MONTH 3 TO MONTH 6	MONTH 6 TO MONTH 9	MONTH 9 TO MONTH 12
Magnitude of Cylinder Vector Difference ≤ 0.5D	n/N	102/147	95/147	109/144	111/141
	(%)	(69.39%)	(64.63%)	(75.69%)	(78.72%)
	(CI)	(61.9, 76.8)	(56.9, 72.4)	(68.7, 82.7)	(72.0, 85.5)
Magnitude of Cylinder Vector Difference ≤ 1D	n/N	140/147	141/147	141/144	140/141
	(%)	(95.24%)	(95.92%)	(97.92%)	(99.29%)
	(CI)	(91.8, 98.7)	(92.7, 99.1)	(95.6,100.0)	(97.9,100.0)
Magnitude of Cylinder Vector Difference (diopters)	Mean	0.343	0.361	0.273	0.244
	Std	0.35	0.30	0.25	0.25
	(CI)	(0.25, 0.44)	(0.27, 0.45)	(0.19, 0.36)	(0.16, 0.33)

The magnitude of the cylinder vector difference plateaus and remains constant over time, with no more than a 0.088 D/month difference between intervals for any of the intervals after the 1 month postoperative visit.

The stability of absolute (non-vector) cylinder is summarized in Table 21 below. The magnitude of the absolute vector difference was no more than 0.5 D for over 92% of subjects at all time intervals. Similarly, the absolute cylinder also remains constant over time, with no more than a 0.02D difference occurring between any of the intervals evaluated.

TABLE 21

Stability of Absolute (Non-Vector) Cylinder

		MONTH 1 TO MONTH 3	MONTH 3 TO MONTH 6	MONTH 6 TO MONTH 9	MONTH 9 TO MONTH 12
Cylinder Magnitude Difference ≤ 0.5 D	n/N	136/147	136/147	138/144	136/141
	(%)	(92.52%)	(92.52%)	(95.83%)	(96.45%)
	(CI)	(88.3, 96.8)	(88.3, 96.8)	(92.6, 99.1)	(93.4, 99.5)
Cylinder Magnitude Difference ≤ 1D	n/N	145/147	146/147	144/144	141/141
	(%)	(98.64%)	(99.32%)	(100.0%)	(100.0%)
	(CI)	(96.8,100.0)	(98.0,100.0)	(100.0,100.0)	(100.0,100.0)
Cylinder Magnitude Difference (diopters)	Mean	0.024	0.002	0.012	0.032
	Std	0.37	0.37	0.29	0.27
	(CI)	(-0.07, 0.12)	(-0.10, 0.10)	(-0.08, 0.10)	(-0.05, 0.12)

7.3.6 Treatment Accuracy

The descriptive statistics for the predictability (accuracy) of the attempted versus achieved manifest sphere and magnitude of vector cylinder are summarized in Table 22 below for the entire cohort and in Table 23 for those eyes within the approved range (≤ +5.00 D sphere, ≤ +2.00 D cylinder, ≤ +5.00 D MRSE).

TABLE 22
Treatment Accuracy for Sphere and Cylinder Magnitude

	BASELINE	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
SPHERE	N=293	N=291	N=291	N=291	N=287	N=279
Mean (SD)	2.48 (1.22)	-0.07 (0.58)	0.05 (0.56)	0.07 (0.56)	0.12 (0.54)	0.17 (0.56)
Attempted (SD)	2.48 (1.22)	2.48 (1.23)	2.47 (1.22)	2.47 (1.22)	2.47 (1.23)	2.47 (1.23)
Achieved (SD)		2.51 (1.46)	2.39 (1.43)	2.37 (1.43)	2.29 (1.39)	2.26 (1.43)
% Achieved		97.64%	91.75%	91.05%	88.56%	85.73%
± 0.5D		68.73%	64.60%	61.17%	62.28%	60.57%
± 1.0D		93.13%	92.10%	93.13%	91.70%	88.89%
CYLINDER	N=149	N=149	N=147	N=147	N=144	N=142
Mean (SD)	1.04 (0.60)	0.38 (0.39)	0.41 (0.44)	0.42 (0.43)	0.42 (0.49)	0.45 (0.47)
Attempted (SD)	1.04 (0.60)	1.04 (0.60)	1.04 (0.60)	1.04 (0.60)	1.05 (0.60)	1.04 (0.60)
Achieved (SD)		0.65 (0.55)	0.63 (0.60)	0.62 (0.56)	0.62 (0.62)	0.59 (0.59)
% Achieved		59.45%	55.26%	57.35%	56.36%	52.74%
± 0.5D		62.42%	58.50%	53.06%	57.93%	53.52%
± 1.0D		90.60%	87.76%	89.12%	86.90%	85.21%

Hyperopic astigmatic treatments performed with the EC-5000 excimer laser using the H70 treatment algorithm yielded excellent treatment results for vector cylinder. At the timepoint of refractive stability (6 months), the eyes in the entire hyperopic astigmatic cohort (see Table 14) achieved 92.4% of the attempted vector cylinder treatment and those that were in the approved range (see Table 23) achieved 93.6% of the attempted vector cylinder treatment. The results for the spherical component of the treatment were not as accurate, but were still good, with the entire cohort of hyperopic astigmatic eyes achieving 85.3% of the attempted spherical treatment and the eyes in the approved cohort achieving 83.3% of the attempted spherical treatment. The percentage of vector cylinder achieved remains constant after 3 months, as does the percentage of spherical treatment achieved.

TABLE 23

Treatment Accuracy for Sphere and Cylinder Magnitude

For Eyes within the Approved Ranges

	BASELINE	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
SPHERE	N=270	N=268	N=268	N=268	N=265	N=256
Mean (SD)	2.31 (1.01)	-0.06 (0.56)	0.05 (0.55)	0.08 (0.54)	0.12 (0.54)	0.17 (0.56)
Attempted (SD)	2.31 (1.01)	2.31 (1.01)	2.31 (1.01)	2.31 (1.01)	2.30 (1.01)	2.29 (1.01)
Achieved (SD)		2.33 (1.27)	2.22 (1.24)	2.19 (1.24)	2.14 (1.22)	2.08 (1.23)
% Achieved		97.41%	91.73%	90.27%	88.66%	85.53%
± 0.5D		71.27%	66.42%	63.81%	64.29%	61.72%
± 1.0D		94.03%	92.91%	93.66%	92.11%	89.06%
CYLINDER	N=128	N=128	N=126	N=126	N=124	N=121
Mean (SD)	0.90 (0.40)	0.32 (0.33)	0.34 (0.35)	0.34 (0.36)	0.36 (0.43)	0.37 (0.40)
Attempted (SD)	0.90 (0.40)	0.90 (0.40)	0.90 (0.40)	0.90 (0.40)	0.90 (0.40)	0.90 (0.40)
Achieved (SD)		0.57 (0.45)	0.56 (0.53)	0.55 (0.49)	0.54 (0.53)	0.52 (0.52)
% Achieved		60.02%	55.69%	58.34%	56.88%	53.38%
± 0.5D		67.19%	63.49%	59.52%	62.90%	58.68%
± 1.0D		94.53%	92.06%	92.86%	89.52%	91.74%

The descriptive statistics for the accuracy of the achieved cylinder magnitude outcome compared to the desired outcome, stratified by the degree of preoperative cylinder at the corneal plane, are summarized in Table 24 below. The hyperopic astigmatic LASIK treatment provides reasonably good accuracy of the amount of achieved cylindrical correction compared to the desired outcome (emmetropia) in the approved cylinder range of +0.5 to +2.0 D. Eyes with +0.5 to +1.0 D of preoperative astigmatism had 53.2%% of the cylinder magnitude treated, while those with preoperative cylinder between +1.01 to 2.00 D achieved 64.7%% of the desired treatment.

TABLE 24 Accuracy of Cylinder to Target						
Preop Cylinder Range*	+0.5 to +1.0 D		+1.01 to +2.0 D		+2.01 to +3.0 D	
No. of Eyes (N)	87		50		8	
Time Point	Preop	6 months	Preop	6 months	Preop	6 months
Mean Cylinder Magnitude (SD)	0.66 (0.14)	0.31 (0.32)	1.37 (0.26)	0.46 (0.40)	2.57 (0.16)	1.02 (0.70)
Mean Attempted Magnitude Change (SD)	0.66 (0.14)		1.37 (0.26)		2.57 (0.16)	
Mean Achieved Magnitude Change (Preop-Postop) (SD)		0.35 (0.33)		0.90 (0.50)		1.54 (0.66)
Percent Achieved/Attempted		53.2%		64.7%		60.5%
% of Eyes within ±0.5 D of Target Magnitude		62.1		46.0		12.5
% of Eyes within ±1.0D of Target Magnitude		96.6		84.0		50.0

(*Cylinder group based on cylinder correction at the corneal plane)

A summary of the intended refractive correction (IRC), surgically induced refractive correction (SIRC), correction ratio (CR), and error ratio (ER) at 6 months postoperatively (timepoint of stability) is provided in Table 25 below.

TABLE 25 Refractive Correction Parameters Stratified by Preoperative Cylinder						
VISIT	CYLINDER GROUP*	N	IRC MEAN(SD)	SIRC MEAN(SD)	CR MEAN(SD)	ER MEAN(SD)
POSTOP MONTH 6	ALL	147	1.04 (0.60)	0.92 (0.54)	0.92 (0.30)	0.42 (0.43)
	0.5D-1.0D	87	0.66 (0.14)	0.64 (0.25)	0.97 (0.31)	0.47 (0.50)
	>1.0D-2.0D	50	1.37 (0.27)	1.18 (0.40)	0.86 (0.28)	0.36 (0.32)
	>2.0D-3.0D	8	2.56 (0.19)	1.92 (0.73)	0.76 (0.30)	0.39 (0.25)
	>3.0D-4.0D	2	3.27 (0.14)	2.60 (1.15)	0.80 (0.39)	0.42 (0.15)

(*Cylinder group based on cylinder correction at the corneal plane)

At 6 months postoperatively, the SIRC of 0.92 for the hyperopic astigmatism cohort closely approximates the intended refractive correction for all eyes treated. This is confirmed by the correction ratio (CR) of 0.92 for all treated eyes in the cohort. Outcomes in higher cylindrical ranges are consistent with those observed in other contemporary LASIK clinical trials.

The mean percent reduction in absolute (non-vector) cylinder is shown in Table 26 below.

TABLE 26

Percent Reduction in Absolute (Non-Vector) Cylinder

Cylinder Group*	n	Mean (range) Percent Reduction
All hyperopic astigmatism eyes	145	57.6% (15.0% - 100.0%)
≥ 0.5 D to ≤ 1.0 D	87	53.2% (-134.5% to - 100.0%)
> 1.0 D to ≤ 2.0 D	50	64.7% (-21.2% to - 100.0%)
> 2.0 D to ≤ 3.0 D	8	60.5% (15.0% to - 100.0%)

(*Cylinder group based on cylinder correction at the corneal plane)

The amount of spherical hyperopia correction that was obtained at 6 months after the LASIK surgery is shown in Table 27 below, stratified by baseline sphere. At 6 months, the LASIK surgery corrected 91% of the sphere that was present before the surgery. The amount of correction achieved was better in those eyes that had higher preoperative sphere before surgery (96.9% to 105.5% in those eyes with more than 2 diopters of sphere compared to 87.4% to 54.3% in those eyes with 2 diopters or less of sphere).

TABLE 27

Sphere Before LASIK Compared to Sphere 6 Months after LASIK Stratified by Baseline Sphere

Preoperative Sphere	0 – 1.0 D	>1.0 – 2.0 D	>2.0 – 3.0 D	>3.0 – 4.0 D	>4.0 – 5.0 D	>5.0D	Total
Eyes in Each Preop Sphere Group % (n/N)	8% (23/291)	35% (103/291)	30% (87/291)	18% (52/291)	6% (18/291)	3% (8/291)	100% (291/291)
Mean Preop Sphere (D)	0.75	1.50	2.43	3.37	4.53	5.5	2.35
Mean Postop Sphere (D) (Range)	0.30 (-1.00 – 0.75)	0.15 (-0.75 – .25)	0.03 (-2.25 – .50)	-0.13 (-3.25 – 1.25)	0.14 (-0.75 – 1.50)	-0.3 (-2.00 – .75)	0.06 (-3.25-1.50)
Mean Postop Reduction in Sphere (Range)	54.3% (-50.0 – 33.3)	87.4% (0.0 – 144.4)	96.9% (29.4 – 178.3)	101.5 (61.5 – 186.7)	98.4 (63.6 – 115.5)	105.5 (86.7 – 138.3)	91.2 (-50.0 – 233.3)

As shown in Table 28 below, the eyes treated for hyperopic astigmatism that had smaller amounts of astigmatism (-1 D or less) before LASIK had an average of slightly more than half (51.1%) of the astigmatism treated at 6 months after the surgery. Those eyes that had larger amounts of astigmatism (>-1D to -2D) had about two-thirds (64%) of the astigmatism treated at 6 months after LASIK.

TABLE 28

Cylinder Magnitude Before LASIK Compared to Cylinder Magnitude 6 Months after LASIK Stratified by Baseline Cylinder Magnitude

Preoperative Cylinder	0.5 – 1.0 D	>1.0 – 2.0 D	Total Range
Eyes in Each Preop Cylinder Group % (n/N)	72% 99/137	28% 38/137	100% 137/137
Mean Preop Cylinder (D)	0.67 (0.50 – 1.00)	1.35 (1.125 – 1.875)	0.85 (0.50 – 1.875)
Mean Postop Cylinder (D) (Range)	0.32 (0.0 – 1.25)	0.46 (0.0 – 1.50)	0.36 (0.0 – 1.50)
Mean Postop Reduction in Cylinder (Range)	51.1% (-150% - 100%)	64.0% (-20% - 100%)	54.7% (-150% - 100%)

7.3.7 Best Spectacle Corrected Visual Acuity (BSCVA)

The changes in lines of best spectacle corrected visual acuity[4] from screening to each postoperative visit are summarized in Tables 29 through 31, respectively, for the entire cohort, as well as, for eyes treated for spherical hyperopia and for hyperopic astigmatism. In the tables, a decrease in lines of BSCVA represents a loss of BSCVA, whereas an increase in lines of BSCVA represents a gain or improvement in BSCVA.

Very little loss of BSCVA occurred in the majority of eyes treated in the study, with 1% or less of the eyes at any postoperative exam reporting a BSCVA worse than 20/25 if the preoperative BSCVA was 20/20 or better. The incidence of new reports of loss of 2 or more lines (≥10 letters) of BSCVA was 1.4% at Month 3, 2.4% at Month 6, 2.1% at Month 9, and 0.7% at Month 12. The overall cumulative rate was 6.5% (19/293 eyes) for the cohort, of which 1.4% (4/293 eyes) had a persistent loss of at least 2 lines (10 letters) of BSCVA; last visit BSCVA was 20/20 for 1 eye, 20/32 for 2 eyes, and 20/40 for 1 eye that had a concomitant posterior subcapsular cataract that diminished the BSCVA. Changes in BSCVA from baseline to each postoperative visit are summarized in Tables 29, 30, and 31 for all eyes treated and the individual cohorts.

[4] BSCVA was recorded as the total number of letters that were correctly identified by the subject. The number of letters identified was converted to lines of visual acuity by dividing the total number of letters observed by 5 (1 line/5 letters). Changes in the number of lines of BSCVA were then calculated.

TABLE 29

Changes in BSCVA from Preop to Postop for All Eyes Treated

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
Decrease > 2 Lines	n/N	0/293	0/291	0/290	1/291	1/287	1/279
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.34%)	(0.35%)	(0.36%)
	(CI)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(-0.3, 1.0)	(-0.3, 1.0)	(-0.4, 1.1)
Decrease 2 Lines	n/N	12/293	2/291	4/290	9/291	10/287	3/279
	(%)	(4.10%)	(0.69%)	(1.38%)	(3.09%)	(3.48%)	(1.08%)
	(CI)	(1.8, 6.4)	(-0.3, 1.7)	(0.0, 2.7)	(1.1, 5.1)	(1.3, 5.6)	(-0.2, 2.3)
Decrease 1 Line	n/N	68/293	47/291	47/290	53/291	48/287	43/279
	(%)	(23.21%)	(16.15%)	(16.21%)	(18.21%)	(16.72%)	(15.41%)
	(CI)	(18.3, 28.1)	(11.8, 20.5)	(11.9, 20.5)	(13.7, 22.7)	(12.3, 21.1)	(11.1, 19.7)
No Change	n/N	158/293	165/291	165/290	154/291	166/287	158/279
	(%)	(53.92%)	(56.70%)	(56.90%)	(52.92%)	(57.84%)	(56.63%)
	(CI)	(48.1, 59.7)	(50.9, 62.5)	(51.1, 62.7)	(47.1, 58.8)	(52.0, 63.7)	(50.7, 62.6)
Increase 1 Line	n/N	48/293	64/291	60/290	67/291	55/287	71/279
	(%)	(16.38%)	(21.99%)	(20.69%)	(23.02%)	(19.16%)	(25.45%)
	(CI)	(12.1, 20.7)	(17.1, 26.8)	(15.9, 25.4)	(18.1, 28.0)	(14.5, 23.8)	(20.2, 30.7)
Increase 2 Lines	n/N	3/293	9/291	12/290	7/291	7/287	3/279
	(%)	(1.02%)	(3.09%)	(4.14%)	(2.41%)	(2.44%)	(1.08%)
	(CI)	(-0.2, 2.2)	(1.1, 5.1)	(1.8, 6.5)	(0.6, 4.2)	(0.6, 4.3)	(-0.2, 2.3)
Increase > 2 Lines	n/N	4/293	4/291	2/290	0/291	0/287	0/279
	(%)	(1.37%)	(1.37%)	(0.69%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 2.7)	(0.0, 2.7)	(-0.3, 1.7)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

TABLE 30

Changes in BSCVA from Preop to Postop for Spherical Hyperopia Eyes

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
Decrease > 2 Lines	n/N	0/144	0/142	0/143	1/144	1/143	1/137
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.69%)	(0.70%)	0.73%)
	(CI)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(-0.7, 2.1)	(-0.7, 2.1)	(-0.7, 2.2)
Decrease 2 Lines	n/N	5/144	1/142	2/143	5/144	5/143	2/137
	(%)	(3.47%)	(0.70%)	(1.40%)	(3.47%)	(3.50%)	(1.46%)
	(CI)	(0.4, 6.5)	(-0.7, 2.1)	(-0.6, 3.4)	(0.4, 6.5)	(0.4, 6.6)	(-0.6, 3.5)
Decrease 1 Line	n/N	32/144	22/142	18/143	23/144	18/143	15/137
	(%)	(22.22%)	(15.49%)	(12.59%)	(15.97%)	(12.59%)	(10.95%)
	(CI)	(15.3, 29.2)	(9.4, 21.6)	(7.0, 18.1)	(9.9, 22.1)	(.0, 18.1)	(5.6, 16.3)
No Change	n/N	83/144	83/142	83/143	81/144	90/143	86/137
	(%)	(57.64%)	(58.45%)	(58.04%)	(56.25%)	(62.94%)	(62.77%)
	(CI)	(49.4, 65.9)	(50.2, 66.7)	(49.8, 66.3)	(48.0, 64.5)	(54.9, 71.0)	(54.5, 71.0)
Increase 1 Line	n/N	20/144	27/142	32/143	28/144	26/143	31/137
	(%)	(13.89%)	(19.01%)	(22.38%)	(19.44%)	(18.18%)	(22.63%)
	(CI)	(8.1, 19.7)	(12.4, 25.6)	(15.4, 29.3)	(12.8, 26.0)	(11.7, 24.6)	(15.5, 29.8)
Increase 2 Lines	n/N	1/144	7/142	7/143	6/144	3/143	2/137
	(%)	(0.69%)	(4.93%)	(4.90%)	(4.17%)	(2.10%)	(1.46%)
	(CI)	(-0.7, 2.1)	(1.3, 8.6)	(1.3, 8.5)	(0.8, 7.5)	(-0.3, 4.5)	(-0.6, 3.5)
Increase > 2 Lines	n/N	3/144	2/142	1/143	0/144	0/143	0/137
	(%)	(2.08%)	(1.41%)	(0.70%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(-0.3, 4.5)	(-0.6, 3.4)	(-0.7, 2.1)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

TABLE 31

Changes in BSCVA from Preop to Postop for Hyperopic Astigmatism Eyes

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
Decrease > 2 Lines	n/N	0/149	0/149	0/147	0/147	0/144	0/142
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
	(CI)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)
Decrease 2 Lines	n/N	7/149	1/149	2/147	4/147	5/144	1/142
	(%)	(4.70%)	(0.67%)	(1.36%)	(2.72%)	(3.47%)	(0.70%)
	(CI)	(1.2, 8.2)	(-0.7, 2.0)	(-0.6, 3.3)	(0.0, 5.4)	(0.4, 6.5)	(-0.7, 2.1)
Decrease 1 Line	n/N	36/149	25/149	29/147	30/147	30/144	28/142
	(%)	(24.16%)	(16.78%)	(19.73%)	(20.41%)	(20.83%)	(19.72%)
	(CI)	(17.1, 31.2)	(10.7, 22.9)	(13.2, 26.3)	(13.8, 27.1)	(14.1, 27.6)	(13.0, 26.4)
No Change	n/N	75/149	82/149	82/147	73/147	76/144	72/142
	(%)	(50.34%)	(55.03%)	(55.78%)	(49.66%)	(52.78%)	(50.70%)
	(CI)	(42.1, 58.5)	(46.9, 63.2)	(47.6, 64.0)	(41.4, 57.9)	(44.5, 61.1)	(42.3, 59.1)
Increase 1 Line	n/N	28/149	37/149	28/147	39/147	29/144	40/142
	(%)	(18.79%)	(24.83%)	(19.05%)	(26.53%)	(20.14%)	(28.17%)
	(CI)	(12.4, 25.2)	(17.8, 31.9)	(12.6, 25.5)	(19.2, 33.8)	(13.5, 26.8)	(20.6, 35.7)
Increase 2 Lines	n/N	2/149	2/149	5/147	1/147	4/144	1/142
	(%)	(1.34%)	(1.34%)	(3.40%)	(0.68%)	(2.78%)	(0.70%)
	(CI)	(-0.5, 3.2)	(-0.5, 3.2)	(0.4, 6.4)	(-0.7, 2.0)	(0.0, 5.5)	(-0.7, 2.1)
Increase > 2 Lines	n/N	1/149	2/149	1/147	0/147	0/144	0/142
	(%)	(0.67%)	(1.34%)	(0.68%)	(0.00%)	(0.00%)	0.00%)
	(CI)	(-0.7, 2.0)	(-0.5, 3.2)	(-0.7, 2.0)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.0)

7.4 Summary of Key Safety and Effectiveness Variables

7.4.1 Key Effectiveness Variables

The effectiveness analyses were based on 291 eyes that were available for analysis at 6 months postoperatively. A summary of key effectiveness variables is provided below in Table 32 for all eyes treated in the cohort. It is expected that at least 50% of the eyes will achieve a postoperative uncorrected visual acuity (UCVA) of 20/20 or better. The cohort of eyes in this study performed well in this category, with 59.8% (174/291) of all eyes treated having an UCVA of 20/20 or better at 6 months postoperatively, which is the time point of refractive stability.

Results from the clinical study demonstrate that eyes treated for spherical hyperopia only and those treated for hyperopic astigmatism met or exceeded the target criteria established for the study. However, eyes treated for spherical hyperopia had a greater proportion that achieved 20/20 or better UCVA (69.4% for spherical cohort, 50.3% for astigmatic cohort), with the proportion achieving 20/40 or better UCVA being the same in both groups (98.6% for spherical and astigmatic cohorts). Similarly, eyes treated for spherical hyperopia had a greater proportion that were within ±0.5 D of attempted MRSE (77.1% for spherical cohort, 60.5% for astigmatic cohort) with the proportion within ±1.0 D of attempted MRSE being similar for both groups (95.1% for spherical cohort, 91.8% for astigmatic cohort).

TABLE 32

Key Effectiveness Outcomes for All Eyes Treated

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
EFFICACY VARIABLES							
MRSE ± 0.50 D	n/N	227/293	227/291	210/291	200/291	197/287	176/279
	(%)	(77.47%)	(78.01%)	(72.16%)	(68.73%)	(68.64%)	(63.08%)
MRSE ± 1.00 D	n/N	281/293	278/291	272/291	272/291	268/287	252/279
	(%)	(95.90%)	(95.53%)	(93.47%)	(93.47%)	(93.38%)	(90.32%)
MRSE ± 2.00 D	n/N	292/293	289/291	290/291	290/291	286/287	279/279
	(%)	(99.66%)	(99.31%)	(99.66%)	(99.66%)	(99.65%)	(100.0%)
UCVA 20/20 or better	n/N	154/293	174/291	163/291	174/291	174/287	170/279
	(%)	(52.56%)	(59.79%)	(56.01%)	(59.79%)	(60.63%)	(60.93%)
UCVA 20/40 or better	n/N	283/293	287/291	286/291	287/291	284/287	277/279
	(%)	(96.59%)	(98.63%)	(98.28%)	(98.63%)	(98.95%)	(99.28%)

Efficacy outcomes for the eyes that are within the approved range (≤ +5.00 D sphere, ≤ +2.00 D cylinder, and ≤ +5.00 D MRSE) are summarized in Table 33 below. As would be expected at 6 months, the approved range cohort shows superior efficacy outcomes, with 72.0% of the eyes achieving a MRSE within ±0.50 D of the attempted parameters compared to 68.7% of the entire cohort. Similarly, 62.7% of the eyes in the approved range cohort had an UCVA of 20/20 or better at 6 months compared to 59.8% of the entire cohort.

TABLE 33

Key Effectiveness Outcomes

Eyes Within the Approved Range

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
EFFICACY VARIABLES							
MRSE ± 0.50 D	n/N	212/270	214/268	198/268	193/268	189/265	166/256
	(%)	(78.52%)	(79.85%)	(73.88%)	(72.01%)	(71.32%)	(64.84%)
MRSE ± 1.00 D	n/N	259/270	259/268	254/268	254/268	250/265	234/256
	(%)	(95.93%)	(96.64%)	(94.78%)	(94.78%)	(94.34%)	(91.41%)
MRSE ± 2.00 D	n/N	269/270	266/268	267/268	267/268	264/265	256/256
	(%)	(99.63%)	(99.25%)	(99.63%)	(99.63%)	(99.62%)	(100.0%)
UCVA 20/20 or better	n/N	149/270	169/268	156/268	168/268	167/265	166/256
	(%)	(55.19%)	(63.06%)	(58.21%)	(62.69%)	(63.02%)	(64.84%)
UCVA 20/40 or better	n/N	262/270	266/268	264/268	266/268	262/265	254/256
	(%)	(97.04%)	(99.25%)	(98.51%)	(99.25%)	(98.87%)	(99.22%)

Summaries of key effectiveness parameters at Month 6 are stratified below by preoperative manifest refraction spherical equivalent (MRSE), preoperative manifest sphere, and preoperative manifest cylinder in Tables 34 through 36, respectively.

TABLE 34

Effectiveness Outcomes at Month 6 Stratified by Baseline MRSE

MRSE (Diopters)		0.00 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	3.01 TO 4.00D	4.01 TO 5.00D	>5.00D	CUM TOTAL
EFFICACY VARIABLES								
MRSE ± 0.50 D	n/N	5/ 10	72/ 97	70/ 93	42/ 58	9/ 19	2/ 14	200/291
	(%)	(50.00%)	(74.23%)	(75.27%)	(72.41%)	(47.37%)	(14.29%)	(68.73%)
MRSE ± 1.00 D	n/N	10/ 10	96/ 97	86/ 93	54/ 58	16/ 19	10/ 14	272/291
	(%)	(100.0%)	(98.97%)	(92.47%)	(93.10%)	(84.21%)	(71.43%)	(93.47%)
MRSE ± 2.00 D	n/N	10/ 10	97/ 97	93/ 93	57/ 58	19/ 19	14/ 14	290/291
	(%)	(100.0%)	(100.0%)	(100.0%)	(98.28%)	(100.0%)	(100.0%)	(99.66%)
UCVA 20/20 or better	n/N	4/ 10	67/ 97	64/ 93	28/ 58	7/ 19	4/ 14	174/291
	(%)	(40.00%)	(69.07%)	(68.82%)	(48.28%)	(36.84%)	(28.57%)	(59.79%)
UCVA 20/40 or better	n/N	10/ 10	97/ 97	91/ 93	57/ 58	19/ 19	13/ 14	287/291
	(%)	(100.0%)	(100.0%)	(97.85%)	(98.28%)	(100.0%)	(92.86%)	(98.63%)

TABLE 35

Key Effectiveness Outcomes at Month 6 Stratified by Baseline Sphere

		0.00 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	3.01 TO 4.00D	4.01 TO 5.00D	5.01 TO 6.00D	CUM TOTAL
EFFICACY VARIABLES								
MRSE ± 0.50 D	n/N	13/ 23	77/103	66/ 87	35/ 52	8/ 18	1/ 8	200/291
	(%)	(56.52%)	(74.76%)	(75.86%)	(67.31%)	(44.44%)	(12.50%)	(68.73%)
MRSE ± 1.00 D	n/N	23/ 23	101/103	79/ 87	48/ 52	15/ 18	6/ 8	272/291
	(%)	(100.0%)	(98.06%)	(90.80%)	(92.31%)	(83.33%)	(75.00%)	(93.47%)
MRSE ± 2.00 D	n/N	23/ 23	103/103	87/ 87	51/ 52	18/ 18	8/ 8	290/291
	(%)	(100.0%)	(100.0%)	(100.0%)	(98.08%)	(100.0%)	(100.0%)	(99.66%)
UCVA 20/20 or better	n/N	12/ 23	70/103	59/ 87	23/ 52	10/ 18	0/ 8	174/291
	(%)	(52.17%)	(67.96%)	(67.82%)	(44.23%)	(55.56%)	(0.00%)	(59.79%)
UCVA 20/40 or better	n/N	22/ 23	103/103	86/ 87	51/ 52	18/ 18	7/ 8	287/291
	(%)	(95.65%)	(100.0%)	(98.85%)	(98.08%)	(100.0%)	(87.50%)	(98.63%)

TABLE 36

Key Effectiveness Outcomes at Month 6 Stratified by Baseline Cylinder

		0.00 TO 0.49D	0.50 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	CUM TOTAL
EFFICACY VARIABLES						
MRSE ± 0.50 D	n/N	111/144	65/ 99	20/ 38	4/ 10	200/291
	(%)	(77.08%)	(65.66%)	(52.63%)	(40.00%)	(68.73%)
MRSE ± 1.00 D	n/N	137/144	92/ 99	36/ 38	7/ 10	272/291
	(%)	(95.14%)	(92.93%)	(94.74%)	(70.00%)	(93.47%)
MRSE ± 2.00 D	n/N	143/144	99/ 99	38/ 38	10/ 10	290/291
	(%)	(99.31%)	(100.0%)	(100.0%)	(100.0%)	(99.66%)
UCVA 20/20 or better	n/N	100/144	54/ 99	19/ 38	1/ 10	174/291
	(%)	(69.44%)	(54.55%)	(50.00%)	(10.00%)	(59.79%)
UCVA 20/40 or better	n/N	142/144	98/ 99	38/ 38	9/ 10	287/291
	(%)	(98.61%)	(98.99%)	(100.0%)	(90.00%)	(98.63%)

Eyes treated for spherical hyperopia or hyperopic astigmatism that have a baseline spherical component of manifest refraction of +5.00 D or less, a baseline spherical component of manifest refraction of +2.00 D or less, and an MRSE of +5.00 D or less show good efficacy and support the indicated range of approval.

7.4.2 Key Safety Variables

The safety analyses were based on 291 eyes that were available for analysis at 6 months postoperatively. A summary of key safety variables is provided below in Table Tables 37, 38, and 39 for all eyes treated in the cohort and the individual cohorts and are stratified by baseline manifest refraction spherical equivalent in Table 40.

TABLE 37

Summary of Key Safety Variables for All Eyes Treated

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
SAFETY VARIABLES							
Loss of 2 or more lines (≥10 letters) BSCVA	n/N	12/293	2/291	4/290	10/291	11/287	4/279
	(%)	(4.10%)	(0.69%)	(1.38%)	(3.44%)	(3.83%)	(1.43%)
BSCVA worse than 20/40	n/N	0/293	0/291	0/290	0/291	0/287	0/279
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Increase > 2D cylinder	n/N	0/293	1/291	1/291	1/291	2/287	1/279
	(%)	(0.00%)	(0.34%)	(0.34%)	(0.34%)	(0.70%)	(0.36%)
BSCVA worse than 20/25 if 20/20 or better preop	n/N	3/270	0/268	1/267	1/268	3/265	3/257
	(%)	(1.11%)	(0.00%)	(0.37%)	(0.37%)	(1.13%)	1.17%)

TABLE 38

Summary of Key Safety Variables for Eyes Treated for Spherical Hyperopia

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
SAFETY VARIABLES							
Loss of 2 or more lines (≥10 letters) BSCVA	n/N	5/144	1/142	2/143	6/144	6/143	3/137
	(%)	(3.47%)	(0.70%)	(1.40%)	(4.17%)	(4.20%)	(2.19%)
BSCVA worse than 20/40	n/N	0/144	0/142	0/143	0/144	0/143	0/137
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Increase > 2D cylinder	n/N	0/144	1/142	1/144	1/144	2/143	1/137
	(%)	(0.00%)	(0.70%)	(0.69%)	(0.69%)	(1.40%)	(0.73%)
BSCVA worse than 20/25 if 20/20 or better preop	n/N	1/141	0/139	1/140	1/141	2/140	2/134
	(%)	(0.71%)	(0.00%)	(0.71%)	(0.71%)	(1.43%)	(1.49%)

TABLE 39

Summary of Key Safety Variables for Eyes Treated for Hyperopic Astigmatism

		WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
SAFETY VARIABLES							
Loss of 2 or more lines (≥10 letters) BSCVA	n/N	7/149	1/149	2/147	4/147	5/144	1/142
	(%)	(4.70%)	(0.67%)	(1.36%)	(2.72%)	(3.47%)	(0.70%)
BSCVA worse than 20/40	n/N	0/149	0/149	0/147	0/147	0/144	0/142
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Increase > 2D cylinder	n/N	0/149	0/149	0/147	0/147	0/144	0/142
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
BSCVA worse than 20/25 if 20/20 or better preop	n/N	2/129	0/129	0/127	0/127	1/125	1/123
	(%)	(1.55%)	(0.00%)	(0.00%)	(0.00%)	(0.80%)	(0.81%)

TABLE 40

Key Safety Outcomes at Month 6 Stratified by Baseline MRSE

MRSE (Diopters)		0.00 TO 1.00D	1.01 TO 2.00D	2.01 TO 3.00D	3.01 TO 4.00D	4.01 TO 5.00D	>5.00D	CUM TOTAL
EFFICACY VARIABLES								
Loss of 2 or more lines (≥10 letters) BSCVA	n/N	0/3	1/57	1/46	4/28	0/8	0/2	6/144
	(%)	(0.00%)	(1.75%)	(2.17%)	(14.29%)	(0.00%)	(0.00%)	(4.17%)
BSCVA worse than 20/40	n/N	0/3	0/57	0/46	0/28	0/8	0/2	0/144
	(%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)
Increase > 2D cylinder	n/N	0/3	0/57	0/46	1/28	0/8	0/2	1/144
	(%)	(0.00%)	(0.00%)	(0.00%)	(3.57%)	(0.00%)	(0.00%)	(0.69%)
BSCVA worse than 20/25 if 20/20 or better preop	n/N	0/3	0/56	0/44	1/28	0/8	0/2	1/141
	(%)	(0.00%)	(0.00%)	(0.00%)	(3.57%)	(0.00%)	(0.00%)	(0.71%)

Very little loss of BSCVA occurred in the majority of eyes treated in the study, with 1% or less of the eyes at any postoperative exam reporting a BSCVA worse than 20/25 if the preoperative BSCVA was 20/20 or better. The incidence of new reports of loss of 2 or more lines (≥10 letters) of BSCVA was 1.4% at Month 3, 2.4% at Month 6, 2.1% at Month 9, and 0.7% at Month 12. The overall cumulative rate was 6.5% (19/293 eyes) for the cohort, of which 1.4% (4/293 eyes) had a persistent loss of at least 2 lines (10 letters) of BSCVA; last visit BSCVA was 20/20 for 1 eye, 20/32 for 2 eyes, and 20/40 for 1 eye that had a concomitant posterior subcapsular cataract that diminished the BSCVA.

7.5 Retreatments

No retreatments were performed during the study; therefore, there are insufficient data to determine the safety or effectiveness of performing LASIK retreatments on eyes that were originally treated for spherical hyperopia or hyperopic astigmatism.

8.0 CONFORMANCE TO STANDARDS

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

9.0 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), 200 Hz eye tracker, laser goggles, calibration unit and plates, cylinder stand (large, small), and buffer tube: 5m (for outside cylinder).

10.0 OPERATOR'S MANUAL

The Operator's Manual (Document Part Number: 16008-P9M2A 10.06) is supplied separately.

Patient Information Booklet

Important Information About: LASIK Treatment for Farsightedness (Hyperopia) using the Nidek EC-5000 Excimer Laser System

Surgical Laser Treatment for Vision Correction of Farsightedness (Hyperopia) from +0.5 to +5.0 D of sphere with or without astigmatic refractive errors from +0.5 to +2.0 D with manifest refraction spherical equivalent (MRSE) of +5.0 D or less

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.

Ask your doctor about certain limitations in the range of correction. You may not qualify for treatment with certain amounts of farsightedness or astigmatism.

Distributed by:
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Document Number: 16008-P812A 10.06

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1 INTRODUCTION

Please read this booklet if you are thinking about having a type of laser eye surgery, called Laser in situ Keratomileusis' (LASIK) to correct your vision for farsightedness (hyperopia) with or without astigmatism. Other ways to correct hyperopia and astigmatism include glasses, contact lenses, and other kinds of vision correction surgery such as photorefractive keratectomy (PRK) and conductive keratoplasty (CK).

This booklet is intended to help you decide how to correct your farsightedness. Please read this booklet completely. Discuss your questions with your doctor to decide if LASIK is the right choice for you. Only a trained and certified doctor can determine whether or not you are a suitable candidate for LASIK.

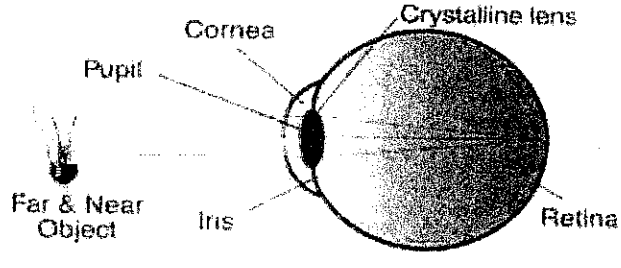
The goal of LASIK is to reduce your need for glasses or contact lenses by changing the shape of your cornea. However, LASIK does not always correct your vision perfectly. The laser may undercorrect or overcorrect your vision so that you still need glasses to see clearly. In some cases LASIK can make your vision permanently worse, so that you cannot even see clearly with glasses.

Both of your eyes may need correction. It is up to you and your doctor to decide if it is best for you to have surgery on both of your eyes or only on one.

2 HOW THE EYE WORKS

The cornea and lens of the eye work like a camera lens to form an image on the retina at the back of the eye. The sharpness of that image depends on the overall shape and size of your eye, the shape of the cornea, and the lens inside your eye.

When light enters the eye, it passes first through the cornea, then the pupil, then through the lens, and finally to the retina, as shown in the drawing below. The cornea and the lens bend the light rays so that they focus, or come together at a single point on the retina.

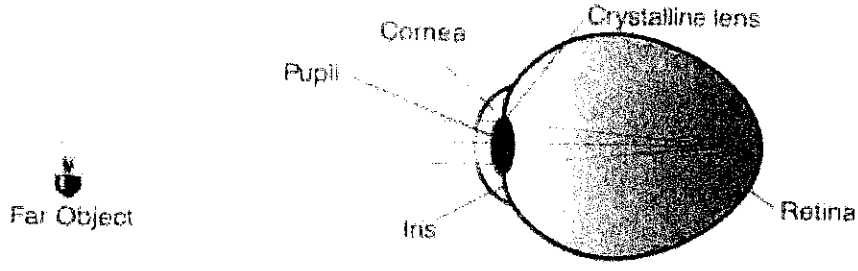


Normal Vision

When the light rays focus either in front or in back of the retina, the pictures that are formed on the retina are blurred and you are said to have a refractive error. Refractive

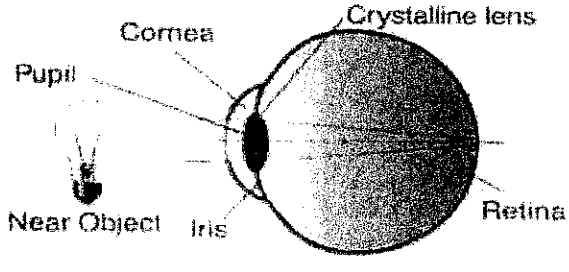
errors are common in people around the world. The three main types of refractive errors are nearsightedness (myopia), farsightedness (hyperopia), and astigmatism.

Nearsightedness occurs when the eye is too long. Nearsighted eyes can see clearly close up but distant objects look blurred because the images are focused in front of the retina. Nearsightedness can be corrected by glasses or contact lenses that move the image back onto the retina. Refractive surgery with a laser can also correct nearsightedness by removing tissue from the center of the cornea. This makes the cornea flatter so that the picture is in focus on the retina instead of in front of the retina.



Nearsightedness (Myopia)

Farsightedness is the opposite of nearsightedness. The eye is too short and images are in focus behind the retina. Eyes that are farsighted have more difficulty seeing near objects than far away objects. The eye has the ability to adjust the shape of its lens to bring nearby objects into focus. This ability is called accommodation. How well the eye can accommodate, or adjust its focus from far to near objects also affects how well the farsighted eye can see far objects as well as near objects. Like nearsightedness, farsightedness can be corrected with glasses, contact lenses or laser surgery that moves the image to the retina. Laser surgery for the treatment of farsightedness removes more tissue in the outer edges of the cornea to make the cornea more curved so that images are in focus on the retina instead of behind the retina.

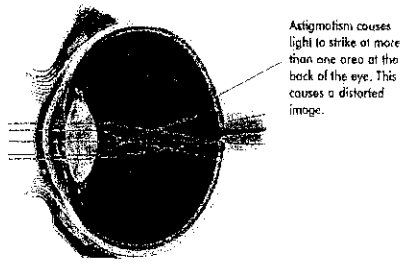


Farsightedness (Hyperopia)

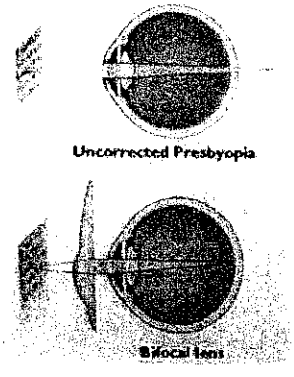
An eye has astigmatism when the cornea is more curved in one direction than another. Some light rays focus in front of the retina and others focus behind it. Since the light rays are not all bent to a single point, the picture that is created on the retina is distorted

or fuzzy. Glasses, contact lenses, and laser surgery each use a cylinder shaped correction that is tilted at an angle to match the angle at which the cornea is curved the least. With the correction, the images focus onto the retina in a single point instead of in scattered points.

ASTIGMATISM



Presbyopia is a naturally occurring change in vision that happens as you age. After you reach the age of 40, the lens in the eye gradually becomes less elastic and begins to lose its ability to accommodate or change its focusing power from far to near objects. As a result, you may begin to have problems seeing objects that are near to you or reading small print at your normal reading distance as you grow older. Presbyopia can occur along with nearsightedness, farsightedness, and astigmatism. There is presently no treatment available that can restore accommodation in patients with presbyopia. However, presbyopia can be corrected by wearing reading glasses whenever you need to see objects that are close or to read or by wearing bifocal glasses or contact lenses that have additional correction placed in the lower segment of the glasses or contact lenses that you look through for reading or seeing near objects as shown in the diagram below.



The type of laser surgery you need depends on the type of refractive error your eye has. Your doctor detects whether you are nearsighted, farsighted, or have astigmatism by determining where the light rays focus on your retina during a regular eye examination. This is done by adjusting your vision with different lenses until the image you see is correctly focused on the retina. This procedure (called a manifest refraction) is used to determine whether you have nearsightedness, farsightedness, or astigmatism and the amount of each refractive error that is present in the eye. The amount of refractive error present in the eye is measured in units called "diopters." In North America, about 25% of the population is nearsighted and about 10% is farsighted.

It is important for you to understand that refractive surgery cannot be undone or easily changed if your vision changes or if the first surgery is not successful. 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. Nearsightedness, farsightedness, and astigmatism can range from very mild to very strong. The range of treatment with the Nidek EC-5000 Excimer Laser System to correct myopia or hyperopia with or without astigmatism covers a large part of that range. Whether you can have LASIK surgery will depend on the type and amount of refractive error that you have as well as other important information about your eyes.

3 WHAT IS LASIK?

LASIK is laser surgery to reshape the cornea to correct near-sightedness (myopia) with or without astigmatism or farsightedness (hyperopia) with or without astigmatism. The laser fires a stream of up to 40 pulses of ultraviolet light per second. Each pulse lasts only a few billionths of a second. Each pulse removes a tiny amount of tissue by evaporating it. The pulses are placed in a pattern that makes the cornea either flatter (nearsightedness) or steeper (farsightedness). Excimer laser light does not penetrate the eye and does not harm the iris, lens, or retina. The laser produces very little heat and is controlled by the doctor during the operation.

Before starting the LASIK procedure, your doctor will place numbing drops on your eye to numb it. Your doctor will then cut a thin flap on the front of the cornea using a microkeratome or another laser designed to cut the flap. The doctor will then fold back this flap and expose the middle layer of the cornea where the laser treatment is performed. This part of the procedure usually takes a couple of minutes. The doctor then performs the LASIK procedure.

The laser treatment usually lasts about 15-40 seconds, depending on the type and amount of correction. During the procedure, you will be asked to look steadily at a light so that your eye does not move. After the laser treatment is complete, the doctor will fold the flap of cornea tissue back into place to complete the procedure.

This procedure is performed on one eye at a time. If all goes well with the first eye and you are having your second eye treated, the second eye may be treated on the same day or on a different day.

4 What Can LASIK Surgery with the Nidek EC-5000 Laser System for Farsightedness Correct?

LASIK surgery with the Nidek EC-5000 Excimer Laser System can correct from +0.5 to +5.0 D of farsightedness with or without astigmatic refractive errors from +0.5 to +2.0 D with manifest refraction spherical equivalent (MRSE) of +5.0 D or less. MRSE is a way of calculating how much farsightedness and astigmatism together that your eye has. If you have farsightedness within this range, LASIK treatment with the EC-5000 may help you see objects that are far away more clearly without eyeglasses or contact lenses. The treatment may also help you see objects that are up close or improve your ability to read.

5 Clinical Study to Evaluate the Benefits of LASIK Treatment for Farsightedness

A clinical study was conducted to determine the benefits and risks of treating farsightedness with or without astigmatism with the Nidek EC-5000 Excimer Laser System. In the study, 149 eyes were treated for farsightedness with astigmatism and 144 eyes were treated only for farsightedness. A total of 148 patients were enrolled and all but 3 patients had both eyes treated in the study. The study was conducted at six centers in the United States and one center in Mexico. Patients enrolled in the study were treated between December 2003 and December 2004. This booklet reports the outcomes for these patients through 1 year after they had LASIK surgery. Each of the tables lists the total number of eyes (N) that are included in each analysis, the number of eyes (n) out of the total number of eyes included in the analysis (n/N) that have the outcome that is reported, and the percentage (%) of eyes that have each outcome reported.

Demographics

Table 1 presents the demographic information for the 148 patients enrolled in the study. Of these, 32% were male and 68% were female. Racial distribution consisted of 70% Caucasian, 28% Hispanic, 1% Black, and 1% Asian. The average age of all the patients was 49.5 years. The youngest patient was 23 years old and the oldest was 69.

TABLE 1 Clinical Study Patient Demographic Characteristics	
	% (n/N)
GENDER	
Male	32% (48/148)
Female	68% (100/148
RACE	
Caucasian	70% (103/148)
Black	1% (2/148)
Asian	1% (2/148)
Hispanic	28% (42/148)
AGE	
Average	49.5 years
Standard Deviation	±8.9 years
Minimum	23 years
Maximum	69 years

Vision Without Glasses After Treatment

A letter chart was used to measure how well patients in the study could see **without** the use of glasses or contact lens before and after the LASIK surgery. As shown in Table 2 below, at 1 month after the LASIK surgery 60% of the eyes could see 20/20 or better **without** any type of glasses or contact lenses and 99% of the eyes could see 20/40 or better. Most states require that you see at least 20/40 or better to obtain a driver's license without wearing glasses or contact lenses.

TABLE 2 Vision Without Glasses						
	PREOP	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
20/20 or better	6%	60%	56%	60%	61%	61%
20/25 or better	9%	84%	85%	86%	83%	82%
20/32 or better	15%	95%	96%	95%	95%	95%
20/40 or better	21%	99%	98%	99%	99%	99%

Vision Without Glasses After Treatment Compared to Vision With Glasses Before Treatment

Table 3 compares how well patients were seeing **without** any glasses or contact lenses after their LASIK surgery compared to how well they were seeing **with** glasses or contact lenses before they had LASIK surgery. *At all post-op visits from 1 month onward, 75-79% of treated eyes had vision without glasses that was within 1 line of their vision with glasses or contact lenses before LASIK, and 20-24% of eyes had vision without glasses that was at least 2 lines worse than their vision with glasses or contact lenses before surgery.* At 12 months, 80% of the patients were seeing nearly as well (within 1 line or better) **without** glasses after the surgery as they did with their glasses before the surgery.

TABLE 3
Vision Without Glasses after LASIK compared to Vision With Glasses Before LASIK

	WEEK 1	MONTH 1	MONTH 3	MONTH 6	MONTH 9	MONTH 12
	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
Vision **without** glasses after LASIK ≥ 2 lines (≥10 letters) better than vision **with** glasses before LASIK	2% (5/293)	3% (9/291)	1% (3/291)	1% (3/291)	1% (4/287)	1% (3/279)
Vision **without** glasses after LASIK within 1 line (5 letters) of vision **with** glasses before LASIK	70% (205/293)	77% (224/291)	78% (227/291)	75% (219/291)	75% (214/287)	79% (220/279)
Vision **without** glasses after LASIK ≥ 2 lines (≥10 letters) worse than vision **with** glasses before LASIK	28% (83/293)	20% (58/291)	21% (61/291)	24% (69/291)	24% (69/287)	20% (56/279)

Changes in Quality of Vision Without Glasses After Treatment Compared to Vision With Glasses Before Treatment

Patients were asked to rate their visual symptoms before their LASIK surgery when using their glasses or contact lenses and after their LASIK surgery without using their glasses or contact lenses. Clinically significant changes in a symptom were considered to have occurred when there was a 10% or greater proportion of subjects that reported an improvement or worsening of a symptom. Using this criterion, there was a clinically significant improvement in night driving (12.4%) and difficulty reading (25.1%), and clinically significant worsening in dryness after LASIK (13.7%), as well as worsening of reading difficulty (10.3%), although this is offset by the number of patients with an improvement in their ability to read (25.1%).

TABLE 4 Change in Subjective Complaints between Baseline and 6 Months			
Symptom	Better than Baseline (2 or more grade change) % (n/N)	No Change from Baseline (0-1 grade change) % (n/N)	Worse than Baseline (2 or more grade change) % (n/N)
LIGHT SENSITIVITY	7.9% (23/291)	89.3% (260/291)	2.7% (8/291)
DIFFICULT NIGHT DRIVING	12.4% (36/291)	85.2% (248/291)	2.4% (7/291)
DIFFICULTY READING	25.1% (73/291)	63.0% (186/291)	10.3% (30/291)
DOUBLE VISION	0.7% (2/291)	97.3% (283/291)	2.1% (6/291)
FLUCTUATION IN VISION	1.4% (4/291)	92.1% (268/291)	6.5% (19/291)
GLARE	8.6% (25/291)	90.0% (262/291)	1.4% (4/291)
HALOS	3.4% (10/291)	93.1% (271/291)	3.4% (10/291)
STARBURSTS	2.1% (6/291)	95.9% (279/291)	2.1% (6/291)
DRYNESS	2.7% (8/291)	83.5% (243/291)	13.7% (40/291)
PAIN	0.3% (1/291)	99.7% (290/291)	0% (0/291)
FOREIGN BODY	0.3% (1/291)	97.6% (284/291)	2.1% (6/291)

6 RISKS OF LASIK TREATMENT FOR FARSIGHTEDNESS

LASIK is a laser surgical procedure involving your eyes and, like any surgical procedure, there are potentially serious risks. Your vision may not be perfect after LASIK surgery and you may need to have additional laser treatment in the same eye. You should consider these risks carefully and discuss them with your doctor before you decide to have LASIK surgery. You should also talk with your doctor about whether it would be better for you to have LASIK surgery in both of your eyes or only one eye.

The risks listed here are based on clinical experience with LASIK cases and the concerns that doctors believe should be considered for this kind of eye surgery. Some risks are related to the corneal flap and not to the laser treatment itself. Possible corneal flap complications could include, but are not limited to:

- Cutting an incomplete flap, irregularly shaped flap, or a flap that is completely free of the cornea;
- Not properly aligning the flap when it is replaced; or,
- Perforating the cornea during the flap cutting procedure.

Other possible corneal flap complications may not be listed here. If a flap complication occurs, you may need to postpone your LASIK surgery until the flap heals. A flap complication may also result in a corneal irregularity that permanently blurs your vision and prevents you from having LASIK surgery.

IMPORTANT

You may need reading glasses after LASIK surgery even if you did not wear them before the surgery. You may not have perfect vision after the surgery. You may need to wear glasses or contact lenses for some activities after the laser surgery or you may need to have additional laser surgery to correct your vision.

Contraindications

You should not have LASIK surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS). These conditions may result in scarring or poor healing after LASIK treatment resulting in reduced vision.
- You are pregnant or nursing. These conditions may affect your preoperative refraction, making it difficult to choose the correct amount of LASIK treatment.
- You show signs of thinning of the cornea (keratoconus). This condition can lead to serious cornea problems that require additional surgical repair and result in poor vision.
- You are taking the following medications: isotretinoin (Accutane®) or amiodarone hydrochloride (Cordaron®). These may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- Your cornea is too thin to allow your doctor to properly cut a corneal flap. LASIK cannot be performed unless a corneal flap is created. You may be able to have other types of refractive surgery that do not require a corneal flap to perform the procedure.

Warnings

Discuss with your doctor if:

- You have diabetes or connective tissue disease. These conditions may also involve your eyes. Eyes that have vision problems from these diseases may affect the accuracy of your refractive results.
- You have been diagnosed with ocular Herpes simplex or ocular Herpes zoster. Herpes are viral infections. Laser treatment may reactivate the infection.

You may have LASIK surgery if your doctor evaluates the severity of your condition and you and your doctor both agree that the benefit of having LASIK surgery is greater than the risk.

You should also be aware that your results may not be as good as those reported in the clinical study if you have more severe farsightedness or astigmatism.

Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser were NOT evaluated in the farsightedness clinical study for the following conditions or situations. Therefore, the safety and effectiveness of performing LASIK is unknown if you have any of these conditions or situations:

- Your vision has changed in the past year. Treatment of unstable vision may affect the accuracy of your refractive results.
- Your eyes have large pupils (> 8mm diameter) in dim or dark light. You may have more problems driving at night if you have large pupils at night and you have LASIK surgery on your eyes.
- You have had other eye problems that could cause problems after the LASIK surgery, such as corneal ulcers, other surgery, scars, or injury to the area of cornea where LASIK will be performed. These types of problems can cause the surface of the cornea to be irregular and may affect the accuracy of your refractive results.
- You are taking medications that affect corneal healing or your vision, such as steroids, antimetabolites, and sumatriptan hydrochloride (Imitrex®). You should discuss all medications you take, even over-the-counter medications, with your eye doctor. Many medications can affect the way your cornea is changed by the laser and the way it heals after LASIK treatment. These may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- You have severe allergies. Your medications may have to change before or after your eye surgery. These medications may change the wetness (moisture level) in your eye. If the medication changes the wetness of your eye, the accuracy of your refractive results may be affected.
- You have dry eyes that were not detected before you decided to have surgery or dry eyes that have not responded to treatment. Your doctor should evaluate you for dry eyes before surgery. Eye dryness may affect the accuracy of your refractive results and your comfort after the surgery may be affected. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery
- You have other eye diseases, such as glaucoma, high pressure in the eye, or diseases of the retina, that could cause you to have complications during or after the surgery.
- 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. The accuracy of your refractive results will be affected if you can not keep your eyes still during treatment.
- Patients under 21 years of age.

If you have any of these conditions or situations, you may have LASIK surgery if your doctor evaluates the severity of your condition or situation and you and your doctor both agree that the benefit of having LASIK surgery is greater than the risk.

Although the effects of LASIK 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 (over 6 mm). These effects may be permanent.

Clinical Study to Evaluate Risks

The clinical study evaluated the safety of using the EC-5000 Excimer Laser System for the treatment of farsightedness with or without astigmatism.

Vision With Glasses Before and After Treatment

Table 5 compares how well patients could see with glasses or contact lenses before and after their LASIK surgery. At 12 months, 27% of the patients saw 1 or 2 lines better with glasses than they did with glasses or contact lenses before surgery and more than half (57%) saw the same. One eye lost more than 2 lines (10 letters on the eye chart) of best corrected vision beginning at 6 months, but this reduction in vision was due to the development of a cataract that was not related to the LASIK surgery.

TABLE 5
Vision with Glasses After Treatment Compared to Before Treatment

	1 WEEK	1 MONTH	3 MONTHS	6 MONTHS	9 MONTHS	12 MONTHS
More than 2 Lines Worse	0%	0%	0%	<1%	<1%	<1%
2 Lines Worse	4%	<1%	1%	3%	3%	<1%
1 line Worse	23%	16%	16%	18%	17%	15%
Same Before and After	54%	57%	57%	53%	58%	57%
1 Line Better	16%	22%	21%	23%	19%	26%
2 lines Better	1%	3%	4%	2%	2%	1%
More than 2 lines Better	1%	1%	1%	0%	0%	0%

[NOTE: One line of vision is equal to seeing 5 letters and 2 lines of vision is equal to seeing 10 letters on the eye chart that is used to measure your vision.]

Adverse Events and Complications

Some patients in the clinical study experienced adverse events or complications during the LASIK surgery procedure or after the LASIK treatment. These are listed in Table 6 below.

TABLE 6
Adverse Events and Complications

	Day of Surgery	Less than 1 Month	1 Month	3 Months	6 Months	9 Months	12 Months
Swelling of cornea		<1%	0%				
Defect in edge of flap	0%	0%	0%	<1%	0%	0%	0%
Cells growing under the flap	<1%	0%	0%	<1%	0.0%	0.0%	<1%
Feeling of something in the eye			1%	0%	0%	<1%	0.0
Pain in the eye			1.4%	0%	0%	0%	0%
Ghost or double images	0%	0%	0.7%	0%	0%	0%	0%
Microkeratome created irregular flap	<1%						
Inflammation of the cornea		4%	<1%	<1%	0%	0%	0%
Dry eyes requiring artificial tears			3%	<1%	1%	0%	0%
Vision with glasses is 2 or more lines worse than before treatment				1%	2%	2%	<1%

Patient Symptoms after Farsighted LASIK Treatment Without Glasses Compared to Before LASIK Treatment With Glasses or Contact Lenses

Patients were asked to rate the following visual symptoms before and after the LASIK treatment. The occurrence of symptoms that were rated as none, mild, moderate, marked, or severe are presented in Table 7. Patient reports of light sensitivity, glare, night driving problems, and difficulty reading all improved after the LASIK treatment. Reports of dryness worsened after LASIK. Fluctuation in vision (changes throughout the day) and foreign body sensation (feeling of something in your eye) also worsened, which is expected since these symptoms commonly occur as a result of the eye dryness. Patients were not asked to rate their satisfaction with the LASIK surgery, nor did they record their use of glasses or contact lenses after the LASIK surgery, therefore, these outcomes were, not evaluated in the clinical study.

TABLE 7 Visual Symptoms Before and After LASIK						
QUESTION	VISIT	NONE	MILD	MODERATE	MARKED	SEVERE
LIGHT SENSITIVITY	SCREENING	71%	20%	6%	2%	1%
	POSTOP MONTH 6	73%	23%	3%	1%	0%
	POSTOP MONTH 12	79%	14%	5%	1%	1%
DIFFICULTY NIGHT DRIVING	SCREENING	68%	19%	9%	2%	1%
	POSTOP MONTH 6	84%	13%	3%	0%	9%
	POSTOP MONTH 12	80%	14%	5%	1%	0%
DIFFICULTY READING	SCREENING	50%	18%	21%	8%	3%
	POSTOP MONTH 6	53%	30%	10%	6%	1%
	POSTOP MONTH 12	47%	32%	14%	6%	1%
DOUBLE VISION	SCREENING	97%	2%	0%	0%	0%
	POSTOP MONTH 6	96%	2%	2%	0%	0%
	POSTOP MONTH 12	92%	7%	1%	0%	0%
FLUCTUATION IN VISION	SCREENING	87%	11%	2%	0%	0%
	POSTOP MONTH 6	64%	29%	5%	2%	0%
	POSTOP MONTH 12	74%	21%	4%	0%	1%
GLARE	SCREENING	79%	12%	6%	2%	1%
	POSTOP MONTH 6	78%	20%	2%	0%	0%
	POSTOP MONTH 12	80%	13%	5%	1%	0%
HALOS	SCREENING	88%	8%	3%	1%	1%
	POSTOP MONTH 6	81%	14%	3%	1%	0%
	POSTOP MONTH 12	84%	11%	4%	1%	0%
STARBURSTS	SCREENING	92%	5%	2%	1%	0%
	POSTOP MONTH 6	84%	14%	2%	0%	0%
	POSTOP MONTH 12	88%	8%	4%	0%	0%
DRYNESS[1]	SCREENING	76%	19%	3%	1%	1%
	POSTOP MONTH 1	32%	44%	21%	2%	1%
	POSTOP MONTH 6	46%	38%	12%	3%	1%
	POSTOP MONTH 12	55%	33%	7%	3%	1%
PAIN	SCREENING	99%	1%	0%	0%	0%
	POSTOP MONTH 6	95%	5%	0%	0%	0%
	POSTOP MONTH 12	97%	1%	1%	0%	0%
FOREIGN BODY	SCREENING	95%	5%	0%	0%	0%
	POSTOP MONTH 6	82%	16%	2%	0%	0%
	POSTOP MONTH 12	84%	12%	3%	1%	0%

[1] Clinically significant increase (≥ 10%) in the proportion of eyes reporting moderate to severe dry eye symptoms at 1 Month (24%) and 6 Months (16%) compared to baseline (5%).

Accuracy of the Farsighted LASIK Treatment

With LASIK surgery, there is a risk that your vision will be corrected either too much or not enough. In the clinical study at 6 months after the LASIK surgery, 69% of all the eyes treated were within ± 0.5 D and 94% of the eyes were within ± 1.0 D of the attempted treatment. In the individual groups, 95% of the eyes treated for farsightedness only and 92% of the eyes treated for farsightedness with astigmatism achieved vision within ±1.0 D of the attempted refraction. Eyes with this amount of remaining farsightedness can usually still see well enough to pass a driver's license test without correction. None of the eyes (0%) in the study had 2.0 D of farsightedness with or without astigmatism remaining after the LASIK surgery (undercorrected) and only one eye (<1%) was corrected by more than 2.0 D MRSE too much (overcorrected) at 6 months postoperatively. The subject with the overcorrected eye developed cataracts in both eyes, which became noticeable at the 6 month examination. Obtaining a reliable and accurate manifest refraction was difficult in this subject because of the cataracts.

The amount of farsightedness correction that was obtained at 6 months after the LASIK surgery is shown in Table 8 below for the different amounts of farsightedness that was treated in the study. At 6 months, the LASIK surgery corrected 91% of the farsightedness that was present before the surgery. The amount of correction achieved was better in those eyes that had more farsightedness before surgery (96.9% to 105.5% in those eyes with more than 2 diopters of farsightedness compared to 87.4% to 54.3% in those eyes with 2 diopters or less of farsightedness).

TABLE 8
Amount of Farsightedness Before LASIK Compared to the Amount of Farsightedness 6 Months after LASIK

Farsightedness Group Before Surgery	0 – 1.0 D	>1.0 – 2.0 D	>2.0 – 3.0 D	>3.0 – 4.0 D	>4.0 – 5.0 D	>5.0D	Total
Eyes in each Farsightedness Group % (n/N)	8% 23/291	35% 103/291	30% 87/291	18% 52/291	6% 18/291	3% 8/291	100% 291/291
Average Amount of Farsightedness Before Surgery	0.75	1.50	2.43	3.37	4.53	5.5	2.35
Average Amount of Farsightedness at 6 Months After Surgery (Range)	0.30 (-1.00 – 0.75)	0.15 (-0.75 – .25)	0.03 (-2.25 – .50)	-0.13 (-3.25 – 1.25)	0.14 (-0.75 – 1.50)	-0.3 (-2.00 – .75)	0.06 (-3.25-1.50)
Average Percent Reduction in the Amount of Farsightedness at 6 Months (Range)	54.3% (-50.0 – 33.3)	87.4% (0.0 – 144.4)	96.9% (29.4 – 178.3)	101.5 (61.5 – 186.7)	98.4 (63.6 – 115.5)	105.5 (86.7 – 138.3)	91.2 (-50.0 – 233.3)

As shown in Table 9 below, the eyes treated for farsightedness with astigmatism that had smaller amounts of astigmatism (-1 D or less) before LASIK had an average of slightly more than half (51.1%) of the astigmatism treated at 6 months after the surgery. Those eyes that had larger amounts of astigmatism (>-1D to -2D) had about two-thirds (64%) of the astigmatism treated at 6 months after LASIK.

TABLE 9 Astigmatism Before LASIK Compared to the Amount of Astigmatism 6 Months after LASIK			
Astigmatism Group Before Surgery	0.5 – 1.0 D	>1.0 – 2.0 D	Total Range
Eyes in each Astigmatism Group % (n/N)	72% 99/137	28% 38/137	100% 137/137
Average Amount of Astigmatism Before Surgery	0.67 (0.50 – 1.00)	1.35 (1.125 – 1.875)	0.85 (0.50 – 1.875)
Average Amount of Astigmatism at 6 Months After Surgery (Range)	0.32 (0.0 – 1.25)	0.46 (0.0 – 1.50)	0.36 (0.0 – 1.50)
Average Percent Reduction in the Amount of Astigmatism at 6 Months (Range)	51.1% (-150% - 100%)	64.0% (-20% - 100%)	54.7% (-150% - 100%)

A patient with an eye that still has some farsightedness or astigmatism after the LASIK surgery may wish to have a second LASIK surgery, or retreatment, to improve the vision in that eye. None of the patients in the clinical study had a retreatment. The safety and effectiveness of retreatments is therefore unknown.

7 ARE YOU A GOOD CANDIDATE FOR FARSIGHTEDNESS LASIK SURGERY?

If you are considering having LASIK treatment for your farsightedness with or without astigmatism performed with the Nidek EC-5000 laser, you must:

- Be at least 21 years of age and have farsightedness with or without astigmatism
- Have healthy eyes that have no eye disease or defects or problems with the cornea (e.g., scars, infection, thin cornea, etc.)
- Have documentation of your eye correction history that show your vision has been stable for the past year before you have your preoperative examination. Stable vision is considered to be a change in manifest refraction spherical equivalent (MRSE) not greater than ±0.5 D in your required glasses or contact lens correction during the past year.
- Understand the risks and benefits of LASIK treatment for your farsightedness with or without astigmatism compared to other methods for correcting your vision.
- Be able to lie flat on your back without difficulty.
- Be able to gaze steadily at a light to keep your eye steady during the laser surgery.
- Be able to tolerate all of the medications (including the numbing drops) that will be used before, during, or after the LASIK surgery. If you have any allergies to any medications, please make sure you tell your doctor.
- Sign an informed consent form provided by your doctor or his/her staff that you agree to have the LASIK surgery and that you have been informed of and understand the risks and benefits of having the surgery.

8 What Can You Expect Before LASIK Surgery?

Before you have laser surgery to correct your vision, you will need to have a complete eye examination. Several tests and measurements will be performed to determine if your eyes are healthy and able to have the surgery. These tests and measurements also determine how much treatment your eyes will need to fully correct your vision. You will also be asked questions about your medical history and any medications you are taking. It is important for you to be truthful and honest with your doctor when you are answering these questions.

WARNING

If you wear contact lenses, you must stop wearing them before the screening eye examination and must leave them out of your eyes until you have the LASIK surgery. Failure to do this could cause you to have poor results from your surgery or complications from the surgery.

The time you must stop wearing contact lenses before your initial examination depends upon the type of lens. Minimum times for stopping are:

- Soft lenses 3 days
- Soft, toric (astigmatism) lenses 14 days
- Hard gas permeable lenses 4 weeks

Your doctor may ask you to stop wearing your contact lenses for a longer period of time. You will also need to come back for a second visit before the surgery or be examined on the day of surgery to confirm that your vision has stabilized since you stopped using your contact lenses.

9 What Happens During the LASIK Surgery?

You will be taken into the laser room and asked to lie on your back in a reclining chair that is located under the part of the laser that shines the laser beam. Before the surgery, numbing (anesthetic) drops will be placed into the eye to be treated. An instrument will be placed between your eyelids to hold them open. A temporary shield usually covers the eye not having surgery. Surgical draping may be placed over your face, exposing only the eye to be treated, to keep the area around the eye as clean as possible. Your doctor may briefly fire the laser onto a piece of plastic so you can hear what the laser will sound like during the treatment.

If your corneal flap is being cut with a microkeratome, a suction ring will be placed on the eye to increase the pressure in the eye. Your vision will go black temporarily as the pressure is increased. The doctor will attach the microkeratome to the suction ring and cut the corneal flap. The doctor will then release the suction and your vision should no longer be black. The doctor will adjust your head to the correct position under the laser. The doctor will then lift the flap and fold it back, much like opening a hinged cabinet

door. This exposes the middle part of the cornea where the laser treatment will be performed.

The doctor will then focus the laser microscope on this middle part of your cornea. You will be asked to look directly at a blinking light and the laser treatment will begin. It is important for you to continue looking at the blinking light during the entire surgery. 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, the laser pulses will be directed to the cornea and small amounts of tissue will be removed from your cornea.

PRECAUTION

It is very important that you keep looking at the blinking fixation light during the procedure, even if the light fades or becomes dim. The success of the treatment depends on you looking steadily at the light throughout the entire treatment.

After the laser surgery is complete, the doctor will fold the corneal flap back into place and smooth the surface. Some drops will be placed in your eye and the instrument holding your eye open and any surgical draping over your face will be removed. You will be allowed to stand up and will be taken to another area where you will wait for a short time to make sure there are no immediate problems from the surgery. Once your doctor checks your eye and determines everything is satisfactory, you will be allowed to go home. You should arrange to have someone drive you home after the surgery as driving immediately after having LASIK surgery is not recommended.

The surgery usually lasts 10 to 15 minutes from start to finish and you are only exposed to the laser beam for a minute or less. The surgery itself is painless because your eye was numbed with anesthetic drops before the start of the surgery. The numbing drops will wear off in about 30 to 60 minutes and your eye may hurt for 1 to 3 days. This is typically described as a "sandy sensation". Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. It is important that you DO NOT RUB the eye for the first 5 days after the surgery. Rubbing the eye can damage the cornea, move the corneal flap, increase the risk of infection, and delay healing of the eye. You will be given instructions for the care of your eye after the surgery. It is important that you (and a family member) understand these instructions before you leave the surgery clinic.

10 What Can You Expect After LASIK Surgery

The information below is provided to help you understand what to expect after you have LASIK surgery performed on one or both of your eyes. Sunglasses may make you more comfortable during the first few days after the surgery. Your doctor may give you a shield to place over your eye while you are sleeping to protect your eye from accidental injury. You doctor may give you drops to use in your eyes after the surgery. It is important to use them as directed to promote healing and lessen the risk of infection in the treated eye.

IMPORTANT

Use the lubricant (moistening) eyedrops and any prescribed eye medications (anti-inflammatory, antibiotic eyedrops) as directed by your doctor. Your results depend upon you following your doctor's instructions.

The first week following surgery:

The following symptoms have been reported up to several weeks following LASIK treatment. Except for the symptoms related to flap complications, they are associated with the normal healing process after treatment and include:

- Discomfort (including mild to moderate pain, pressure, scratchiness, burning sensation, and dryness) may last for 1 to 3 days after surgery, for which your eye doctor can provide medications.
- The feeling that something is in your eye.
- Swelling of the cornea.
- A problem with healing of the corneal flap, including damage to the flap, loss or misalignment of the flap, or growth of cornea surface cells under the flap. If needed, the doctor may lift the flap to clean the inner layer of the cornea and reposition the flap to improve healing.
- Blurred vision and tearing or watery eyes may occur as the cornea and the flap heal.
- Sensitivity to bright lights.

The first one to six months following surgery:

The following symptoms may occur during the first six months after LASIK surgery while your eye continues to heal:

- Eye dryness, which may be accompanied by a fluctuation in your vision or a feeling that something is in your eye

CAUTION

You should contact your doctor if you notice any pain, sudden change, or loss of vision in the eye. Eye pain or sudden loss of vision can indicate a serious problem that requires immediate medical attention.

11 Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if LASIK is right for you:

- What other options are available for correcting my farsightedness and astigmatism?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of farsightedness and astigmatism correction?
- What quality of vision can I expect in the first few months after surgery?
- If LASIK 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 LASIK if I need them?
- How is LASK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having LASIK surgery?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK surgery in my other eye?
- What vision problems might I have if I have LASIK surgery only on one eye?

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

12 SELF-TEST

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

1	LASIK surgery is risk free.	☐ TRUE	☐ FALSE
2	It does not matter if I wear my contact lenses when my doctor told me not to.	☐ TRUE	☐ FALSE
3	The laser does all the work, I just have to lie on the chair and close my eyes.	☐ TRUE	☐ FALSE
4	After the surgery, there is a good chance that I will be less dependent on eyeglasses.	☐ TRUE	☐ FALSE
5	I may need reading glasses after laser surgery.	☐ TRUE	☐ FALSE
6	There is a risk that I may lose some vision after laser surgery.	☐ TRUE	☐ FALSE
7	It does not matter if I am pregnant.	☐ TRUE	☐ FALSE
8	If I have an autoimmune disease, I am still a good candidate for LASIK.	☐ TRUE	☐ FALSE

Answers to SELF-TEST are found in Section 14.

13 SUMMARY OF IMPORTANT INFORMATION

- LASIK is a permanent operation to the cornea that cannot be easily changed.
- LASIK may not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before LASIK. You will need documentation that your farsightedness with or without astigmatism has changed less than 1.0 diopter over the past year.
- Pregnant and nursing women should wait until they are not pregnant and not nursing to have LASIK surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- LASIK may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- Alternatives to LASIK for the correction of farsightedness with or without astigmatism include glasses, contact lenses, and PRK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having LASIK.
- Before considering laser vision correction, you should:
    - Have a complete eye examination.
    - Talk with one or more eye care professionals about the potential benefits of laser refractive surgery and the complications, risks, and time required for healing.

14 ANSWERS TO SELF-TEST QUESTIONS

1. False (see Risks on page 11); 2. False (see Before Surgery on page 17); 3. False (see The During Surgery on page 18); 4. True (see Benefits on page 9); 5. True (see Risks on page 11); 6. True (see Risks on page 11); 7. False (see Warnings on page 12); 8. False (see Contraindications on page 11).

15 GLOSSARY

This section contains definitions of terms used in this information booklet. Please ask your doctor any questions you may have about these terms.

Accommodation: the ability of the eye to change its focus from distant objects to near objects.

Acuity: (see Visual Acuity)

Antibiotic: a drug used to treat or prevent infection. Usually administered as eye drops before and/or after refractive surgery.

Anti-Inflammatory Drug: a drug used to reduce or prevent inflammation. Usually administered as eye drops after refractive surgery.

Astigmatism: a refractive error in which the eye focuses more strongly in one orientation than another, so a beam of light focuses to two crossed lines, one in front of the other, instead of a point. For example, a hyperopic astigmatic eye might focus a horizontal line one diopter behind the retina and a vertical line three diopters behind the retina.

Cataract: an opacity or clouding of the lens inside the eye that can cause a loss of vision.

Collagen Vascular Disease: a condition that may result in inflammation of swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are systemic lupus erythematosis and rheumatoid arthritis.

Contraindication: any special condition for which the treatment is not allowed.

Cornea: the clear, front covering of the eye. The cornea is the first part of the eye that bends (or refracts) light rays and provides most of the focusing power.

Diopter: the unit of measurement of refractive power and refractive error. A negative diopter value signifies an eye with myopia and a positive diopter value signifies an eye with hyperopia.

Dry Eye Syndrome: a common condition that occurs when the eye does not produce enough tears to keep the eye moist and comfortable. Common symptoms of dry eye include pain, stinging, burning, scratchiness, and intermittent blurring of vision.

Endothelium: the inner layer of cells on the inside surface of the cornea.

Epithelium: The outermost layer of cells of the cornea and the eye's first defense against infection.

Excimer Laser: an ultraviolet light laser used in refractive surgery to remove corneal tissue.

Farsightedness: the common name for hyperopia.

FDA: the abbreviation for the Food and Drug Administration. The FDA is the United States governmental agency responsible for the evaluation and approval of medical devices.

Femtosecond Laser: a computer-controlled laser specially designed to create a corneal flap that is of precise dimensions and thickness.

Ghost Image: a fainter, displaced, second image of the object you are viewing.

Glare: scattered light in the eye that decreases vision.

Halos: rings around lights due to optical imperfections in or in front of the eyes.

Haze: corneal clouding that causes a sensation of looking through smoke or fog.

Herpes (simplex or zoster): a type of infection caused by a virus that can recur.

Hyperopia: the inability to see near objects as clearly as distant objects, and the need for accommodation to see distant objects clearly. Hyperopia occurs when the eye is too short and light rays focus behind the retina.

Immunodeficiency Disease: a condition that alters the body's ability to fight infection. An example is autoimmune deficiency disease (AIDS).

Inflammation: the body's reaction to trauma, infection, or a foreign substance, often associated with pain, heat, redness, swelling, and/or loss of function of the affected area.

Informed Consent Form: a document that describes and explains a medical or surgical treatment to prospective patients and discloses the risks, benefits, and alternatives to the treatment.

In Situ: a Latin term meaning "in place" or not removed.

Intraocular Pressure: fluid pressure inside the eye.

Iris: the colored ring of tissue behind the cornea and immediately in front of the lens.

Keratectomy: the surgical removal of corneal tissue.
Keratitis: inflammation of the cornea.

Keratoconus: a disorder characterized by an irregular corneal surface (cone-shaped), resulting in blurred and distorted images.

Keratomileusis: carving of the cornea to reshape it.

Laser: the acronym for "light amplification by stimulated emission of radiation." A laser is an instrument that produces a powerful beam of light that can evaporate tissue.

LASIK: the acronym for "laser assisted in situ keratomileusis," which refers to creating a flap in the cornea with a microkeratome or femtosecond laser and using a laser to reshape the underlying cornea.

Lens: a part of the eye that provides some focusing power. The lens is able to change shape allowing the eye to focus at different distances.

Microkeratome: a surgical device that is affixed to the eye by use of a vacuum ring. When secured, a very sharp blade cuts a layer of the cornea at a predetermined depth.

Monovision: the purposeful adjustment of one eye for near vision and the other eye for distance vision.

Myopia: the inability to see distant objects as clearly as near objects. In myopia, the eye is too long and light rays focus in front of the retina.

Nearsightedness: the common name for myopia.

Ophthalmologist: a medical doctor specializing in the diagnosis and medical or surgical treatment of visual disorders and eye disease.

Optometrist: a primary eye care provider who diagnoses, manages, and treats refractive errors and some disorders of the visual system and eye diseases.

Overcorrection: an outcome of refractive surgery where the achieved amount of correction is more than desired.

PRK: the acronym for photorefractive keratectomy, which is a procedure involving the removal of the surface layer of the cornea (epithelium) by scraping and use of a computer controlled excimer laser to reshape the cornea.

Presbyopia: a condition in which the eye has lost the ability to accommodate, or to maintain a clear image (focus) as objects are moved closer. Presbyopia is due to reduced elasticity of the lens with increasing age.

Pupil: the opening in the center of the iris that changes size to control the amount of light that enters the eye in response to changes in lighting. It gets larger in dim lighting conditions and gets smaller in brighter lighting conditions.

Refract: the bending of light as it passes from one medium into another.

Refraction: a test to determine the refractive power of the eye.

Refractive Errors: imperfections in the focusing power of the eye, for example, hyperopia, myopia, and astigmatism.

Refractive Power: the ability of an object, such as the eye, to bend light as light passes through it.

Refractive Surgeon: an ophthalmologist who specializes in performing surgery to correct refractive errors.

Regression: a decrease in the amount of vision correction that occurs over time after refractive surgery.

Retina: a layer of fine sensory tissue that lines the inside wall of the eye. The retina acts like the film in a camera to capture images, transforms the images into electrical signals, and sends the signals to the brain.

Sclera: the tough, white outer layer of the eyeball that, along with the cornea, protects the eyeball.

Snellen Visual Acuity Chart: one of the many charts used to measure vision. Snellen visual acuity is recorded as 20/xx (e.g., 20/20 is considered to be "normal" vision).

Stroma: the middle, thickest layer of tissue in the cornea. This is the area from which the laser removes tissue during a LASIK procedure.

Undercorrection: an outcome of refractive surgery where the achieved amount of correction is less than the intended amount.

Visual Acuity: the clearness of vision; the ability to distinguish details and shapes.