VISX STAR S2™ Excimer Laser System

Laser Assisted In Situ Keratomileusis (LASIK)

Photorefractive Keratectomy (PRK)

Professional Use Information

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the STAR S2™ Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the STAR S2 Excimer Laser System Operator's Manual.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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Revision	Description	Date	ECN #
A	LASIK Myopia Data Added	1/11/00	7079
B	PRK Hyperopia with astigmatism Data Added	10/23/00	7298
C	Blend Zones Instructions Added	3/28/01	7713
D	LASIK Hyperopia with Astigmatism Data Added	4/30/01	7873

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General Warnings

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

Performance of procedures, use of controls, or any other adjustments other than those specified herein may result in a hazardous condition.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK) or Photorefractive Keratectomy (PRK) surgery.

GAS HANDLING: High-pressure gas cylinders are contained in a protected compartment within the STAR S2™ Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with "Gas Safety" (Section 4.5) and "Gas Maintenance" (Section 14.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

The premix (argon/fluorine) gas mixture used in this laser system is highly toxic. VISX, Incorporated, recommends that anyone working with the gas cylinders: 1) be trained in the proper handling of toxic and compressed gases, 2) know the location of the emergency exhaust fan/room purifier switch, 3) have easy access to all required protective equipment, and 4) be familiar with safety procedures and Materials Safety Data Sheets (MSDS) provided by the site's safety officer. Gas discharge into the atmosphere may be evidenced by a sharp, penetrating odor and by eye, nose, and throat irritation.

SKIN AND EYE EXPOSURE: The STAR S2 System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. The fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms, including surgical instruments, is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance from the primary beam.

PRECAUTIONS: Carefully read all instructions prior to use.The laser beam is invisible. The user cannot tell if the laser is emitting radiation by looking for the beam. Observe all contraindications, warnings, and precautions noted in this manual. Failure to do so may result in patient and/or user complications.

ELECTROMAGNETIC FIELD (EMF): The thyratron emits an electromagnetic pulse which is shielded by the metal coverings of the STAR S2™ Excimer Laser System. This metal covering reduces the EMF below the limits set by applicable standards for electromagnetic compliance.

WARNING: The effects of electromagnetic emissions from the excimer laser system on other devices, such as cardiac pacemakers or implanted defibrillators, is unknown. Operation of the laser in proximity to such devices is not recommended.

AIRBORNE CONTAMINANTS: Airborne contaminants which are produced by the ablation process are captured in proximity to the cornea near the point of production and fed into an aspirator with a filter. This aspirator is designed to prevent any of the products of ablation from contaminating the surgical suite.

1.0 Device Description

The STAR S2™ System is designed to create a superficial lamellar keratectomy on exposed corneal tissue. Corneal tissue is removed by a process known as Ablative Photodecomposition. Ablative Photodecomposition occurs when far-ultraviolet radiation reacts with organic molecules, resulting in the photochemical breakdown of the molecular bonds without a significant local thermal effect. The source of the far-ultraviolet photons is a high-efficiency, gas-discharge excimer laser that electronically excites a combination of argon and fluorine, producing an ultraviolet wavelength of 193 nm.

The STAR S2 Excimer Laser System combines submicron precision of tissue removal by an excimer laser with a sophisticated computer controlled delivery system. Features and components of the STAR S2 System include:

Excimer Laser
An argon-fluoride excimer laser module, with an output wavelength of 193 nm.

Gas Management System
A gas cabinet containing a working gas cylinder for laser operation; a gas cleaning system; a gas leak audio alarm with a sensor to detect fluorine (one part-per-million); a gas discharge system, using an activated charcoal filter to absorb fluorine; an emergency safety system using a positive-action solenoid safety valve, which automatically seals the premix cylinder in the event of a power failure; and a second charcoal scrubber to neutralize fluorine in case of a leak.

Laser Beam Delivery System
Beam shaping and homogenizing optics designed to produce a uniform, coaxial beam profile; a spatial integrator and beam rotator for temporal integration; and an iris diaphragm and rotating slit blades used to shape the beam.

Patient Management System
An operating microscope with reticle, used to observe a patient procedure and to facilitate accurate focus and laser beam alignment; a debris-removal system designed to evacuate the debris plume that occurs during ablation; a patient operating chair used to align the patient for treatment; a video camera and monitor used to record and monitor patient treatment; an illumination device used to illuminate the patient's eye for observation and treatment, and a fixation LED used by the patient to maintain proper alignment during treatment.

Computer Control
An IBM-compatible computer and video monitor; a computer keyboard with trackball for user interface; a printer; a VisionKey card driver; and system software.

VisionKey Card
A write-once-read-many (WORM) optical memory card designed to allow compilation, storage, and printout of essential patient data and procedural information.

2.0 Indications, Contraindications, Warnings, Precautions, and Adverse Events

2.1 Indications for Use

Laser Assisted In Situ Keratomileusis (LASIK) procedure using the STAR S2™ System is intended for use:

- in patients with documented evidence of a change in manifest refraction of no more than 0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and
- in patients 18 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -14.0 D with or without refractive astigmatism from 0.5 to 5.0 D*; or
- in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with or without refractive astigmatism up to +3.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D.

Photorefractive Keratectomy (PRK) procedure using the STAR S2 System is intended for use:

- in patients with documented evidence of a change in manifest refraction of no more than 0.5 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and
- in patients 18 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -6.0 D spherical equivalent at the corneal plane, with no more than 1.0 D of refractive astigmatism; or
- in patients 21 years of age or older in treatments for the reduction or elimination of myopia (nearsightedness) of no more than -12.0 D spherical myopia at the spectacle plane with no more than 4.0 D of refractive astigmatism*; or
- in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +1.0 and +6.0 D sphere at the spectacle plane with no more than 1.0 D of refractive astigmatism; or
- in patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with refractive astigmatism from 0.5 to 4.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D.

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* Caution must be used to calculate treatment in MINUS CYLINDER at the spectacle plane (vertex distance 12.5 mm) before entering the refraction into the laser in order to conform with the Indications for Use.

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Refer to the preceding General Warnings section of this Professional Use Information Manual, in addition to the warnings and precautions found in this section.

2.2 Contraindications

Laser refractive surgery is contraindicated:

- in patients with collagen vascular, autoimmune or immunodeficiency diseases.
- in pregnant or nursing women.
- in patients with signs of keratoconus.
- in patients who are taking one or both of the following medications: isotretinoin (Accutane®*); amiodarone hydrochloride (Cordarone®†).

2.3 Warnings

- The decision to perform laser refractive surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease, or an immunocompromised status, should be approached cautiously. The safety and effectiveness of the STAR S2 System has not been established in patients with these conditions.
- Laser refractive surgery is not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster*.
- Lower uncorrected visual acuity rates of 20/20 and 20/40 may be anticipated with higher degrees of correction of refractive error.

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* Accutane is a registered trademark of Hoffmann-La Roche Inc.

† Cordarone is a registered trademark of Sanofi.

2.4 Precautions

A. General

There is no safety and effectiveness information for PRK refractive treatments greater than -12.0 D of myopia, greater than +6.0 D of hyperopia, or greater than 4.0 D of refractive astigmatism.

There is no safety and effectiveness information for LASIK refractive treatments greater than -14.0 D of myopia or greater than 5.0 D of refractive astigmatism.

There is not sufficient safety and effectiveness information for LASIK refractive treatments greater than +5.0 D of hyperopia or greater than +3.0 D of refractive astigmatism.

To avoid corneal ectasia, the posterior 250 microns (μm) of corneal stroma should not be violated by the laser or the microkeratome.

Of the eyes treated in the PRK trials, only 21/200 (10.5%) of highly myopic eyes had myopia between -10 and -12 diopters and only 13/275 (4.7%) of hyperopic eyes had hyperopia between +4 and +6 diopters. These populations were not sufficient to determine the level of effectiveness or the complication rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

PRK patients with **+4.0 to +6.0 D of spherical hyperopia** may be at a greater risk of regression of correction.

2.1% of hyperopic PRK patients with pre-operative Best Spectacle-Corrected Visual Acuity (BSCVA) of 20/20 or better, had post-operative BSCVA of worse than 20/25, but not worse than 20/32.

PRK patients treated for hyperopic astigmatism greater than or equal to 5 diopters spherical equivalent pre-operatively are less stable and have lower predictability with a greater probability of undercorrection.

LASIK treatment for astigmatism at or below +1.0 D may not be effective for some patients. Because of limitations in measurements of accuracy, there may be a greater incidence of large axis shifts with little or no reduction of cylinder magnitude. In this study, 45% of eyes with pre-operative astigmatism at or below +1 D had as much or more astigmatism after surgery than before. This type of result may cause visual distortions that are more disturbing to the patient than the original condition.

LASIK treatment of cylinder >3 D may result in a greater incidence of significant residual astigmatism (>1 D) and axis shift.

Sufficient data were provided to evaluate LASIK treatment to -14.0 diopters of sphere and -5.0 diopters of cylinder; however, there were insufficient eyes treated with a combination of -12.0 diopters of sphere and -3.5 or higher diopters of myopic cylinder to determine the level of effectiveness or the complication rates for this refractive error range with the same reliability as for eyes with less severe refractive errors.

The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined. It is possible, following laser refractive surgery, that patients 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. Visual performance possibly could be worsened by large pupil sizes or decentered pupils.

Astigmatic patients between the ages of 21 and 30 should be reminded that, due to larger pupils, they are more likely than the over-30-year-old population to experience a degradation in visual performance under these conditions.

The safety and effectiveness of the STAR S2™ System have **NOT** been established:

- for PRK treatment of astigmatism in patients with refractive cylinder of less than 0.75 D.
- for PRK hyperopia treatment of patients with refractions less than +1.0 D.
- for LASIK and PRK treatment in patients with progressive myopia, progressive astigmatism, ocular disease, corneal abnormality, previous corneal surgery, or trauma in the ablation zone.
- for LASIK and PRK surgery in patients with corneal neovascularization within 1.0 mm of the ablation zone.
- for PRK in patients under 21 years of age with myopia greater than -6.0 D, with no more than 1.0 D of refractive astigmatism.
- for PRK in patients under 21 years of age with hyperopia between +1.0 and +6.0 D spherical equivalent, with no more than 1.0 D of refractive astigmatism.
- for PRK in patients under 21 years of age with hyperopia between +0.5 and +5.0 D spherical equivalent, with refractive astigmatism between +0.5 and +4.0 D.
- for LASIK in patients under 21 years of age with hyperopia between +0.5 and +5.0 D, with or without refractive astigmatism up to +3.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D.
- for LASIK or PRK surgery in patients under 18 years of age.

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- over the long term: more than 3 years after PRK surgery for low myopia; more than 1 year after PRK surgery for high myopia with astigmatism or hyperopia with or without astigmatism; or more than 6 months after LASIK surgery for myopia with or without astigmatism or hyperopia with or without astigmatism.
- for PRK in patients with a history of keloid formation.
- for LASIK and PRK surgery in patients who are taking sumatriptan (Imitrex®*).
- for PRK in patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery.
- for LASIK in patients who have had prior incisional refractive surgery.
- for LASIK in patients with myopia greater than -14.0 D or refractive astigmatism greater than 5.0 D.
- for LASIK in patients with hyperopia greater than +5.0 D sphere, refractive astigmatism greater than +3.0 D, or a maximum manifest refraction spherical equivalent (MRSE) of greater than +6.0 D.
- for PRK in patients with hyperopic astigmatism greater than +5.0 D sphere or greater than +6.0 D of manifest refraction spherical equivalent.
- for LASIK and PRK retreatment of hyperopic astigmatism.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for laser refractive surgery:

- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.
- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for hard lenses. Prior to treatment and after at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard (PMMA) lenses must have 3 central keratometry readings and manifest refractions taken at 1 week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.

*Imitrex is a registered trademark of Glaxo Group Ltd.

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- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo laser refractive surgery.
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- Baseline evaluation of patients requesting refractive surgery should be performed within 30 days of the laser refractive surgery.
- The patient should have the ability to tolerate local or topical anesthesia.
- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the laser refractive procedure.
- The patient must be able to understand and give an informed consent.
- Patients must be clearly informed of all alternatives for the correction of myopia, hyperopia, and astigmatism. These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries such as radial keratotomy or automated lamellar keratoplasty.

C. Procedure

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam.

All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

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D. Post-Procedure

1) LASIK

The following post-operative examinations are recommended on day 1 or day 2, and at 1, 3, and 6 months:

- Uncorrected Visual Acuity (UCVA or VA-sc).
- Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc).
- Manifest refraction.
- Intraocular pressure (Goldmann applanation) at 3 months.
- Slit-lamp examination.
- Keratometry and videokeratography at 3 and 6 months.

2) PRK

A slit-lamp examination should be performed on a daily basis until re-epithelialization is complete. After re-epithelialization, the following examinations are recommended on a schedule of at least 1, 3, 6, and 12 months:

- Uncorrected Visual Acuity (UCVA or VA-sc).
- Manifest refraction with the Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc).
- Intraocular pressure (IOP).
- Slit-lamp examination, including corneal clarity evaluation.
- Videokeratography at 6 months (sooner only if unanticipated events occur during the healing process).
- If topical steroids are used post-operatively, patients should be monitored for development of possible steroid side-effects, including but not limited to ocular hypertension, glaucoma, and/or cataract.

2.5 LASIK and PRK Adverse Events

There was no patient death related to the use of the STAR S2™ System.

The following transient complications might be expected with patients undergoing the PRK procedure: moderate pain (1 to 4 days), foreign body sensation, tearing, photophobia, redness, itching/scratchiness, burning, dryness, headache, blurred vision, corneal swelling, and pupil enlargement.

Other adverse events that might be expected with patients undergoing the PRK procedure but have not been observed in the VISX® clinical studies are corneal perforations, intraocular infections, hyphemas, hypopyon, post-treatment lens abnormalities with vision loss, significant overcorrections, persistent corneal decompensation/edema, or cystoid macular edema.

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Adverse events that might be expected with patients undergoing the LASIK procedure are glare, halos, monocular diplopia/polyopia, surface irregularity associated with cap healing, irregular ablations, decentered ablations, foreign body sensation, corneal scarring, keratitis (infectious or sterile) with the possible sequelae of corneal ulceration or perforation, dellen formation, foreign bodies in the interlamellar interface, vitreoretinal hemorrhage, cataract, corneal decompensation, and tenderness to touch.

Excimer laser energy has the potential to induce micromechanical damage to endothelial cells, induce cataracts, and cause mutations. These effects have not been observed in any clinical use, nor have they been reproducible in various animal and *in vitro* test systems.

2.5.1 LASIK Adverse Events and Complications

A. Myopia with or without Astigmatism

Twelve hundred and seventy-six (1276) eyes were used for safety analyses. Eight hundred and sixty-seven (867) eyes were followed for at least 6 months. The following Adverse Events (AEs) occurred at a rate of less than 1% at 6 months: Loss of 2 or more lines of BSCVA; BSCVA less than 20/40; increase of 2 D or more of cylinder; BSCVA less than 20/25 when the pre-operative eye was 20/20 or better; flap edema; interface epithelium; persistent staining; stromal edema; uncontrolled IOP; and wrinkling of the cap.

The following Adverse Events (AEs) did not occur: Corneal infiltrate or ulcer; melting of the flap; late onset of haze; retinal detachment; retinal vascular accidents.

Intra-operative complications are presented in Table 2-1.

Table 2-1 — Myopia with or without Astigmatism Intra-Operative Complications (LASIK) (n = 1276)

Damage to Epithelium	7 (0.5%)
Epithelial Defect	8 (0.6%)
Free Cap	54 (4.2%)
Oval Keratectomy	9 (0.7%)
Small Flap	2 (0.2%)
Small Flap with Thin Flap	1 (0.1%)
Surgery Aborted: Inadequate Flap	2 (0.2%)
Thin Flap	4 (0.3%)

Patient Findings

Patients graded their glare, halo, and visual fluctuations complaints before and at 3 months post-operatively. Severe glare was reported in 9% of subjects pre-operatively while 6% of subjects complained of severe glare at 3 months post-operatively. Severe halos were reported in 9% of subjects pre-operatively while 4% of subjects complained of severe halos at 3 months post-operatively. Four percent of subjects reported severe fluctuations pre-operatively while 2% of subjects complained of severe fluctuations at 3 months post-operatively.

B. Hyperopia with or without Astigmatism

One hundred and sixty-nine (169) eyes were used for safety analyses. One hundred and fifty-eight (158) eyes were followed for at least 6 months. At the 3 and 6-month visits, no eye lost more than 2 lines of BSCVA. At the final visit, only 1 eye (0.6%) had a BSCVA worse than 20/40 and no eye with a pre-operative BSCVA of 20/20 or better had a post-operative BSCVA of worse than 20/40 at any visit.

The following Adverse Events (AEs) did not occur: Corneal infiltrate or ulcer; melting of the flap; late onset of haze; retinal detachment; retinal vascular accidents. Adverse events for 1 month and later are presented in Table 2-2. Complications for 1 month and later are presented in Table 2-3.

Table 2-2 — Hyperopia with or without Astigmatism Adverse Events (LASIK)

Adverse Event Description	1 M (n = 169)		3 M (n = 163)		6 M (n = 158)	
	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	0*	0.0	0	0.0	0	0.0
Corneal epithelial defect involving the keratectomy at 1 month or later	0	0.0	0	0.0	0	0.0
Corneal edema at 1 month or later (specify "flap" or "bed" or both)	0	0.0	0	0.0	0	0.0
Epithelium in the interface with loss of 2 or more lines of BSCVA	0	0.0	0	0.0	0	0.0
Lost, misplaced or misaligned flap	0	0.0	0	0.0	0	0.0
Melting of the flap (LASIK only)	0	0.0	0	0.0	0	0.0
Uncontrolled IOP >10mm Hg or Any reading > 25 mm Hg	0	0.0	0	0.0	0	0.0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more of BSCVA					0	0.0
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later					0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0
Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0

* Two cases of ILK (intrastromal lamellar keratitis) were reported in the immediate post-operative period. Both cases resolved without sequelae within 1 week of onset.

3.1.2 Hyperopia with or without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have hyperopia from +0.5 to +6.0 diopters (D) with or without astigmatism ≤+6.0 D. One hundred and sixty-nine (169) eyes comprised the cohort of eyes used for safety evaluations. Of these 169 eyes, 12 eyes were excluded from effectiveness analyses due to a spherical treatment magnitude of > 5 D and one eye was excluded due to failure to establish pre-operative refractive stability. Effectiveness evaluations were done on 156 eyes from the 169-eye cohort. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopic syndrome.

A. About the Study

Treated eyes were followed for at least 3 months. Analyses of results were performed at 1, 3, and 6 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, stability, and vector analysis. Safety analyses included loss of 2 or more lines of best spectacle-corrected visual acuity (BSCVA), BSCVA of 20/40 or worse, haze with loss of BSCVA, intraocular pressure, adverse events, and complications. The post-operative spectacle/contact lens wear frequency was not assessed.

B. Patient Accountability

One hundred and sixty-nine (169) eyes of 89 subjects treated at six centers in the United States were evaluated for safety. One hundred and fifty-six (156) eyes were evaluated for effectiveness. More than 93% of the 169 eyes were available for analysis at 1, 3, and 6 months visits. Table 3-14 presents the accountability for all eyes treated in the study.

Table 3-14 — Hyperopia with or without Astigmatism (LASIK): Patient Accountability (n = 169)

1 M		3 M		6 M	
%	n/N	%	n/N	%	n/N
100	169/169	96.4	163/169	98.8	158/160

3.1.2 Hyperopia with or without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have hyperopia from +0.5 to +6.0 diopters (D) with or without astigmatism ≤+6.0 D. One hundred and sixty-nine (169) eyes comprised the cohort of eyes used for safety evaluations. Of these 169 eyes, 12 eyes were excluded from effectiveness analyses due to a spherical treatment magnitude of > 5 D and one eye was excluded due to failure to establish pre-operative refractive stability. Effectiveness evaluations were done on 156 eyes from the 169-eye cohort. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopic syndrome.

A. About the Study

Treated eyes were followed for at least 3 months. Analyses of results were performed at 1, 3, and 6 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, stability, and vector analysis. Safety analyses included loss of 2 or more lines of best spectacle-corrected visual acuity (BSCVA), BSCVA of 20/40 or worse, haze with loss of BSCVA, intraocular pressure, adverse events, and complications. The post-operative spectacle/contact lens wear frequency was not assessed.

B. Patient Accountability

One hundred and sixty-nine (169) eyes of 89 subjects treated at six centers in the United States were evaluated for safety. One hundred and fifty-six (156) eyes were evaluated for effectiveness. More than 93% of the 169 eyes were available for analysis at 1, 3, and 6 months visits. Table 3-14 presents the accountability for all eyes treated in the study.

Table 3-14 — Hyperopia with or without Astigmatism (LASIK): Patient Accountability (n = 169)

1 M		3 M		6 M	
%	n/N	%	n/N	%	n/N
100	169/169	96.4	163/169	98.8	158/160

C. Data Analysis and Results

1) Pre-Operative Characteristics

The mean age of the 89 patients participating in this trial was 50.6 ± 10.7 years. There were 45 women and 44 men. Table 3-15 presents refractive treatment stratified by sphere and cylinder.

Table 3-15 — Hyperopia with or without Astigmatism (LASIK): Refractive Treatment Stratified by Sphere and Cylinder (n = 169)

Sphere	Cylinder															
	0 D		>0 to ≤1 D		>1 to ≤2 D		>2 to ≤ 3 D		>3 to ≤4 D		>4 to ≤5 D		>5 to ≤6 D		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
>0 to ≤1 D	0	0.0	4	5.7	5	11.6	5	21.7	4	36.4	0	0.0	1	25.0	19	11.2
>1 to ≤2 D	5	33.3	25	35.7	6	14.0	4	17.4	1	9.1	0	0.0	3	75.0	44	26.0
>2 to ≤3 D	4	26.7	10	14.3	5	11.6	3	13.0	0	0.0	2	66.7	0	0.0	24	14.2
>3 to ≤4 D	5	33.3	16	22.9	11	25.6	2	8.7	4	36.4	1	33.3	0	0.0	39	23.1
>4 to ≤5 D	1	6.7	10	14.3	12	27.9	7	30.4	1	9.1	0	0.0	0	0.0	31	18.3
>5 to ≤6 D	0	0.0	5	7.1	4	9.3	2	8.7	1	9.1	0	0.0	0	0.0	12	7.1
Total	15	8.9	70	41.4	43	25.4	23	13.6	11	6.5	3	1.8	4	2.4	169	100

2) Uncorrected Visual Acuity (UCVA)

Pre-operatively 9.2% (13/141) of eyes targeted for emmetropia had an uncorrected visual acuity (UCVA) of 20/40 or better; at the 3 and 6-month visits, 97.0% (131/135 and 129/133) of these eyes had UCVA of 20/40 or better. Table 3-16 presents the UCVA of eyes targeted for emmetropia over time.

Table 3-16 — Hyperopia with or without Astigmatism (LASIK): UCVA Over Time (All Eyes Targeted for Emmetropia, n = 141)

	Pre-Op (n = 141)	1 M (n = 141)	3 M (n = 135)	6 M (n = 133)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
20/20 or better	0 0.0 (0.0, 8.3)	61 43.3 (35.1, 51.4)	62 45.9 (37.5, 54.3)	64 48.1 (39.6, 56.6)
20/25 or better	1 0.7 (0.0, 2.1)	93 66.0 (58.1, 73.8)	95 70.4 (62.7, 78.1)	89 66.9 (58.9, 74.9)
20/32 or better	6 4.3 (0.9, 7.6)	116 82.3 (76.0, 88.6)	119 88.1 (82.7, 93.6)	116 87.2 (81.5, 92.9)
20/40 or better	13 9.2 (4.4, 14.0)	128 90.8 (86.0, 95.6)	131 97.0 (94.2, 99.9)	129 97.0 (94.1, 99.9)
20/80 or better	68 48.2 (40.0, 56.5)	141 100 (91.7, 100)	135 100 (91.6, 100)	133 100 (91.5, 100)
20/200 or better	128 90.8 (86.0, 95.6)	141 100 (91.7, 100)	135 100 (91.6, 100)	133 100 (91.5, 100)
Worse than 20/200	13 9.2 (4.4, 14.0)	0 0.0 (0.0, 8.3)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 8.5)
Not Reported	0	0	0	0
Total	141 100	141 100	135 100	133 100

Analysis of UCVA as a measure of effectiveness is most meaningful for eyes with the ability to achieve BSCVA of at least 20/20 pre-operatively. These eyes have the capacity to achieve UCVA of 20/20 post-operatively. Of the eyes targeted for emmetropia, 115/141 met this criteria. At 3 months 99.1% (112/113) and at 6 months 100% (108/108) of these eyes had UCVA of 20/40 or better.

While pre-operatively, no eye had UCVA of 20/20 or better; at 3 months 54.0% (61/113) of eyes had UCVA of 20/20 or better and this increased to 56.5% at 6 months. Table 3-17 presents the distance UCVA of eyes targeted for emmetropia over time with a pre-operative BSCVA of 20/20 or better.

Table 3-17 — Hyperopia with or without Astigmatism (LASIK): UCVA Over Time (Eyes Targeted for Emmetropia, with a Pre-Op BSCVA of 20/20 or Better, n = 115)

	Pre-Op (n = 115)	1 M (n = 115)	3 M (n = 113)	6 M (n = 108)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
20/20 or better	0 0.0 (0.0, 9.1)	58 50.4 (41.3, 59.6)	61 54.0 (44.8, 63.2)	61 56.5 (47.1, 65.8)
20/25 or better	1 0.9 (0.0, 2.6)	87 75.7 (67.8, 83.5)	87 77.0 (69.2, 84.8)	81 75.0 (66.8, 83.2)
20/32 or better	5 4.3 (0.6, 8.1)	103 89.6 (84.0, 95.2)	104 92.0 (87.0, 97.0)	101 93.5 (88.9, 98.2)
20/40 or better	12 10.4 (4.8, 16.0)	108 93.9 (89.5, 98.3)	112 99.1 (97.4, 100)	108 100 (90.6, 100)
20/80 or better	62 53.9 (44.8, 63.0)	115 100 (90.9, 100)	113 100 (90.8, 100)	108 100 (90.6, 100)
20/200 or better	106 92.2 (87.3, 97.1)	115 100 (90.9, 100)	113 100 (90.8, 100)	108 100 (90.6, 100)
Worse than 20/200	9 7.8 (2.9, 12.7)	0 0.0 (0.0, 9.1)	0 0.0 (0.0, 9.2)	0 0.0 (0.0, 9.4)
Not Reported	0	0	0	0
Total	115 100	115 100	113 100	108 100

3) Best Spectacle-Corrected Visual Acuity (BSCVA)

Loss of BSCVA can be anticipated due to a surgical or healing effect and the optical effect of minification (approximately 7.0 D of corneal correction accounts for a 1 line loss of resolving power). At both the 3 and 6-month visits, 6 eyes (less than 4%) lost 2 lines of BSCVA, but no eye lost more than 2 lines of BSCVA. Table 3-18 presents the change in lines of BSCVA.

Table 3-18 — Hyperopia with or without Astigmatism (LASIK): Change in BSCVA Over Time (All Eyes, n = 169)

	1 M (n = 169)	3 M (n = 163)	6 M (n = 156)
	n % (95% CI)	n % (95% CI)	n % (95% CI)
Decrease > 2 Lines	2 1.2 (0.0, 2.8)	0 0.0 (0.0, 7.7)	0 0.0 (0.0, 7.8)
Decrease > 1 to ≤ 2 Lines*	20 11.8 (7.0, 16.7)	12 7.4 (3.4, 11.4)	14 9.0 (4.5, 13.5)
Decrease > 0 to ≤ 1 Line	67 39.6 (32.3, 47.0)	69 42.3 (34.7, 49.9)	56 35.9 (28.4, 43.4)
No Change	58 34.3 (27.2, 41.5)	54 33.1 (25.9, 40.4)	53 34.0 (26.5, 41.4)
Increase >0 to ≤1 Line	19 11.2 (6.5, 16.0)	27 16.6 (10.9, 22.3)	33 21.2 (14.7, 27.6)
Increase > 1 to ≤ 2 Lines	3 1.8 (0.0, 3.8)	1 0.6 (0.0, 1.8)	0 0.0 (0.0, 7.8)
Increase > 2 Lines	0 0.0 (0.0, 7.5)	0 0.0 (0.0, 7.7)	0 0.0 (0.0, 7.8)
Not Reported	0	0	2
Total	169 100	163 100	156 100

*Loss of 2 lines of BSCVA: 1 M = 6 (3.6%), 3 M = 6 (3.7%), and 6 M = 6 (3.8%).

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4) Accuracy of Outcome

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refractive cylinder and sphere. At 3 months post-operatively, 74% (111/150) of eyes were within 0.50 D and 93% (140/150) were within 1.00 D of attempted sphere correction, and 65% (97/150) of eyes were within 0.50 D and 90% (135/150) were within 1.00 D of attempted cylinder correction. These results were maintained through 6 months. Table 3-19 presents the accuracy of sphere and cylinder over time.

Table 3-19 — Hyperopia with or without Astigmatism (LASIK): Accuracy of Sphere (to Target) and Cylinder (to Zero) Component (n = 156)

	1 M (n = 156)	3 M (n = 150)	6 M (n = 144)
	n % (95% CI)	n % (95% CI)	n % (95% CI)
Sphere			
± 0.50 D	113 72.4 (65.4, 79.4)	111 74.0 (67.0, 81.0)	109 75.7 (68.7, 82.7)
± 1.00 D	144 92.3 (88.1, 96.5)	140 93.3 (89.3, 97.3)	137 95.1 (91.6, 98.7)
Cylinder			
± 0.50 D	102 65.4 (57.9, 72.9)	97 64.7 (57.0, 72.3)	102 70.8 (63.4, 78.3)
± 1.00 D	144 92.3 (88.1, 96.5)	135 90.0 (85.2, 94.8)	133 92.4 (88.0, 96.7)

LASIK treatment of cylinder >3 D may result in a greater incidence of significant residual astigmatism (>1 D) and axis shift.

5) Accuracy of MRSE Over Time

At 3 months post-operatively, 70.7% (106/150) of eyes were within 0.50 D and 94.7% (142/150) were within 1 D of attempted MRSE. At 6 months, 76.4% (110/144) and 91 (131/144) were within 0.50 D and 1.0 D, respectively. Over the course of the follow-up period, no eye was overcorrected by more than 2 D and approximately 1% of eyes were undercorrected by more than 2 D. Table 3-20 presents the accuracy of MRSE over time.

Table 3-20 — Hyperopia with or without Astigmatism (LASIK): Accuracy of MRSE: Attempted versus Achieved (All Eyes, n = 156)

MRSE	Pre-Op (n = 156)	1 M (n = 156)	3 M (n = 150)	6 M (n = 144)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
± 0.50 D	0 0.0 (0.0, 7.8)	113 72.4 (65.4, 79.4)	106 70.7 (63.4, 78.0)	110 76.4 (69.5, 83.3)
± 1.00 D	2 1.3 (0.0, 3.0)	144 92.3 (88.1, 96.5)	142 94.7 (91.1, 98.3)	131 91.0 (86.3, 95.7)
± 2.00 D	34 21.8 (15.3, 28.3)	156 100 (92.2, 100)	148 98.7 (96.8, 100)	143 99.3 (97.9, 100)
Not Reported	0	0	0	2
Overcorrected		**(Myopic)**		
< -1.00 D		2 1.3 (0.0, 3.0)	1 0.7 (0.0, 2.0)	1 0.7 (0.0, 2.1)
< -2.00 D		0 0.0 (0.0, 7.8)	0 0.0 (0.0, 8.0)	0 0.0 (0.0, 8.2)
Undercorrected		**(Hyperopic)**		
> +1.00 D		10 6.4 (2.6, 10.3)	7 4.7 (1.3, 8.0)	12 8.3 (3.8, 12.8)
> +2.00 D		0 0.0 (0.0, 7.8)	2 1.3 (0.0, 3.2)	1 0.7 (0.0, 2.1)

6) Stability of Outcome

Stability of outcome is evaluated by the cohort of eyes with a refraction at each visit. The number of available eyes in the effectiveness cohort with every visit is the limiting factor of stability analysis. This cohort contains 140 eyes.

7) MRSE

Between the 1 and 3-month visits, 97.9% (137/140) of eyes experienced a change of 1 D or less. Between the 3 and 6-month visits, 95.7% (134/140) of eyes experienced a change of 1 D or less. Refractive stability is reached at 3 months and confirmed at the 6-month visit. The difference in the percentage of eyes with a change of ≤1 D between 1-and 3-months and 3-and 6-months is not statistically significantly different from zero. Table 3-21 presents refractive stability over time.

Table 3-21 — Hyperopia with or without Astigmatism (LASIK): Refractive Stability (Eyes with 1, 3, and 6-month visits, n = 140)

Change in MRSE	1 and 3 M	3 and 6 M
	n % (95% CI)	n % (95% CI)
≤ 1.00 D	137 97.9	134 95.7
95% CI for %	(95.5, 100)	(92.4, 99.1)
MRSE (D)		
Mean	0.07	0.06
SD	0.46	0.45
95% CI for Mean	(0.14, -0.01)	(0.14, -0.01)

At the 1-month visit, the mean refractive spherical equivalent is 0.08 D. From the point of defined stability (3 months) to the next visit (6 months) the mean MRSE changed 0.09 D, or 0.03 D per month. There is no statistically significant difference between the mean presented at 3 and 6 months. Table 3-22 presents the mean MRSE over time.

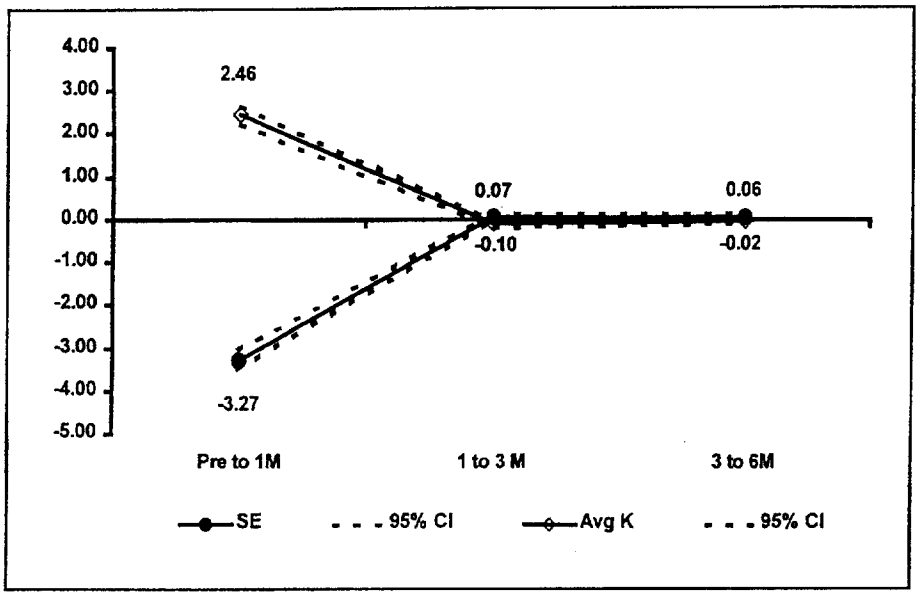
Table 3-22 — Hyperopia with or without Astigmatism (LASIK): Mean MRSE Over Time (Eyes Targeted for Emmetropia, n = 141)

	1 M (n = 141)	3 M (n = 135)	6 M (n = 131)
MRSE (D)			
Mean	0.08	0.12	0.21
SD	0.55	0.51	0.52
95% CI	0.17 to -0.01	0.21 to 0.04	0.30 to 0.12

8) Keratometry

From the point of defined stability (3 months) to the next visit (6 months), the mean keratometry changed 0.01 D. When plotted over time, the mean of the differences in manifest refraction spherical equivalent (MRSE) and average keratometry (Avg K) illustrates that stability is achieved by the 3-month visit. This trend is further supported by almost no change between the 3 and 6-month visits. Figure 1 presents the mean of the differences in MRSE and Avg K.

Figure 1: Mean of the Differences in MRSE and Avg K (Eyes with Visits at 1, 3, and 6 Months, n = 140)



9) Refractive Cylinder

Stability of refractive cylinder is achieved at 3 months post-operatively and confirmed at 6 months. There is no statistically significant difference between the data before 1-and 3-months and the data at 3-and 6-months. Table 3-23 presents stability of refractive cylinder.

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Table 3-23 — Hyperopia with or without Astigmatism (LASIK): Stability of Refractive Cylinder (Eyes with 1, 3 and 6-month visits, n = 140)

Change in Cylinder	1 and 3 M	3 and 6 M
	n % (95% CI)	n % (95% CI)
≤ 1.00 D	136 97.1	136 97.1
95% CI for %	(94.4, 99.9)	(94.4, 99.9)
Cyl (D)		
Mean	0.03	-0.01
SD	0.46	0.43
95% CI for Mean	(-0.05, 0.10)	(-0.08, 0.06)

10) Vector Analysis

The vector magnitude ratio (SIRC/IRC) is an indicator of procedure effectiveness. Vector analysis was performed on the 136 eyes that had their 3-month visit (point of stability) and had an astigmatic procedure (no spherical treatments were included). At 3 months, the spherical SIRC/IRC is 98% and the cylindrical SIRC/IRC is 110% indicating a greater incidence of over-correction among eyes with lower amounts of astigmatism (<1 D).

Table 3-24 — Hyperopia with or without Astigmatism (LASIK): Vector Magnitude (n = 136)

	Sphere					Cylinder				
	Pre	Post	IRC	SIRC	SIRC/IRC*	Pre	Post	IRC	SIRC	SIRC/IRC
Mean	2.5	-0.2	4.4	4.3	0.98	1.5	0.5	-1.7	-1.8	1.1
Median	2.3	0.0	4.0	4.0	1.00	1.3	0.5	-1.3	-1.5	1.2
SD	1.2	0.7	1.8	1.8		1.2	0.5	1.3	1.3	
Min	0.0	-2.8	1.3	1.2		0.3	0.0	-6.8	-7.2	
Max	4.8	1.3	8.6	8.5		6.0	2.3	0.0	-0.1	

* SIRC = Surgically Induced Refractive Change. IRC = Intended Refractive Change.

11) Retreatments

Procedures performed to improve refractive outcome:

Four eyes underwent LASIK retreatments (4/169 or 2.4%) during the study, mostly due to initial over-correction. Post-operatively, 2 of these eyes had significant residual refractive error and the other 2 had no residual refractive error (plano). The small number of retreatments is insufficient to yield clinically useful information, however caution should be taken to assure refractive stability before performing additional procedures.

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12) Patient Symptoms

Patient questionnaires reflected the following patient symptoms after treatment.

Table 3-25 — Hyperopia with or without Astigmatism (LASIK): Patient Symptoms: Comparison of Vision after Surgery (All Eyes with a Treatment Sphere ≤5.00 D, N = 156)*

	3 M (N = 147)							6 M (N = 144)						
	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (− ≥ 2)		NR	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (− ≥ 2)		NR
	n	%	n	%	n	%	n	n	%	n	%	n	%	n
Sharpness and Clarity	24	16.3	116	78.9	7	4.8	0	22	15.3	112	77.8	10	6.9	0
Consistency of Vision	19	12.9	122	83.0	6	4.1	0	19	13.2	115	79.9	10	6.9	0
Sustained Close Work	21	14.3	121	82.3	5	3.4	0	22	15.3	118	81.9	4	2.8	0
Daylight Driving	18	12.2	123	83.7	6	4.1	0	18	12.5	120	83.3	6	4.2	0
Night Driving	18	12.2	123	83.7	6	4.1	0	23	16.0	114	79.2	7	4.9	0
Night Vision with Glare	22	15.0	117	79.6	8	5.4	0	26	18.1	112	77.8	6	4.2	0
Reading in Dim Light	14	9.5	123	83.7	10	6.8	0	15	10.5	119	83.2	9	6.3	1
General Vision in Dim Light	19	12.9	118	80.3	10	6.8	0	19	13.2	116	80.6	9	6.3	0
Overall Visual Comfort	23	15.6	116	78.9	8	5.4	0	24	16.8	116	81.1	3	2.1	1

* This table reflects responses to a patient questionnaire on a scale of 1 (poor) to 5 (excellent). Responses at 3 and 6 months were compared to pre-operative responses. The results presented reflect changes in uncorrected vision compared to baseline.

In this study, at the point of stability, patients were asked a series of questions about their vision, including clarity, consistency, sustained close work, driving in day and night lighting, reading and vision in dim light, and visual comfort. For subjects with a pre-operative MRSE > 2.00 D, an average of 3.7% responded that they preferred their vision prior to the LASIK treatment (range 0 – 7.1%). This average was higher (11.5%) among subjects with a pre-operative MRSE < 2.00 D (range 0 – 21.2%). VISX® recommends that all patients be counseled carefully to establish realistic expectations before they proceed with the surgical correction of refractive error.

13) Adverse Events and Complications

Refer to Tables 2-2, 2-3, and 2-4 in Section 2.5.1.

14) Summary of Key Safety and Effectiveness Variables

They key safety and effectiveness variables for all eyes are presented in Table 3-26. The key safety and effectiveness variables stratified by treatment MRSE are presented in Table 3-27.

Table 3-26 — Hyperopia with or without Astigmatism (LASIK): Summary of Key Safety and Effectiveness Variables (All Eyes, n = 169)

Criteria	1 M n % (95% CI)	3 M n % (95% CI)	6 M n % (95% CI)
Effectiveness Variables			
n =115*, †	n = 115	n = 113	n = 108
UCVA 20/20 or better	58 50.4 (41.3, 59.6)	61 54.0 (44.8, 63.2)	61 56.5 (47.1, 65.8)
UCVA 20/40 or better	108 93.9 (89.5, 98.3)	112 99.1 (97.4, 100)	108 100 (90.6, 100)
n = 141 *, ‡	n = 141	n = 135	n = 133
UCVA 20/20 or better	61 43.3 (35.1, 51.4)	62 45.9 (37.5, 54.3)	64 48.1 (39.6, 56.6)
UCVA 20/40 or better	128 90.8 (86.0, 95.6)	131 97.0 (94.2, 99.9)	129 97.0 (94.1, 99.9)
n = 156	n = 156	n = 150	n = 144
MRSE ± 0.50 D	113 72.4 (65.4, 79.4)	106 70.7 (63.4, 78.0)	110 76.4 (69.5, 83.3)
MRSE ± 1.00 D	144 92.3 (88.1, 96.5)	142 94.7 (91.1, 98.3)	131 91.0 (86.3, 95.7)
MRSE ± 2.00 D	156 100 (92.2, 100)	148 98.7 (96.8, 100)	143 99.3 (97.9, 100)
Stability			
n = 140**		n = 140	n = 140
Change ≤ 1.00 D		137 97.9 (95.5,100)	134 95.7 (92.4, 99.1)
Mean Change in MRSE		0.07 ± 0.46 (0.14, -0.01)	0.06 ± 0.45 (0.14, -0.01)
Safety Variables			
n = 169	n = 169	n = 163	n = 156
Loss of ≥ 2 lines BSCVA	8 4.7 (1.5, 7.9)	6 3.7 (0.8, 6.6)	6 3.8 (0.8, 6.8)
Loss of > 2 lines BSCVA	2 1.2 (0.0, 2.8)	0 0.0 (0.0, 7.7)	0 0.0 (0.0, 7.8)
BSCVA worse than 20/40	3 1.8 (0.0, 3.8)	2 1.2 (0.0, 2.9)	1 0.6 (0.0, 1.9)
Increase > 2 D cylinder	0 0.0 (0.0, 7.5)	0 0.0 (0.0, 7.7)	0 0.0 (0.0, 7.8)
n = 134†	n = 134	n = 132	n = 124
BSCVA worse than 20/40	0 0.0 (0.0, 8.5)	0 0.0 (0.0, 8.5)	0 0.0 (0.0, 8.8)

* Excluding eyes intentionally overcorrected for monovision.

† BSCVA 20/20 or better pre-operatively.

‡ Includes eyes with a pre-operative BSCVA worse than 20/20.

** Includes only eyes with all visits.

Table 3-27 — Hyperopia with or without Astigmatism (LASIK): Summary of Key Safety and Effectiveness Variables at Stability Endpoint at 3 Months (Stratified by Treatment MRSE)

Criteria	Up to 2.00 n/N, % (% CI)	>2 to 3.00 n/N, % (% CI)	>3 to 4.00 n/N, % (% CI)	>4 to 5.00 n/N, % (% CI)	>5 to 6.00 n/N, % (% CI)	>6 to 7.00 n/N, % (% CI)	>7 to 8.00 n/N, % (% CI)	Cum Total n/N, % (% CI)
Effectiveness Variables								
n = 113*,†	**n = 29**	**n = 31**	**n = 21**	**n = 15**	**n = 17**	**n = 0**		**n = 113**
UCVA 20/20 or better	18 62.1 (44.4, 79.7)	20 64.5 (47.7, 83.4)	11 52.4 (31.0, 73.7)	8 53.3 (28.1, 78.6)	4 23.5 (3.4, 43.7)	n/a		61 54.0 (44.8, 63.2)
UCVA 20/40 or better	29 100 (81.8, 100)	31 100 (82.4, 100)	20 95.2 (86.1, 100)	15 100 (74.7, 100)	17 100 (76.2, 100)	n/a		112 99.1 (97.4, 100)
n = 135*,‡	**n = 29**	**n = 38**	**n = 26**	**n = 17**	**n = 24**	**n = 1**		**n = 135**
UCVA 20/20 or better	18 62.1 (44.4, 79.7)	21 55.3 (39.5, 71.1)	11 42.3 (23.3, 61.3)	8 47.1 (23.3, 70.8)	4 16.7 (1.8, 31.6)	0 0.0 (0.0, 98.0)		62 45.9 (37.5, 54.3)
UCVA 20/40 or better	29 100 (81.8, 100)	38 100 (84.1, 100)	23 88.5 (76.2, 100)	17 100 (76.2, 100)	23 95.8 (87.8, 100)	1 100 (2.0, 100)		131 97.0 (94.2, 99.9)
n = 150	**n = 30**	**n = 39**	**n = 34**	**n = 20**	**n = 26**	**n = 1**		**n = 150**
MRSE ± 0.50 D	23 76.7 (61.5, 91.8)	31 79.5 (66.8, 92.2)	22 64.7 (48.6, 80.8)	13 65.0 (44.1, 85.9)	16 61.5 (42.8, 80.2)	1 100 (2.0, 100)		106 70.7 (63.4, 78.0)
MRSE ± 1.00 D	29 96.7 (90.2, 100)	38 97.4 (92.5, 100)	31 91.2 (81.6, 100)	18 90.0 (76.9, 100)	25 96.2 (88.8, 100)	1 100 (2.0, 100)		142 94.7 (91.1, 98.3)
MRSE ± 2.00 D	30 100 (82.1, 100)	39 100 (84.3, 100)	32 94.1 (86.2, 100)	20 100 (78.1, 100)	26 100 (80.8, 100)	1 100 (2.0, 100)		148 98.7 (96.8, 100)
n = 140	**n = 26**	**n = 36**	**n = 32**	**n = 19**	**n = 26**	**n = 1**		**n = 140**
Stability ± 1.00 D	26 100 (80.8, 100)	36 100 (83.7, 100)	31 96.9 (90.8, 100)	17 89.5 (75.7, 100)	26 100 (80.8, 100)	1 100 (2.0, 100)		137 97.9 (95.5, 100)
Mean Change in MRSE	0.01 ± 0.37 (-0.13, 0.15)	0.06 ± 0.32 (-0.04, 0.17)	0.17 ± 0.50 (0.00, 0.34)	-0.01 ± 0.64 (-0.30, 0.28)	0.04 ± 0.51 (-0.15, 0.24)	0.25**		0.07 ± 0.46 (-0.01, 0.14)
Safety Variables								
n = 163	**n = 30**	**n = 39**	**n = 34**	**n = 21**	**n = 29**	**n = 7**	**n = 3**	**n = 163**
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 17.9)	0 0.0 (0.0, 15.7)	0 0.0 (0.0, 16.8)	3 14.3 (0.0, 29.3)	2 6.9 (0.0, 16.1)	0 0.0 (0.0, 37.0)	1 33.3 (0.0, 86.7)	6 3.7 (0.8, 6.6)
Loss of > 2 lines BSCVA	0 0.0 (0.0, 17.9)	0 0.0 (0.0, 15.7)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 21.4)	0 0.0 (0.0, 18.2)	0 0.0 (0.0, 37.0)	0 0.0 (0.0,56.6)	0 0.0 (0.0, 7.7)
Increase > 2 D cylinder	0 0.0 (0.0, 17.9)	0 0.0 (0.0, 15.7)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 21.4)	0 0.0 (0.0, 18.2)	0 0.0 (0.0, 37.0)	0 0.0 (0.0, 56.6)	0 0.0 (0.0, 7.7)
n = 132†	**n = 30**	**n = 32**	**n = 28**	**n = 16**	**n = 21**	**n = 3**	**n = 2**	**n = 132**
BSCVA worse than 20/40	0 0.0 (0.0, 17.9)	0 0.0 (0.0, 17.3)	0 0.0 (0.0, 18.5)	0 0.0 (0.0, 24.5)	0 0.0 (0.0, 21.4)	0 0.0 (0.0, 56.6)	0 0.0 (0.0, 69.3)	0 0.0 (0.0, 8.5)

* Excluding eyes intentionally overcorrected for monovision.

† BSCVA 20/20 or better pre-operatively.

‡ Includes eyes with a pre-operative BSCVA worse than 20/20.

** It is not possible to calculate standard deviation and confidence intervals with an "n" of one.

3.2 PRK Clinical Results

3.2.1 Low Myopia

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the primary eye have myopia of -1.0 to -6.0 D spherical equivalent at the corneal plane with astigmatism less than or equal to 1 D.

Patients who exhibited any of the following conditions were excluded: keratoconus; active ocular disease likely to affect wound healing; unstable central keratometry readings with irregularly shaped mires or corneascope photographs with broken central rings; use of systemic medications likely to affect wound healing; and an immunocompromised status.

A. About the Study

Nine hundred and nine (909) eyes treated at 6.0 mm comprised the cohort of eyes used for safety evaluations. These 909 eyes were treated between May 1992 and May 1995. Efficacy evaluations were done on 480 eyes from the 909-eye cohort. These 480 eyes were treated between May 1992 and October 1993 at nine participating centers. The patients were evaluated pre-operatively, every 24 to 48 hours post-operatively until re-epithelialization, and at 1, 3, 6, 12, 18, and 24 months post-treatment.

Both pre- and post-operatively, the patients were asked whether they experienced any visual symptoms. Following surgery, satisfaction with the procedure was assessed periodically. Objective measurements included: uncorrected and best spectacle-corrected visual acuity (UCVA and BSCVA), manifest refraction, keratometry, intraocular pressure (IOP), pachymetry, clinical assessment of corneal clarity (haze), the anterior chamber, vitreous, retina and lens, and assessment of complications or adverse events.

Additional post-operative evaluations were performed in subsets of subjects as follows: cycloplegic refraction, corneal topography, glare testing, contrast sensitivity, endothelial cell counts, and visual fields.

B. Patient Accountability

The cohort evaluated for safety contained 909 eyes. The cohort evaluated for efficacy contained 480 eyes representing the subset of eyes that met the inclusion criteria and completed ≥2 years of follow-up.