

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 VISX STAR S2™ Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the VISX 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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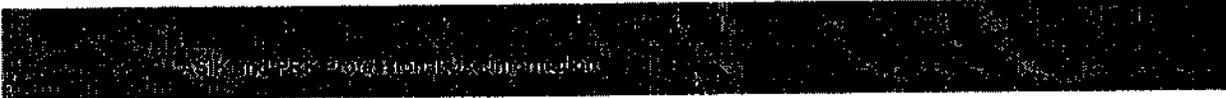


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General Warnings

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 VISX 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 VISX 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. This laser system is not for use in mobile clinics. Device performance in a mobile clinic has not been tested.

ELECTROMAGNETIC FIELD (EMF): The thyatron emits an electromagnetic pulse which is shielded by the metal coverings of the VISX 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 VISX 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 VISX 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 VISX 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 VISX 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 LASIK 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.

Photorefractive Keratectomy (PRK) procedure using the VISX 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.



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

- * 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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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 VISX 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.

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.

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

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

†Cordarone is a registered trademark of Sanofi.

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.

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.

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.

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 VISX 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 treatment of hyperopia in patients with refractions less than +0.5 D.
- for LASIK and PRK in patients with progressive myopia, progressive astigmatism, ocular disease, corneal abnormality, previous corneal surgery, or trauma in the ablation zone.
- for LASIK and PRK 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 or PRK in patients under 18 years of age.
- 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; more than 1 year after PRK surgery for hyperopia; or more than 6 months after LASIK surgery for myopia with or without astigmatism.
- for PRK in patients with a history of keloid formation.
- for LASIK and PRK 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 treated for myopia with or without astigmatism who have had prior incisional refractive surgery.
- for LASIK in patients with myopia greater than -14.0 D and astigmatism greater than -5.0 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 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

*Imitrex is a registered trademark of Glaxo Group Ltd.

patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.

- 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.

D. Post-Procedure

1) 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) 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.

2.5 PRK and LASIK Adverse Events

There was no patient death related to the use of the VISX 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.

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 PRK Adverse Events

A. Low Myopia

Nine hundred and nine (909) eyes of 676 subjects were used for safety analyses. Five hundred and forty-two (542) eyes were followed for at least 24 months.

Adverse events for 1 month and later are presented in Table 2-1.

**Table 2-1 — Low Myopia Adverse Events (PRK)
Eyes Treated with 6.0 mm Ablation Zone (n = 909)***

Adverse Event Description	3 to 6 M (n = 846)**		12 M (n = 520)**		≥ 24 M (n = 542)**	
	n	%	n	%	n	%
1. Loss ≥ 2 Lines of BSCVA	50	6.0 [♦]	11	2.2	1	0.2
2. Pre-treatment BSCVA 20/20 or Better With Post-treatment BSCVA Worse than 20/25	52	6.4 [♦]	10	2.1 [♦]	7	1.3
With Post-treatment BSCVA Worse than 20/40	7	0.9	1	0.2	0	0
3. Overcorrection: > 1 D	44	5.2	6	1.2	7	1.3
> 2 D	9	1.1	1	0.2	3	0.6
4. Increase in Refractive Cylinder: ≥ 1 D	46	5.5	16	3.1	16	3.0
≥ 2 D	3	0.4	0	0	0	0
5. Glare Testing: Abnormal (≥ 2 line loss in BSCVA with glare)	1	1.0 [♦]	1	1.7 [♦]	0	0
6. IOP Increase: > 5 to 10 mm Hg	61	7.3	9	1.8 [♦]	19	3.6 [♦]
> 10 mm Hg	7	0.8	0	0	0	0
7. Corneal Haze ≥ Grade 2	11	1.3	3	0.6	1	0.2
8. Corneal Infection/Ulcer/Infiltrate	0	0	0	0	0	0
9. Corneal Decompensation/Edema	0	0	0	0	0	0
10. Lens Abnormality Post-treatment †	2	0.2	1	0.2	3	0.6
11. Secondary Surgical Intervention: Single Retreatments	1	0.1	22	4.2	2	0.4
Double Retreatments	0	0	0	0	0	0
Other Refractive Procedures	4	0.5	14	2.7	9	1.7
12. Subjective Patient Responses ^{††} : "Double/Ghost Images" ^{††}						
Somewhat Worse	14	1.7	3	0.6	4	0.7
Much Worse	9	1.1	5	1.0	3	0.6
"Sensitivity to Bright Lights" ^{‡,††}						
Somewhat Worse	30	3.5	19	3.7	14	2.6
Much Worse	5	0.6	6	1.6	2	0.4
"Difficulty with Night Vision" ^{‡,††}						
Somewhat Worse	29	3.4	14	2.7	11	2.0
Much Worse	12	1.4	13	2.5	10	1.8

* Last Observation - Post-retreatment data not included.

** For all adverse events, percentages are given as:

number of eyes with at least one occurrence observed at the specified study visit
number of eyes examined at the specified study visit

♦ These values were calculated using an (n) value slightly smaller than the (n) shown in the column heading due to missing measurements.

† Adverse Event #10: lens abnormality post-treatment counted by first occurrence.

†† Reflects patient responses obtained from subjective questionnaires.

‡ Results of questionnaire responses were not validated by glare testing in a clinical setting.

B. High Myopia

Two hundred (200) eyes of 157 subjects were used for safety analyses. One hundred and fifty-six (156) eyes were followed for at least 12 months.

During clinical trials, no new issues of patient safety or effectiveness were identified in the greater than -10 diopter range of pre-operative myopia. Because of the low numbers of patients (10.5%, 21/200) with myopia between the -10 and -12 diopters treated in these trials, there may not have been a sufficient population to determine the level of effectiveness or the complication rates for this refractive error range.

Adverse events for visits 6 months and later are presented in Table 2-2.

Table 2-2 — High Myopia Adverse Events* (PRK) (n = 200)

Adverse Event Description	6M (n = 199)		12M (n = 156)		
	n	%	n	%	
1. Loss of ≥ 2 lines BSCVA due to All Causes	17	8.5	9	5.8	
	15	7.5	8	5.1	
2. Pre-treatment BSCVA 20/20 or Better with a Post-treatment BSCVA Worse than 20/25 Post-treatment BSCVA Worse than 20/40	14	7.0	7	4.5	
	0	0	2	1.3	
3. IOP Increase**					
	> 5 mm Hg from baseline	5	2.7	1	0.7
	> 10 mm Hg from baseline	2	1.1	0	0
> 25 mm Hg	1	0.5	0	0	
4. Corneal Haze†					
	With loss of ≥ 2 lines BSCVA	7	3.5	2	1.3
With loss of > 2 lines BSCVA	4	2.0	2	1.3	
5. Retreatments not for primary undercorrection	0	0	3	1.5	

* Patient survey not conducted for subjective evaluations of vision after surgery.

** There is a lower "n" for IOP data due to missing values (6M n=185 and 12M n=148).

† There is a lower "n" for Haze data due to missing values (12M n=153).

C. Myopia with Astigmatism

One hundred and sixteen (116) eyes of 71 subjects, treated at five U.S. centers, were used for safety analyses. Eighty-two (82) of these eyes were followed for at least 2 years.

Adverse events for visits 6 months and later are presented in Table 2-3. They are ordered by frequency at final visit.

Table 2-3 — Myopia with Astigmatism Adverse Events (PRK) (n = 116)

Adverse Event Description	6 M (n = 108)		12 M (n = 92)		Final Visit [‡] (n = 82)	
	n	%	n	%	n	%
1. Loss of ≥ 2 lines BSCVA						
Due to Any Cause	5	4.6	6	6.5	7	8.5*
Due to Corneal Causes	4	3.7	4	4.3	4	4.9*
2. Pre-treatment BSCVA 20/20 or Better						
With Post-treatment BSCVA						
Worse than 20/25	5	4.8	4	4.3	5	6.1
Worse than 20/40	0	0	2	2.2	0	0
3. Secondary Surgical Intervention						
Retreatments	0	0	4	4.3	5	6.1
4. IOP Increase						
> 5 to 10 mm Hg	8	7.4	2	2.2	2	2.4
>10 mm Hg	0	0	0	0	0	0
5. Corneal Haze ≥ Grade 2	2	1.9	4	4.3	1	1.2
6. Secondary Surgical Intervention						
Other Refractive Procedures	0	0	1	1.1	0	0
7. Subjective Patient Responses^{††}:						
"Double/Ghost Images" ^{††}						
Somewhat Worse	5	4.6	1	1.1	5	6.1
Much Worse	1	0.9	4	4.3	0	0
"Sensitivity to Bright Lights" ^{††}						
Somewhat Worse	13	12.0	6	6.5	6	7.3
Much Worse	5	4.6	6	6.5	7	8.5
"Difficulty with Night Vision" ^{††}						
Somewhat Worse	16	14.8	9	9.8	13	15.9
Much Worse	12	11.1	8	8.7	6	7.3

Percentages of safety outcomes are reported as:

number of eyes with at least one occurrence observed/reported at the specified study visit
 number of eyes examined at the specified study visit

* Includes two eyes in one patient who had cataract formation upon enrollment and one eye of one patient who had a stroke; these losses of BSCVA were not attributed to corneal wound healing. At no time did any eye lose BSCVA beyond 20/50 and at the Final Visit no eye was worse than 20/40-1.

‡ The final visit occurred at 24 ± 3 months after treatment.

†† Reflects patient responses obtained from subjective questionnaires.

D. Hyperopia

One hundred and twenty-four (124) subjects, treated at eight U.S. centers were used for safety analyses. The subjects were followed for at least 12 months.

Adverse events are presented in Table 2-4.

Table 2-4 — Hyperopia Adverse Events (PRK)

Adverse Event Description*	6 M (n = 201)		12 M (n = 115)	
	n	%	n	%
1. Decrease in BSCVA:				
> 2 Lines	2	1.0	1	0.9
2 Lines	0	0	3	2.6
Worse than 20/40	0	0	1	0.9
2. Pre-treatment BSCVA 20/20 or Better with a Post-treatment BSCVA Worse than 20/25 Post-treatment Worse than 20/40	0	0	2	2.1*
	0	0	0	0
3. Increase >2.0 D Cylinder	0	0	1	0.9
4. Corneal Haze ≥ Grade 2	0	0	1	0.9
5. IOP Increase				
> 5 to 10 mm Hg	1	0.5*	1	0.9*
> 10 mm Hg	0	0	0	0
6. Overcorrection >1.0 D	4	2.0	3	2.6
7. Subjective Patient Responses^{††}				
"Double/Ghost Images"^{**††}				
Somewhat Worse	6	3.0	6	5.2
Much Worse	4	2.0	1	0.9
"Sensitivity to Bright Lights"^{**††}				
Somewhat Worse	11	5.5	7	6.1
Much Worse	1	0.5	1	0.9
"Difficulty with Night Vision"^{**††}				
Somewhat Worse	8	4.0	5	4.3
Much Worse	2	1.0	2	1.7

* The percentage of adverse events reported reflects the actual number of occurrences reported divided by the number of data points available for each visit. Therefore, the percent reported may differ from the apparent value due to missing data points.

** Extensive contrast sensitivity and glare testing under mesopic and photopic conditions did not yield any statistically significant losses, nor any losses that could be interpreted as clinically significant.

†† Reflects patient responses obtained from subjective questionnaires.

E. Hyperopia with Astigmatism

Two hundred and seventy-six (276) eyes of 172 subjects, treated at seven U.S. centers were used for safety analyses.

Adverse events are presented in Table 2-5.

Table 2-5 — Hyperopia with Astigmatism Adverse Events (PRK)

Adverse Event Description	1 M (n = 275)		3 M (n = 272)		6 M (n = 272)		9 M (n = 255)		12 M (n = 237)	
	n	%	n	%	n	%	n	%	n	%
1. Corneal Infiltrate/ Ulcer	3*	1.1	0	0.0	0	0.0	0	0.0	0	0.0
2. Persistent Epithelial Defect at 1 Month or Later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
3. Uncontrolled IOP >5mm Hg or any reading >25 mm Hg	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
4. Late Onset of Haze Beyond 6 Months with Loss of >2 Lines of BSCVA					0	0.0	0	0.0	0†	0.0
5. 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	0	0.0	0	0.0
6. Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
7. Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

*Three eyes developed corneal infiltrates that were associated with the immediate post-operative period with a contact lens in place and all resolved without clinically significant sequelae.

†While there was 1 eye that had a 2 line loss of BSCVA at the 12-month visit, this was not considered an adverse event because it was noted to resolve after discontinuation of serzone medication.

Table 2-5A — Hyperopia with Astigmatism Patient Symptoms: Comparison of Vision After Surgery (All Eyes with a Pre-Operative Sphere \leq 5.0 and Questionnaire, n = 206)

Patient Symptom Description	Worsen (≥ 2)*		Worsen (≥ 2)*	
	6 M (n = 203)		12 M (n = 180)	
	n	%	n	%
1. Sharpness and Clarity	7	3.4	11	6.1
2. Consistency of Vision	4	2.0	3	1.7
3. Sustained Close Work	13	6.5	19	10.6
4. Daylight Driving	6	3.0	9	5.0
5. Night Driving	6	3.0	6	3.4
6. Night Vision with Glare	5	2.5	7	3.9
7. Reading in Dim Light	8	4.0	16	9.0
8. General Vision in Dim Light	17	8.5	25	14.0
9. Overall Visual Comfort	0	0.0	0	0.0

* This table reflects the responses to a patient questionnaire on a scale of 1 (poor) to 5 (excellent). Responses at 6 and 12 months were compared to the pre-operative responses. The results presented reflect changes in response from baseline.

The following post-operative complications were noted at a frequency of less than 1% at any visit: corneal edema, recurrent corneal erosion, foreign body sensation, ghost/double images.

2.5.2 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 2-6.

Table 2-6 — LASIK Intra-Operative Complications (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.

3.0 PRK and LASIK Clinical Results

3.1 PRK Clinical Results

3.1.1 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 refractive 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 corneal topography 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 was comprised of 909 eyes treated. The cohort evaluated for efficacy was comprised of 480 eyes representing the subset of eyes that met the inclusion criteria and completed ≥ 2 years of follow-up.

C. Data Analysis And Results

1) Pre-Operative Characteristics

Pre-operative characteristics are presented for 480 eyes treated with a 6.0 mm ablation zone and ≥ 2 years follow-up:

Table 3-1 — Low Myopia: Pre-Operative UCVA (n = 480)*

20/100 or Worse		20/50 to 20/80		20/25 to 20/40	
n	%	n	%	n	%
454	94.6	24	5.0	2	0.4

* Percentages may not add to 100.0 due to rounding.

Table 3-2 — Low Myopia: Pre-Operative BSCVA (n = 480)*

20/40		20/30 to 20/25		20/20 or Better	
n	%	n	%	n	%
1	0.2	13	2.7	466	97.1

* Percentages may not add to 100.0 due to rounding.

Table 3-3 — Low Myopia: Pre-Operative Myopia/Spherical Equivalent (n = 480)*

-1 to < -2 D		-2 to < -3 D		-3 to < -4 D		-4 to < -5 D		-5 to -6 D	
n	%	n	%	n	%	n	%	n	%
37	7.7	75	15.6	119	24.8	128	26.7	121	25.2

* Percentages may not add to 100.0 due to rounding.

2) Post-Operative Results

Table 3-4 represents a summary of efficacy data for 480 eyes treated and ≥ 2 years follow-up stratified by pre-treatment myopia. This table presents data based on the Last Observed (LO) data analysis. The LO analysis presents data from the initial treatment only; thus, data for eyes after retreatment are excluded.

Table 3-4 — Low Myopia: Efficacy > 2 Years Follow-up**
 First Treatment Only (Last Observed) (n = 480)

Pre-treatment Myopia	-1 to <-2 D (n = 37 Eyes)		-2 to <-3 D (n = 75 Eyes)		-3 to <-4 D (n = 119 Eyes)		-4 to <-5 D (n = 128 Eyes)		-5 to -6 D (n = 121 Eyes)		ALL (n = 480 Eyes)	
	n	%	n	%	n	%	n	%	n	%	n	%
1. UCVA 20/20 or Better (Pre-treatment: n = 0)	26	70.3	51	68.0	66	55.5	77	60.2	60	49.6	280	58.3
2. UCVA 20/25 or Better (Pre-treatment: n = 0)	32	86.5	63	84.0	92	77.3	103	80.5	93	76.9	383	79.8
3. UCVA 20/40 or Better (Pre-treatment: n = 2)	35	94.6	72	96.0	110	92.4	121	94.5	112	92.6	450	93.8
4. Dev. From Intended Within ± 1 D	33	91.7 [‡]	69	92.0	111	93.3	113	88.3	106	87.6	432*	90.2 [‡]
5. Dev. From Intended ≤ 1 D (Not Overcorrected)	36	100.0 [‡]	74	98.7	119	100.0	127	99.2	118	97.5	474*	99.0 [‡]
6. Dev. From Intended ≥ -1 D (Not Undercorrected)	33	91.7 [‡]	70	93.3	111	93.3	114	89.1	109	90.1	437*	91.2 [‡]
7. Cases with BSCVA 20/20 or Better Pre-treatment and UCVA of 20/25 or Better AND a Spherical Equivalent Between -1.0 D and +0.5 D Post-treatment	30	85.7 [‡]	61	82.4 [‡]	86	74.8 [‡]	95	76.0 [‡]	87	75.7 [‡]	359* [†]	77.4 [‡]
8. Spherical Equivalent > +1 D	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1*	0.2

* One patient did not stay to have refractive exam.

† 15 other eyes had pre-treatment BSCVA worse than 20/20.

** Follow-up based upon eyes treated on or before 10/20/93.

‡ These values were calculated using an (n) value slightly smaller than the (n) shown in the column heading due to missing measurements.

a) Uncorrected Visual Acuity (UCVA)

Table 3-5 shows the distribution of uncorrected visual acuity, pretreatment and post-treatment. Pre-operatively, 0.4% of eyes had a UCVA better than or equal to 20/40. At 1 month after treatment, 32.3% of the eyes had a UCVA of 20/20 or better and 89.7% were 20/40 or better. At 2 years or more post-treatment, 58.3% of the patients were 20/20 or better and 93.8% were 20/40 or better.

Table 3-5 — Low Myopia: Uncorrected Visual Acuity (UCVA) (n = 480)

Visual Acuity	Preop (n = 480)		1 M (n = 436)		3 M (n = 415)		6 M (n = 421)		12 M (n = 344)		18 M (n = 294)		≥ 24 M (n = 480)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
20/20 or Better	0	0.0	141	32.3	187	45.1	235	55.8	219	63.7	193	65.6	280	58.3
20/25 - 20/40	2	0.4	250	57.3	197	47.5	163	38.7	108	31.4	87	29.6	170	35.4
20/50 - 20/80	24	5.0	40	9.2	28	6.7	23	5.5	16	4.7	13	4.4	28	5.8
20/100 or Worse	454	94.6	5	1.1	3	0.7	0	0.0	1	0.3	1	0.3	2	0.4

b) Reduction of Myopia

In Table 3-6, the spherical equivalent data (based upon manifest refraction) demonstrates the reduction of myopia, with most cases near emmetropia (defined as a spherical equivalent within ± 1 D of intended) post-treatment. At 1 month post-treatment, 86.9% of the eyes were ± 1 D and at ≥ 24 months post-treatment this percentage had increased to 90.8%.

There is an initial hyperopic overshoot in some cases at 1 month post-treatment (10.6% of eyes had a spherical equivalent of $\geq +1$ D). However, there is a statistically significant decrease of this effect at 1 and 2 years post-treatment (1.2% and 0.4% of eyes, respectively, remained $\geq +1$ D).

Table 3-6 — Low Myopia: Reduction of Myopia (n = 480)

Spherical Equivalent	Preop (n = 480)		1 M (n = 434)		3 M (n = 411)		6 M (n = 419)		12 M (n = 342)		18 M (n = 294)		≥ 24 M (n = 479*)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Myopia ≥ -3 D	368	76.7	1	0.2	2	0.5	4	1.0	1	0.3	1	0.3	1	0.2
Myopia -2 - ≤ -3 D	75	15.6	3	0.7	7	1.7	3	0.7	1	0.3	2	0.7	3	0.6
Myopia -1 - ≤ -2 D	37	7.7	30	6.9	41	10.0	34	8.1	42	12.3	33	11.2	61	12.7
± 0.5 D	0	0.0	297	68.4	286	69.6	300	71.6	254	74.3	214	72.8	339	70.8
± 1 D	1	0.2	377	86.9	370	90.0	387	92.4	309	90.4	269	91.5	435	90.8
Hyperopia +1 - $\leq +2$ D	0	0.0	37	8.5	10	2.4	7	1.7	3	0.9	2	0.7	2	0.4
Hyperopia +2 - $\leq +3$ D	0	0.0	7	1.6	3	0.7	1	0.2	1	0.3	0	0.0	0	0.0
Hyperopia $\geq +3$ D	0	0.0	2	0.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* One patient did not stay to have refractive exam.

c) Deviation from Intended Correction (Predictability of Outcome)

In Table 3-7, the predictability of outcome has been assessed as the extent of deviation from intended correction (i.e., difference between achieved correction and intended correction). The intended final refractive error may not have been plano in certain cases (i.e., intended undercorrection for monovision). The percent of cases within ± 0.5 D and ± 1 D, respectively, of attempted correction remains relatively stable throughout the 24-month period. At 2 or more years, 90.2% of cases were within ± 1 D of attempted correction.

Table 3-7 — Low Myopia: Deviation From Intended Correction (n = 480)

Diopter	1 M (n = 434)		3 M (n = 411)		6 M (n = 419)		12 M (n = 342)		18 M (n = 294)		≥ 24 M (n = 479*)	
	n	%	n	%	n	%	n	%	n	%	n	%
± 0.5	261	60.1	265	64.5	288	68.7	233	68.1	203	69.0	309	64.5
± 1	363	83.6	362	88.1	384	91.6	310	91.6	270	91.8	432	90.2

* One patient did not stay to have refractive exam.

3) Stability of Outcome

Stability of mean line improvement in UCVA and mean deviation from intended correction between the 12- to 18-month, 18- to 24-month, and 12- to 24-month time periods were assessed to evaluate stability of the visual and refractive outcome. There are no statistically significant differences in mean lines improved between any of the time periods assessed ($p > 0.75$). Therefore, the mean line improvement in UCVA following treatment with the VISX STAR S2 System remains stable over the 12-, 18-, and 24-month periods. When all eyes evaluated at each visit are plotted, the curve is not statistically significantly different.

Stability of the mean spherical equivalent has been assessed at each of the 1-, 3-, 6-, 12-, 18-, and 24-month time points following initial treatment. Results of this analysis show that the mean pre-operative refractive error of -4.07 D was reduced to almost plano (-0.08 D) at 1 month following treatment. At 3 months the mean myopia is -0.19 D and remains unchanged at 6, 12, 18, and 24 months. There is no statistically significant difference in the amount of myopia at each follow-up period ($p > 0.15$).

Myopic shift (regression of effect) has also been assessed using the data available at pretreatment, 1, 3, 6, 12, 18, and 24 months. Myopic shift based on mean spherical equivalent over time during the follow-up period is not statistically significant ($p > 0.15$). Although 43/247 eyes (17.4%) had a myopic shift of -0.5 D from 12 to 24 months, only 7/247 (2.8%) of those eyes had a myopic shift of ≥ -1 D.



4) Retreatments

Retreatment data are presented for the initial cohort of the 909 eyes treated with a 6.0 mm ablation zone. Patients were eligible for retreatment after 6 months of follow-up. Thirty-three eyes (3.6%) were retreated. The data analyses for retreatment are presented in Table 3-8 through Table 3-12.

Table 3-8 — Low Myopia: Summary of Retreatment (n = 909)

Reason for Retreatment	Number of Eyes	Percentage of Retreated Eyes (n = 33)	Percentage of All Eyes (n = 909)
Regression*	9	27.3	1.0
Undercorrection**	12	36.4	1.3
Regression w/Haze	5	15.2	0.6
Undercorrection w/ Regression and Haze †	3	9.1	0.3
Other: Decentered Ablation, Haze, Induced Cylinder	4	12.1	0.4
Total	33	100.0	3.6

* Regression: a myopic change in spherical equivalent of more than 0.5 D.

** Undercorrection: deviation from intended correction of ≤ 0.5 D.

† Haze: a grade of ≥ 1 at any time prior to retreatment.

Table 3-9 — Low Myopia: UCVA in Retreatment Cases (n = 33)*

UCVA	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
Better than 20/20	0	0.0	0	0.0	2	7.1
20/20 – 20/40	0	0.0	0	0.0	20	71.4
20/50 – 20/80	0	0.0	28	84.8	4	14.3
20/100 or worse	33	100.0	5	15.2	2	7.1
Total	33	100.0	33	100.0	28**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit ≥ 6 months after retreatment.

Table 3-10 — Low Myopia: BSCVA in Retreatment Cases (n = 33)*

BSCVA	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
Better than 20/20	4	12.1	2	6.1	4	14.8
20/20	27	81.8	21	63.6	18	66.7
20/25	2	6.1	5	15.2	4	14.8
20/30	0	0.0	4	12.1	0	0.0
20/40	0	0.0	0	0.0	1	3.7
20/50	0	0.0	1	3.0	0	0.0
Total	33	100.0	33	100.0	27**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have visit \geq 6 months after retreatment. One eye had missing BSCVA at the visit after retreatment.

Table 3-11 — Low Myopia: Spherical Equivalent in Retreatment Cases (n = 33)*

Spherical Equivalent	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
Myopia > -3 D	28	84.8	2	6.1	1	3.6
Myopia > -2 -- -3 D	4	12.1	5	15.2	1	3.6
Myopia > -1 -- -2 D	1	3.0	15 ^o	45.5	4	14.3
\pm 0.5 D	0	0.0	2	6.1	14	50.0
\pm 1 D	0	0.0	10	30.3	22	78.6
Hyperopia > +1 -- +2 D	0	0.0	1	3.0	0	0.0
Total	33	100.0	33	100.0	28**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit \geq 6 months after retreatment.

Table 3-12 — Low Myopia: Haze in Retreatment Cases (n = 33)*

Haze	Pre-Treatment		Before Retreatment		After Retreatment	
	n	%	n	%	n	%
0.0 – 0.5 Trace	33	100.0	28	84.8	25	92.6
1 – 1.5 Mild	0	0.0	3	9.1	1	3.7
2.0 Moderate	0	0.0	2	6.1	0	0.0
3.0 Severe	0	0.0	0	0.0	1	3.7
Total	33	100.0	33	100.0	27**	100.0

* Represents 33/909 (3.6%) of eyes requiring retreatment.

** 5 eyes did not have a visit ≥ 6 months after retreatment. One eye had missing Haze score at visit after retreatment.

5) Adverse Events

Refer to Table 2-1 in Section 2.5.1.

3.1.2 High Myopia

A prospective, non-randomized, unmasked, multicenter PRK clinical study was conducted. The refractive inclusion criteria specified that the primary eye have myopia of between -6.0 and -12.0 D spherical myopia at the spectacle plane (with a vertex distance of 12.5 mm), and concomitant reduction or elimination of refractive astigmatism of up to 4.0 D at the spectacle plane (with a vertex distance of 12.5 mm) as determined by minus cylinder refraction. There were a total of 200 eyes treated (157 primary eyes and 43 fellow eyes). 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; use of systemic medications likely to affect wound healing; or patients with an immunocompromised status.

A. About the Study

Treated eyes were followed for at least 12 months. Analyses of results were performed for 6 months and 12 months visits. Effectiveness analyses included: reduction of astigmatism, vector analysis (intended versus achieved, residual cylinder), stability of correction over time, and uncorrected visual acuity. Safety analyses included: closely examining best spectacle corrected acuity losses of two or more lines ("significant losses"), slit lamp findings (e.g., haze), and IOP increases. Eyes with examinations at the 6-month and 12-month visits prior to retreatment are included in the effectiveness analyses. This approach is meant to present the data and not overstate effectiveness results. Safety issues are reported regardless of treatment or retreatment.

B. Patient Accountability

Two hundred (200) eyes of 157 subjects, treated at two international centers (one in Canada and one in England), were used for safety and effectiveness analyses. One hundred and fifty-six (156) eyes out of 171 were available for follow-up visits at 12 months.

C. Data Analysis and Results

1) Pre-Operative Characteristics

Pre-operative characteristics for the 200 eyes are presented in Table 3-13.

Table 3-13 — High Myopia: Pre-Op Refractive Error Stratified by Diopter Sphere and Cylinder (n = 200)

Pre-Op Cylinder	Pre-Operative Sphere						Total	
	6.1 to 7.0	7.1 to 8.0	8.1 to 9.0	9.1 to 10.0	10.1 to 11.0	11.1 to 12.0	n	%
	n = 87	n = 49	n = 27	n = 20	n = 10	n = 7		
0.00	20	10	4	3	1	1	39	19.5
0.01 to 1.00	36	20	13	10	4	4	87	43.5
1.01 to 2.00	23	14	9	4	4	2	56	28.1
2.01 to 3.00	7	2	0	2	1	0	12	6.0
3.01 to 4.00	1	3	1	1	0	0	6	3.0

2) Post-Operative Results

a) Uncorrected Visual Acuity (UCVA)

At 12 months following treatment, 140/156 (89.7%) of eyes were 20/40 or better, 125/156 (80.1%) were 20/30 or better and 79/156 (50.6%) were 20/20 or better. No eye was worse than 20/200 unaided.

Table 3-14 presents a matrix that summarizes the post-operative uncorrected visual acuities of eyes treated stratified by pre-operative UCVA. While no eye was better than 20/200 pre-operatively, regardless of the pre-operative UCVA, the majority of eyes (88.9% at 6 months and 89.7% at 12 months) were 20/40 or better after treatment. This represents a substantial improvement in uncorrected visual acuity sustained over time.

Table 3-14 — High Myopia: Post-Operative UCVA Stratified by Pre-Operative UCVA

Pre-Op (n = 200)		6 M (n = 199)				12 M (n = 156)			
UCVA	n	< 20/20	20/20-25	20/30-40	> 20/40	< 20/20	20/20-25	20/30-40	> 20/40
20/200	6	1	4	0	1	1	3	1	1
20/400-600	50	9	26	10	5	8	24	10	3
≥ 20/800	144	23	67	37	16	15	48	30	12
Total	200	33 (16.7)	97 (48.7)	47 (23.6)	22 (11.1)	24 (15.4)	75 (48.1)	41 (26.3)	16 (10.3)

b) **Best Spectacle Corrected Visual Acuity (BSCVA)**

Best spectacle corrected visual acuity (BSCVA) was analyzed at the 6-month and 12-month visits. No eye was worse than 20/40 pre-treatment.

At the 12-month visit, 126/156 (80.8%) are 20/20 or better and 153/156 (98.1%) are 20/40 or better. Three eyes had a BSCVA that was worse than 20/40, although none was worse than 20/80. One of these eyes had progressive nuclear sclerosis which decreased the BSCVA from 20/20 to 20/80 (this patient later recovered BSCVA to 20/20 following lens extraction). The reduction of BSCVA in the other two eyes were attributed to an anomalous refraction and decentered ablation (which later recovered to 20/30) in one eye and an irregular astigmatism in the other eye (this eye was 20/40 at pre-op).

Table 3-15 — High Myopia: 12-Month BSCVA Stratified by Diopter of Pre-Operative Sphere (n = 156)

Post-Op	Pre-Operative Sphere						Total	
	6.1 to 7.0	7.1 to 8.0	8.1 to 9.0	9.1 to 10.0	10.1 to 11.0	11.1 to 12.0	n	%
BSCVA	n = 71	n = 38	n = 20	n = 15	n = 7	n = 5		
20/10-12	13	2	4	2	0	0	21	13.5
20/15-16	25	12	6	1	0	0	44	28.2
20/20	25	19	5	7	3	2	61	39.1
20/25	4	3	3	1	2	2	15	9.6
20/30	2	2	0	3	2	1	10	6.4
20/40	0	0	2	0	0	0	2	1.3
< 20/40	2**	0	0	1*	0	0	3	1.9

* 8885115-2 (20/40 to 20/60—due to irregular astigmatism)

** 0189 (20/16 to 20/60—due to an anomalous refraction and decentered ablation) and 9411-1 (20/20 to 20/60—due to progressive nuclear sclerosis)

Best spectacle corrected visual acuity was also assessed by the number of lines of visual acuity gained or lost compared to baseline. This analysis was conducted on data from the 6-month and 12-month data. Seventeen (17/199 or 8.5%) eyes lost 2 lines or more of BSCVA at 6 months post-op, though not one of these eyes had an acuity that was worse than 20/40. By 12 months, the number of eyes that lost 2 or more lines of BSCVA had diminished to nine eyes (9/156 or 5.8%) and four (4/156 or 2.6%) had lost more than 2 lines of BSCVA.

c) Reduction of Mean Spherical Equivalent

The mean spherical equivalent was reduced at all time periods examined. The mean pre-treatment manifest refractive spherical equivalent was -8.27 D. At 6 months -0.16 D was the mean spherical equivalent or a mean reduction of 8.11 D (a mean reduction of 98%). At 12 months the mean spherical equivalent was -0.25 D which represents a mean spherical equivalent reduction of 8.02 D (a mean reduction of 97%).

Table 3-16 — High Myopia: Mean Spherical Equivalent Over Time

	Pre Op (n = 200)	6 M (n = 199)	12 M (n = 156)
Mean	-8.27	-0.16	-0.25
Median	-7.88	0.00	-0.13
SD	1.47	1.12	1.02
Min	-12.00	-7.00	-4.25
Max	-6.25	3.00	2.50

3) Stability of Outcome

The stability of outcome is demonstrated by a change of 1 D or less in manifest spherical equivalent between the 6 and 12-month visits. Of the 200 eyes initially treated, 155 had both a 6 and 12-month refraction. Of these, there were 133/155 eyes (85.8%) that had a change of not more than 1 D of manifest spherical equivalent between the 6 and 12-month visit.

The reduction in spherical equivalent is stable and the difference between the 6 and 12-month values are not statistically significant ($p > 0.05$).

4) Retreatments

Three eyes were retreated (3/200 or 1.5%) during the study during the initial 12 months after primary treatment. In each case retreatment resulted in visual recovery to at least the pre-operative level. Table 3-17 below summarizes the 3 retreatment cases that occurred during the 12-month follow-up period. Retreatment was performed to address post-operative irregular videokeratographic maps, regression and haze, and irregular astigmatism.

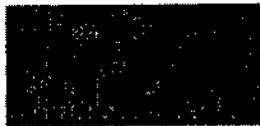


Table 3-17 — High Myopia: Re-Treatment Summary

Subject ID	Pre-Treatment		Pre-Retreatment		Post-Retreatment at Last Visit	
	UCVA	BSCVA	UCVA	BSCVA	UCVA	BSCVA
7491-2	800	20	200	40	100	15
7432834	800	20	400	40	200	20
9797-1	800	20	200	30	25	20

5) Refractive Cylinder Over Time

Table 3-18 — High Myopia: Observed Cylinder Over Time

	Pre-Op (n = 200)	6-Month (n = 199)	12-Month (n = 156)
Mean	-0.99	-0.43	-0.41
Median	-0.75	-0.25	-0.25
SD	0.85	0.56	0.56
Min	0.0	0.0	0.0
Max	4.00	4.00	3.25

6) Adverse Events

Refer to Table 2-2 in Section 2.5.1.

3.1.3 Myopia with Astigmatism

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 with between 0.75 and 4.5 D of refractive astigmatism. There were a total of 116 eyes treated (71 primary eyes and 45 fellow eyes). 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; use of systemic medications likely to affect wound healing; or immunocompromised status.

A. About the Study

One hundred and sixteen (116) eyes were treated. These eyes were treated between August 1993 and June 1995. The patients were evaluated pre-operatively, every 24 to 48 hours post-operatively until re-epithelialization, and at 1, 3, 6, 12, and 21 months or later after-treatment. Eyes were analyzed for: reduction of astigmatism, vector analysis of intended versus achieved refractive correction, residual refractive cylinder, stability of refractive correction over time, and uncorrected visual acuity.

Additional parameters were analyzed by closely examining best spectacle visual acuity losses of two lines or more (significant losses), endothelial cell counts, contrast sensitivity results, glare results, patient subjective symptoms (e.g., worsening of double vision, sensitivity to bright lights, and night vision disturbances), clinical signs (e.g., haze), and IOP increases, in addition to the adverse events as reported by the investigators and monitored throughout the course of the study.

B. Patient Accountability

One hundred and sixteen (116) eyes of 71 subjects, treated at five centers in the United States, were used for safety and effectiveness analyses. Eighty-two (82) eyes out of 91 were available for follow-up visits at 24 months or longer.

C. Data Analysis and Results

1) Pre-Operative Characteristics

Pre-operative characteristics for the 116 eyes are presented in Table 3-19.

Table 3-19 — Myopia with Astigmatism: Cohort Pre-Operative Refractive Characteristics (n = 116)

All Cohort Eyes (n = 116)	Spherical Equivalent	Spherical Myopia	Astigmatism
Mean	-4.34 D	-3.52	-1.64 D
SD	1.41	1.52	0.71
Range	-1.38 -- -6.63 D	0.00 -- -6.00 D	-0.75 -- -4.00 D

2) Post-Operative Results

The following table represents the number of eyes in which data were collected for the particular field at the indicated visit interval.

Table 3-20 — Myopia with Astigmatism: Eyes Tested at Each Visit*

	Examined	Refracted	BSCVA	UCVA	Con Sen	Glare
Pre-Op	116	116	116	115	111	111
6 M	108	106	104	106	90	87
12 M	92	89	89	90	74	74
Final Visit	84	82	82	82	66	67

* Not all parameters were available for each patient at each examination.

a) Uncorrected Visual Acuity (UCVA)

Table 3-21 is a distribution of uncorrected visual acuities (UCVA) stratified by pre-operative refractive cylinder the at final visit. At the final visit 91.5% (75/82) of eyes treated attained 20/40 or better vision without correction and 81.7% (67/82) attained an uncorrected visual acuity of 20/30 or better. No eye was able to attain 20/40 uncorrected acuity pre-operatively.

Table 3-21 — Myopia with Astigmatism: Final Visit UCVA of Cohort Eyes Stratified by Diopter of Pre-Operative Cylinder (n = 82*)

	0.75 - 1.0	1.1 - 2.0	2.1 - 3.0	3.1 - 4.0
	All Eyes	All Eyes	All Eyes	All Eyes
≥ 20/20	12	18	3	0
< 20/20 - 20/30	8	19	6	1
< 20/30 - 20/40	2	4	1	1
< 20/40 - 20/50	1	2	1	0
< 20/50 - 20/60	0	0	0	0
< 20/60 - 20/70	0	0	0	0
< 20/70 - 20/100	1	1	1	0
< 20/100 - 20/200	0	0	0	0
< 20/200 - 20/800	0	0	0	0
CF or Worse	0	0	0	0
TOTAL	24	44	12	2

* UCVA data for 2 eyes were not available at this visit.

Table 3-22 — Myopia with Astigmatism: Cylinder Magnitude and Axis (n = 116)

	6 M (n = 106)*	12 M (n = 89)**	Final Visit (n = 82) †
Sphere (SIRC/IRC)‡	3.18/3.27 97.2%	3.30/3.36 98.2%	3.22/3.31 97.3%
Cylinder (SIRC/IRC)‡	1.25/1.47 85.0%	1.18/1.43 82.5%	1.14/1.44 79.2%
Mean absolute vector axis error	7.2°	10.49°	11.5°
Mean vector magnitude error	-0.22 D	-0.25 D	-0.3 D

* The refractive data for 2 eyes are not available for this visit.

** The refractive data for 3 eyes are not available for this visit.

† The refractive data for 2 eyes are not available for this visit.

‡ Surgically Induced Refractive Change/Intended Refractive Change.

b) Reduction of Mean Spherical Equivalent

The mean spherical equivalent (S.E.) was reduced at all time periods examined (Table 3-23). Not all eyes were targeted for emmetropia; the mean target was -0.10 D. The mean pretreatment manifest refractive S.E. was -4.34 D. The mean S.E. was reduced by 92.9% at the final visit.

Table 3-23 — Myopia with Astigmatism: Reduction of Mean Spherical Equivalent

	6 M (n = 106)*	12 M (n = 89)**	Final Visit (n = 82) †
Mean	4.06	4.15	4.03
Median	4.19	4.13	4.13
SD	1.72	1.60	1.64
Min	-0.88	0.88	0.00
Max	8.00	8.63	8.63

* The refractive data for 2 eyes are not available for this visit.

** The refractive data for 3 eyes are not available for this visit.

† The refractive data for 2 eyes are not available for this visit.

c) Deviation from Intended Correction (Predictability of Outcome)

The predictability of outcome has been assessed as the extent of deviation from intended correction (i.e., difference between achieved correction and intended correction) by considering mean reduction in spherical equivalent and cylinder over time. The intended final refractive error was not plano in all cases (i.e., intended undercorrection for monovision); the resultant mean intended result was reduced by 92.9% at the final visit. The reduction in absolute cylinder was 62% at the final visit.

Predictability of outcome was also examined by performing vector analyses of the refractive data from follow-up visits. Because astigmatic corrections have three components (sphere, cylinder, and axis), an accurate outcomes assessment can be obtained only with a vector analysis to determine the magnitude and direction of change. A summary of the results is included in Table 3-22.

3) Stability of Outcome

Stability of outcome is presented by assessment of UCVA, spherical equivalent refractive error, and refractive cylinder over time. Over the course of the study, a significant number of eyes (86.7%, 86.6%, and 91.5% at the 6-month, 12-month, and final visit, respectively) achieved and maintained uncorrected visual acuity of 20/40 or better. The mean reduction in spherical equivalent was 4.06 D (SD 1.72) at 6 months, 4.15 D (SD 1.60) at 12 months, and 4.03 D (SD 1.64) at the final visit. The mean pretreatment cylinder was -1.64 (SD 0.71). The mean observed cylinder was -0.55 D (SD 0.54) at the final visit. The reduction in absolute mean cylinder was 1.15 (SD 0.79) at 6 months, 1.08 (SD 0.81) at 12 months, and 1.05 (SD 0.73) at the final visit. This represents a 67%, 64%, and 62% reduction in cylinder at each time point, respectively.

4) Retreatments

Nine eyes were retreated (9/116 or 7.8%) during the study. The majority were retreated for initial undercorrection of refractive error.

Table 3-24 — Myopia with Astigmatism: Retreatment Summary

Patient	Pre-Treatment		Pre-Retreatment		Post-Retreatment **	
	UCVA	BSCVA	UCVA	BSCVA	UCVA	BSCVA
1	80 - 2	25 + 3	50	20 - 2	25	20
2	400	20 - 2	80 + 4	25 *	60	20
3	CF	20	40	20	20	20
4	CF	25	50 + 3	25 - 1	25 - 3	25 - 1
5	400	12	50 - 2	15	30	20 - 3
6	CF	20	25 + 2	20	25 + 1	20
7	80	20	50	20	30	20
8	200	15	20 - 1	15	30	15
9	125	10	50	15	30	15

* The data listing indicates this BSCVA to be 20/80+4 in error; the correct value is included for accuracy.

** Last visit available.

5) Cylinder Axis Shift

Table 3-25 — Myopia with Astigmatism: Distribution of Axis Shift between Pre-Op and Final Visit Stratified by Pre-Op Cylinder (n = 82)*

Axis Shift (degrees)	0.75 - 1.0 (n = 24)	1.1 - 2.0 (n = 44)	2.1 - 3.0 (n = 12)	3.1 - 4.0 (n = 2)
0 - 15	21	33	9	2
16 - 30	1	7	2	0
31 - 45	1	2	0	0
46 - 60	1	1	0	0
61 - 75	0	0	0	0
76 - 90	0	1	1	0

* The refractive data for 2 eyes are not available for this visit.

6) Adverse Events

Refer to Table 2-3 in Section 2.5.1.

3.1.4 Hyperopia

A prospective, non-randomized, unmasked, multicenter PRK clinical study was conducted. The refractive inclusion criteria specified that the primary eye have hyperopia of between +1.0 and +4.0 D spherical equivalent and no more than 1.0 D of refractive astigmatism. The difference between the manifest and cycloplegic refractions may be no more than 0.75 D. There were a total of 124 patients treated in the United States supplemented with clinical data from a Canadian study on refractive errors from +4.0 to +6.0 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; use of systemic medications likely to affect wound healing; or immunocompromised status.

A. About the Study

Treated eyes were followed for at least 12 months. Analyses of results were performed for 1, 3, 6, 9, and 12 months visits. Effectiveness analyses included distance uncorrected visual acuity, uncorrected near acuity, refractive error, stability of outcome, and predictability of outcome.

Additional parameters were analyzed by examining absolute and relative best spectacle visual acuity over time, haze, intraocular pressure, induced astigmatism, contrast sensitivity, endothelial cell study, adverse events, and complications.

B. Patient Accountability

One hundred and twenty-four (124) eyes of 124 subjects treated at eight centers in the United States were used for safety and effectiveness analyses. One hundred and twenty-four (124) eyes were available for follow-up visits at 12 months.

C. Data Analysis and Results

1) Visual Acuity

Table 3-26 presents the distance uncorrected visual acuity (UCVA) pre-operatively and at 1, 3, 6, 9, and 12 months post-operatively. Pre-operatively, 5.4% of eyes were 20/20 or better. This increased to 53.3%, 69.7%, and 63.9% post-operatively at 6, 9, and 12 months, respectively. While 17.9% of eyes were 20/40 or better pre-operatively, 96.0%, 98.0%, and 94.8% were 20/40 or better post-operatively at 6, 9, and 12 months, respectively.

Table 3-26 — Hyperopia: Uncorrected Visual Acuity (UCVA)

Visual Acuity	Pre-op (n = 166)		1 M (n = 166)		3 M (n = 158)		6 M (n = 150)		9 M (n = 99)		12 M (n = 97)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/20 or Better	9	5.4	22	13.3	52	32.9	80	53.3	69	69.7	62	63.9
20/25 or Better	13	7.8	44	26.5	96	60.8	110	73.3	84	84.8	78	80.4
20/32 or Better	20	12.0	79	47.6	126	79.7	135	90.0	93	93.9	91	93.8
20/40 or Better	29	17.5	100	60.2	139	88.0	144	96.0	97	98.0	92	94.8

Of hyperopic patients who were 20/20 or better pre-operatively and who were examined 12 months post-operatively, 9% lost more than one line of Best Spectacle Corrected Visual Acuity (BSCVA) and no eye was worse than 20/32. **Note:** It can be anticipated that there will be a small BSCVA loss on image minification.

2) Refractive Error

All investigators were instructed to use a full plus refracting technique to assure measurement of maximum manifest hyperopia without cycloplegia. Cycloplegia was performed on all patients pre-operatively to confirm the full plus refraction and to preclude any patient with a large amount of latent hyperopia from being treated. Cycloplegic refractions were repeated at the 6 and 12-month visits. Table 3-27 presents the mean manifest refraction spherical equivalent pre-operatively, and at 1, 3, 6, 9, and 12 months post-operatively.

**Table 3-27 — Hyperopia: Manifest Refraction Spherical Equivalent Over Time
All Eyes Targeted for Emmetropia**

	Pre-Op	1 M	3 M	6 M	9 M	12 M
n	192	192	183	175	116*	115
Mean (D)	2.28	-0.86	-0.50	-0.18	0.00	0.11
SD	0.84	0.68	0.80	0.51	0.51	0.58
Min	0.38	-3.50	-2.88	-2.00	-1.50	-1.63
Max	4.00	1.00	1.00	1.38	1.75	2.25
Mean + 95% CI	2.40	-0.76	-0.41	-0.10	0.10	0.21
Mean - 95% CI	2.16	-0.95	-0.59	-0.25	-0.09	0.00

*One patient did not have a manifest refraction at this visit.

3) Stability of Outcome

Table 3-28 presents the mean change in manifest refraction spherical equivalent for all eyes that had 1, 3, 6, 9, and 12-month visits (n = 107). Between the 9 and the 12-month visits, there was a mean change of 0.11 ± 0.45 D and 104 eyes (97.2%) experienced a change of not more than 1.00 D.

Table 3-28 — Hyperopia: Refractive Stability: Mean of the Differences in MRSE (All US Eyes With 1, 3, 6, 9, and 12-Month Visits, n = 107)

Mean Pre SE +2.47 D	1 and 3 M		3 and 6 M		6 and 9 M		9 and 12 M	
	n	%	n	%	n	%	n	%
≤ 1.00 D	87	81.3	98	91.6	102	95.3	104	97.2
Mean Difference	0.41		0.32		0.16		0.10	
SD	0.74		0.56		0.49		0.45	
95% CI	0.55		0.42		0.25		0.19	
	0.26		0.21		0.07		0.02	

In consideration of the unique accommodative patterns of hyperopic subjects, refractive stability was further analyzed as a function of corneal power stability and resultant non-corneal power variation. The mean of the two meridians measured by standard keratometry (Mean K) was analyzed for the pre-operative, 1, 3, 6, 9, and 12-month post-operative follow-up visits to demonstrate corneal stability. Total refractive change at these time points was examined through changes in mean refractive spherical equivalent (MRSE) in the same eyes.

Table 3-29 presents the mean change of the Mean K for all eyes having a target of emmetropia that had 1, 3, 6, 9, and 12-month data (n = 105). Between 1 and 3 month visits, there was a mean change of -0.55 ± 0.88 D; between 3 and 6 months, there was a mean change of -0.22 ± 0.69 D; between 6 and 9 months, there was a mean change of -0.11 ± 0.47 D; and between 9 and 12 months, there was a mean change of -0.03 ± 0.35 D.

Table 3-29 — Hyperopia: Refractive Stability: Mean of the Differences in Keratometry
 (All US Eyes With 1, 3, 6, 9, and 12-Month Visits, n = 105)

	1 and 3 M		3 and 6 M		6 and 9 M		9 and 12 M	
	n	%	n	%	n	%	n	%
≤ 1.00 D	78	74.3	90	85.7	97	92.4	105	100
Mean Difference	-0.54		-0.22		-0.11		-0.03	
SD	0.88		0.69		0.47		0.35	
95% CI	-0.38 -0.71		-0.09 -0.35		-0.02 -0.20		0.04 -0.09	

The stability of the keratometry means when compared to their corresponding manifest spherical equivalent means and the predictive value of age are most significant and indicate the role of accommodative variation as the most probable factor in the apparent instability of measurement of the refractive state. This supports the overall stability of the induced corneal change.

Table 3-30 presents a combination of eyes with pre-operative refractive errors between +1.00 D and +6.00 D (n = 145) from both the U.S. and Canadian studies that were treated identically and had follow-up visits at 3, 6, 9, and 12 months post-operatively.

Table 3-30 — Hyperopia: Refractive Stability: Mean of the Differences in MRSE
 (All Eyes +1 to +6 D With Visits 3 to 12 Months, n = 145)

Mean Pre SE +2.54 D	3 to 6 M		6 to 9 M		9 to 12 M	
	n	%	n	%	n	%
≤ 1.00 D	134	92.4	140	96.6	142	97.9
Mean Difference	0.34		0.15		0.11	
SD	0.53		0.46		0.42	
95% CI	0.25 0.42		0.08 0.22		0.04 0.18	

4) Predictability of Outcome

Predictability of outcome was determined by comparing the intended MRSE with the achieved MRSE at each visit. Since target MRSE is not a factor in determining the accuracy of the procedure, all eyes were used in this analysis. Table 3-31 presents predictability of outcome as measured by post-operative manifest refraction spherical equivalent within ± 1.00 D and ± 0.50 D.

Table 3-31 — Hyperopia: Predictability of Outcome: Intended vs. Achieved (All Eyes)

	1 M (n = 222)		3 M (n = 213)		6 M (n = 201)		9 M* (n = 116)		12 M (n = 115)	
	n	%	n	%	n	%	n	%	n	%
Within 0.50 D	78	35.1	119	55.9	149	74.1	91	78.4	87	75.7
Within 1.00 D	144	64.9	172	80.8	182	90.5	111	95.7	106	92.2

*One eye did not have a refraction at this visit.

5) Adverse Events

Refer to Table 2-4 in Section 2.5.1.

3.1.5 Hyperopia with Astigmatism

A prospective, non-randomized, unmasked, multicenter PRK clinical study was conducted. The refractive inclusion criteria specified that the primary eye have naturally occurring hyperopia of between +0.5 and +6.0 D sphere at the spectacle plane with between +0.5 and +4.0 D of refractive astigmatism at the spectacle plane, as determined by manifest refraction. The difference between the manifest and cycloplegic refractions may be no more than 0.75 D and no more than 15 degrees (axis). There were a total of 172 patients treated in the United States. 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; use of systemic medications likely to affect wound healing; or immunocompromised status.

A. About the Study

Analyses of results were performed for 1, 3, 6, 9, and 12 months visits. Effectiveness analyses included distance uncorrected visual acuity, uncorrected near acuity, refractive error, stability of outcome, predictability of outcome, and cylinder correction analysis.

Additional parameters were analyzed by examining best spectacle visual acuity, change in best spectacle visual acuity, haze, intraocular pressure, induced astigmatism, contrast sensitivity, endothelial cell study, adverse events, and complications.

B. Patient Accountability

Two hundred and seventy-six (276) eyes of 172 subjects treated at seven centers in the United States were used for safety and effectiveness analyses. Subject accountability was 99%, 93%, and 88% at 6, 9, and 12 months.

C. Data Analysis and Results

1) Summary of Safety and Effectiveness

The key safety and effectiveness variables over time are presented in Table 3-32. The key safety and effectiveness variables stratified by pre-op MRSE at 12 months are presented in Table 3-33.

Table 3-32 — Hyperopia with Astigmatism: Summary of Key Safety and Effectiveness Variables Over Time

Criteria	1 M		3 M		6 M		9 M		12 M	
	n	% (95% CI)								
Visual Acuity										
n = 192 [†]	n = 191		n = 188		n = 190		n = 178		n = 167	
UCVA 20/20 or better	30	15.7 (10.5, 20.9)	85	45.2 (38.1, 52.3)	114	60.0 (53.0, 67.0)	109	61.2 (54.1, 68.4)	98	58.7 (51.2, 66.2)
UCVA 20/40 or better	136	71.2 (64.8, 77.6)	171	91.0 (86.9, 95.1)	187	98.4 (96.6, 100)	174	97.8 (95.6, 99.9)	163	97.8 (95.3, 99.9)
n = 234 [‡]	n = 233		n = 230		n = 231		n = 218		n = 205	
UCVA 20/20 or better	31	13.3 (8.9, 17.7)	87	37.8 (31.6, 44.1)	116	50.2 (43.8, 56.7)	113	51.8 (45.2, 58.5)	100	48.8 (41.9, 55.6)
UCVA 20/40 or better	160	68.7 (62.7, 74.6)	205	89.1 (85.1, 93.2)	223	96.5 (94.2, 98.9)	208	95.4 (92.6, 98.2)	195	95.1 (92.2, 98.1)
n = 252	n = 251		n = 248		n = 249		n = 231		n = 217	
MRSE \pm 0.50 D	84	33.5 (27.6, 39.3)	157	63.3 (57.3, 69.3)	159	63.9 (57.9, 69.8)	144	62.3 (56.1, 68.6)	132	60.8 (54.3, 67.3)
MRSE \pm 1.00 D	178	70.9 (65.3, 76.5)	215	86.7 (82.5, 90.9)	217	87.1 (83.0, 91.3)	187	81.0 (75.9, 86.0)	166	76.5 (70.9, 82.1)
MRSE \pm 2.00 D	231	92.0 (88.7, 95.4)	242	97.6 (95.7, 99.5)	244	98.0 (96.2, 99.7)	226	97.8 (96.0, 99.7)	210	96.8 (94.4, 99.1)
Stability (MRSE)										
n = 207 ^{**}			n = 207							
Change \leq 1.00 D			167	80.7 (75.3, 86.1)	176	85.0 (80.2, 89.9)	196	94.7 (91.6, 97.7)	198	95.7 (92.9, 98.4)
Mean			0.53		0.44		0.19		0.11	
Safety (ADSD-DE)										
n = 276	n = 275		n = 272		n = 272		n = 254		n = 237	
Loss of \geq 2 Lines BSCVA	37	13.5 (9.4, 17.5)	8	2.9 (0.9, 4.9)	6	2.2 (0.5, 4.0)	3	1.2 (0.0, 2.5)	1	0.4 (0.0, 1.2)
Loss of $>$ 2 Lines BSCVA	22	8.0 (4.8, 11.2)	5	1.8 (0.2, 3.4)	4	1.5 (0.0, 2.9)	0	0.0 (0.0, 6.1)	0	0.0 (0.0, 6.4)
BSCVA worse than 20/40	6	2.2 (0.5, 3.9)	1	0.4 (0.0, 1.1)	2	0.7 (0.0, 1.8)	2	0.8 (0.0, 1.9)	1	0.4 (0.0, 1.2)
Increase $>$ 2 D Cylinder	0	0.0 (0.0, 5.9)	0	0.0 (0.0, 5.9)	0	0.0 (0.0, 5.9)	0	0.0 (0.0, 6.1)	0	0.0 (0.0, 6.4)
n = 220 [†]	n = 219		n = 216		n = 217		n = 201		n = 188	
BSCVA worse than 20/40	1	0.5 (0.0, 1.3)	0	0.0 (0.0, 6.7)	0	0.0 (0.0, 6.7)	0	0.0 (0.0, 6.9)	0	0.0 (0.0, 7.1)

* 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 3-33 — Summary of Key Safety and Effectiveness Variables Stratified by Pre-Op MRSE (12 Months)

Criteria	1 to 1.99	2 to 2.99	3 to 3.99	4 to 4.99	5 to 5.99	6 to 6.99	7 to 7.99	Cum Total
	n/N, (%) (%CI)	n/N, (%) (%CI)	n/N, (%) (%CI)	n/N, (%) (%CI)				
Effectiveness Variables								
n = 167	n = 37	n = 53	n = 37	n = 26	n = 12	n = 2		n = 167
UCVA 20/40 or better*†	36 97.3 (92.1, 100)	52 98.1 (94.5, 100)	35 94.6 (87.3, 100)	26 100 (80.8, 100)	12 100 (71.7, 100)	2 100 (30.7, 100)		163 97.6 (95.3, 99.9)
n = 205	n = 40	n = 59	n = 48	n = 34	n = 20	n = 4		n = 205
UCVA 20/40 or better*‡	39 97.5 (92.7, 100)	57 96.6 (92.0, 100)	44 91.7 (83.8, 99.5)	33 97.1 (91.4, 100)	18 90.0 (76.9, 100)	4 100 (51.0, 100)		195 95.1 (92.2, 98.1)
n = 217	n = 41	n = 63	n = 53	n = 34	n = 22	n = 4		n = 217
MRSE +/- 0.50 D	32 78.0 (65.4, 90.7)	40 63.5 (51.6, 75.4)	30 56.6 (43.3, 69.9)	18 52.9 (36.2, 69.7)	9 40.9 (20.4, 61.5)	3 75.0 (32.6, 100)		132 60.8 (54.3, 67.3)
MRSE +/- 1.00 D	39 95.1 (88.5, 100)	52 82.5 (73.2, 91.9)	38 71.7 (59.6, 83.8)	24 70.6 (55.3, 85.9)	10 45.5 (24.6, 66.3)	3 75.0 (32.6, 100)		166 76.5 (70.9, 82.1)
Safety Variables								
n = 237	n = 41	n = 63	n = 53	n = 34	n = 28	n = 12	n = 6	n = 237
Loss of ≥ 2 Lines BSCVA	0 0.0 (0.0, 15.3)	0 0.0 (0.0, 12.3)	0 0.0 (0.0, 13.5)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 18.5)	0 0.0 (0.0, 28.3)	1 16.7 (0.0, 46.5)	1 0.4 (0.0, 1.2)
Loss of > 2 lines BSCVA	0 0.0 (0.0, 15.3)	0 0.0 (0.0, 12.3)	0 0.0 (0.0, 13.5)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 18.5)	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 40.0)	0 0.0 (0.0, 6.4)
BSCVA Worse than 20/40	0 0.0 (0.0, 15.3)	0 0.0 (0.0, 12.3)	1 1.9 (0.0, 5.5)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 18.5)	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 40.0)	1 0.4 (0.0, 1.2)
n = 188	n = 38	n = 57	n = 41	n = 26	n = 17	n = 6	n = 3	n = 188
BSCVA Worse than 20/40†	0 0.0 (0.0, 15.9)	0 0.0 (0.0, 13.0)	0 0.0 (0.0, 15.3)	0 0.0 (0.0, 19.2)	0 0.0 (0.0, 23.8)	0 0.0 (0.0, 40.0)	0 0.0 (0.0, 56.6)	0 0.0 (0.0, 7.1)

*Excluding eyes intentionally overcorrected for monovision.

†BSCVA 20/20 or better pre-operatively.

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

2) Stability of Outcome

Tables 3-34 through 3-37 present stability of MRSE, Avg K, mean MRSE over time, and mean MRSE at 12 months stratified by diopter of pre-operative MRSE.

Table 3-34 — Hyperopia with Astigmatism: Stability of MRSE (Eyes with 1, 3, 6, 9, and 12-month visits, n = 207)

MRSE	1 and 3M		3 and 6M		6 and 9M		9 and 12M	
	n	% (95% CI)						
Change ≤ 1.00 D	165	79.7 (74.2, 85.2)	176	85.0 (80.2, 89.9)	196	94.7 (91.6, 97.7)	198	95.7 (92.9, 98.4)
Mean	0.53		0.44		0.19		0.11	
SD	0.74		0.58		0.51		0.49	
95% CI	(0.43, 0.63)		(0.36, 0.52)		(0.12, 0.26)		(0.04, 0.18)	

Table 3-35 — Hyperopia with Astigmatism: Stability of Avg K (Eyes with 1, 3, 6, 9, and 12-month visits, n = 207)

Avg K	1 and 3M		3 and 6M		6 and 9M		9 and 12M	
	n	% (95% CI)						
Change ≤ 1.00 D	161	77.8 (72.1, 83.4)	187	91.2 (86.3, 94.4)	188	92.6 (86.9, 94.8)	201	98.0 (94.8, 99.4)
Mean	-0.50		-0.35		-0.19		-0.08	
SD	0.86		0.51		0.50		0.41	
95% CI	(-0.62, -0.38)		(-0.42, -0.28)		(-0.26, -0.12)		(-0.13, -0.02)	

To evaluate mean MRSE over time it is important to consider only those eyes targeted for emmetropia at each visit. Between 9 and 12 months 95.7% of eyes changed no more than one diopter of MRSE with a mean change of 0.11 D. Figure 1 presents the mean of the differences in MRSE and Avg K.

Figure 1 — Stability: Mean of the Differences MRSE and Avg K

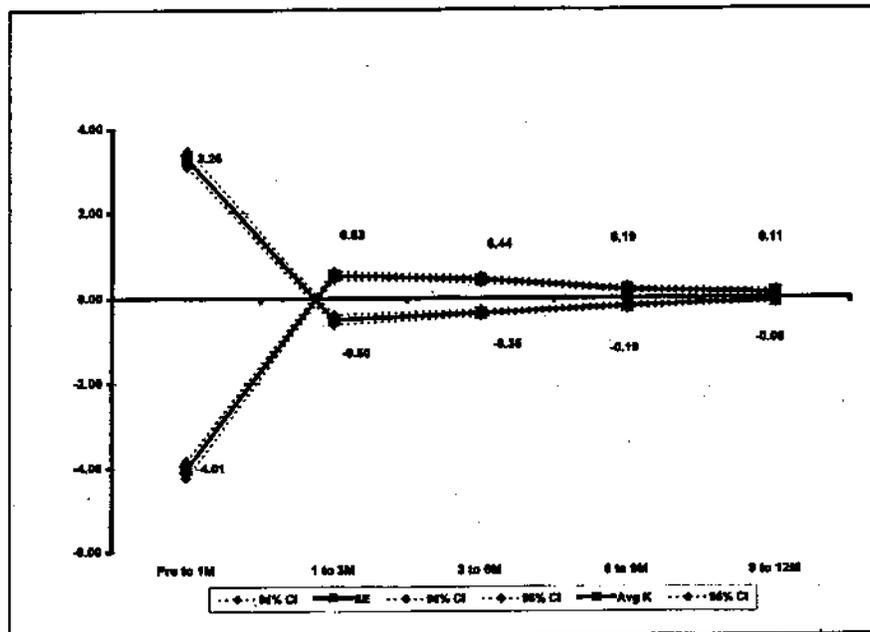


Table 3-36 — Hyperopia with Astigmatism: Mean MRSE Over Time for Eyes Targeted for Emmetropia (n = 234)

MRSE (D)	1 M (n = 233)	3 M (n = 230)	6 M (n = 231)	9 M (n = 218)	12 M (n = 205)
Mean	-0.75	-0.18	0.20	0.38	0.50
SD	0.81	0.64	0.61	0.67	0.70
95% CI	(-0.65, -0.85)	(-0.09, -0.26)	(0.28, 0.12)	(0.47, 0.29)	(0.59, 0.40)

Table 3-37 — Hyperopia with Astigmatism: Mean MRSE at 12 Months Stratified by Diopter of Pre-Operative MRSE (Eyes Targeted for Emmetropia, n = 205)

MRSE (D)	1 to 1.99 (n = 40)	2 to 2.99 (n = 59)	3 to 3.99 (n = 48)	4 to 4.99 (n = 34)	5 to 5.99 (n = 20)	6 to 6.99 (n = 4)
Mean	0.31	0.34	0.59	0.58	0.95	0.72
SD	0.53	0.59	0.74	0.77	0.82	1.17
95% CI	(0.14, 0.47)	(0.19, 0.49)	(0.38, 0.80)	(0.32, 0.84)	(0.59, 1.31)	(-0.43, 1.87)

3) Uncorrected Visual Acuity (UCVA)

Pre-operatively, 0.4% (1/234) and 7.3% (17/234) eyes were 20/20 and 20/40, respectively. Post-operatively, 50.2% (116/231), 51.8% (113/218), and 48.8% (100/205) eyes had a UCVA of 20/20 or better at 6, 9, and 12 months. In addition, 96.5% (223/231), 95.4% (208/218), and 95.1% (195/205) eyes had a UCVA of 20/40 or better at 6, 9, and 12 months. Table 3-38 presents the distance uncorrected visual acuity of eyes targeted for emmetropia over time.

Table 3-38 — Hyperopia with Astigmatism: UCVA Over Time (Eyes Targeted for Emmetropia, n = 234)

	Pre-Op (n = 234)		1 M (n = 233)		3 M (n = 230)		6 M (n = 231)		9 M (n = 218)		12 M (n = 205)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
20/20 or better	1	0.4 (0.0, 1.3)	31	13.3 (8.9, 17.7)	87	37.8 (31.6, 44.1)	116	50.2 (43.8, 56.7)	113	51.8 (45.2, 58.5)	100	48.8 (41.9, 55.6)
20/25 or better	2	0.9 (0.0, 2.0)	70	30.0 (24.2, 35.9)	140	60.9 (54.6, 67.2)	164	71.0 (65.1, 76.8)	158	72.5 (66.5, 78.4)	140	68.3 (61.9, 74.7)
20/32 or better	5	2.1 (0.3, 4.0)	124	53.2 (46.8, 59.6)	178	77.4 (72.0, 82.8)	203	87.9 (83.7, 92.1)	188	86.2 (81.7, 90.8)	173	84.4 (79.4, 89.4)
20/40 or better	17	7.3 (3.9, 10.6)	160	68.7 (62.7, 74.6)	205	89.1 (85.1, 93.2)	223	96.5 (94.2, 98.9)	208	95.4 (92.6, 98.2)	195	95.1 (92.2, 98.1)
20/53 or better	73	31.2 (25.3, 37.1)	224	96.1 (93.7, 98.6)	228	99.1 (97.9, 100)	231	100 (93.6, 100)	216	99.1 (97.8, 100)	202	98.5 (96.9, 100)
20/80 or better	97	41.5 (35.1, 47.8)	229	98.3 (96.6, 100)	229	99.6 (98.7, 100)	231	100 (93.6, 100)	218	100 (93.4, 100)	205	100 (93.2, 100)
20/200 or better	209	89.3 (85.4, 93.3)	233	100 (93.6, 100)	230	100 (93.5, 100)	231	100 (93.6, 100)	218	100 (93.4, 100)	205	100 (93.2, 100)
Worse than 20/200	25	10.7 (6.7, 14.6)	0	0.0 (0.0, 6.4)	0	0.0 (0.0, 6.5)	0	0.0 (0.0, 6.4)	0	0.0 (0.0, 6.6)	0	0.0 (0.0, 6.8)

4) Predictability of Outcome

Predictability of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At 6 months or later no eye was overcorrected by more than 2 D while approximately 2.0% of eyes were undercorrected by more than 2 D. The target outcomes for accuracy of MRSE (50% within 0.50 D and 75% within 1.00 D of attempted correction) are exceeded at 3 months and later. Table 3-32 (see section C.1) presents the accuracy of MRSE over time. Table 3-39 presents the number and percentage of eyes over and undercorrected over time. Table 3-40 presents this information at 12 months stratified by pre-operative MRSE.

Table 3-39 — Hyperopia with Astigmatism: Predictability of Outcome — Attempted vs. Achieved (n = 252)

	Pre-Op (n = 252)		1 M (n = 251)		3 M (n = 248)		6 M (n = 249)		9 M (n = 231)		12 M (n = 217)	
	n	%	n	%	n	%	n	%	n	%	n	%
	(95% CI)		(95% CI)		(95% CI)		(95% CI)		(95% CI)		(95% CI)	
Overcorrected												
<-1.00 D	0	0.0	65	25.9	21	8.5	4	1.6	3	1.3	4	1.8
	(0.0, 6.2)		(20.5, 31.3)		(5.0, 11.9)		(0.0, 3.2)		(0.0, 2.8)		(0.1, 3.6)	
<-2.00 D	0	0.0	18	7.2	2	0.8	0	0.0	0	0.0	0	0.0
	(0.0, 6.2)		(4.0, 10.4)		(0.0, 1.9)		(0.0, 6.2)		(0.0, 6.4)		(0.0, 6.7)	
Undercorrected												
>+1.00 D	0	0.0	8	3.2	12	4.8	28	11.2	41	17.7	47	21.7
	(0.0, 6.2)		(1.0, 5.4)		(2.2, 7.5)		(7.3, 15.2)		(12.8, 22.7)		(16.2, 27.1)	
>+2.00 D	0	0.0	2	0.8	4	1.6	5	2.0	5	2.2	7	3.2
	(0.0, 6.2)		(0.0, 1.9)		(0.0, 3.2)		(0.3, 3.8)		(0.3, 4.0)		(0.9, 5.6)	



Table 3-40 — Hyperopia with Astigmatism: Accuracy of MRSE: Attempted vs. Achieved at 12 Months Stratified by Diopter of Pre-Op MRSE

	1 to 1.99 (n = 41)	2 to 2.99 (n = 63)	3 to 3.99 (n = 53)	4 to 4.99 (n = 34)	5 to 5.99 (n = 22)	6 to 6.99 (n = 4)	Cum Total (n = 217)
	n/N % (% CI)	n/N % (% CI)	n/N % (% CI)	n/N % (% CI)	n/N % (% CI)	n/N % (% CI)	n/N % (% CI)
Overcorrected							
<-1.00 D	0 0.0 (0.0, 15.4)	3 4.8 (0.0, 10.0)	0 0.0 (0.0, 13.5)	1 2.9 (0.0, 8.6)	0 0.0 (0.0, 20.9)	0 0.0 (0.0, 49.0)	4 1.8 (0.0, 3.6)
<-2.00 D	0 0.0 (0.0, 15.4)	0 0.0 (0.0, 12.3)	0 0.0 (0.0, 13.5)	0 0.0 (0.0, 16.8)	0 0.0 (0.0, 20.9)	0 0.0 (0.0, 49.0)	0 0.0 (0.0, 6.7)
Undercorrected							
>+1.00 D	2 4.9 (0.0, 11.5)	8 12.7 (4.5, 20.9)	15 28.3 (16.2, 40.4)	9 26.5 (11.6, 41.3)	12 54.5 (33.7, 75.4)	1 25.0 (0.0, 67.4)	47 21.7 (16.2, 27.1)
>+2.00 D	1 2.4 (0.0, 7.2)	0 0.0 (0.0, 12.3)	2 3.8 (0.0, 8.9)	1 2.9 (0.0, 8.6)	2 9.1 (0.0, 21.1)	1 25.0 (0.0, 67.4)	7 3.2 (0.9, 5.6)

Predictability of outcome was also evaluated by analysis of attempted versus achieved manifest refractive cylinder and sphere. At 1 month post-operatively, cylinder correction easily met minimum target values and at 3 months so did the spherical component of the refraction. Of the 217 eyes examined at 12 months post-operatively, 67.3% (146) of eyes were within 0.50 D and 84.8% (184) were within 1.00 D of attempted sphere correction, and 65.9% (143) of eyes were within 0.50 D and 93.1% (202) were within 1.00 D of attempted cylinder correction.



5) Cylinder Correction Analysis

Table 3-41 presents the cylinder vector magnitude at 12 months for all eyes targeted for emmetropia. There was a mean intended refractive change (IRC) of 1.6 D cylinder. At the final visit, there was a mean surgically induced refractive change (SIRC) of 1.55 D cylinder. The SIRC/IRC indicates surgical efficiency of 97% in the reduction of cylinder. Table 3-42 presents cylinder correction efficacy stratified by pre-operative cylinder at 12 months.

Table 3-41 — Hyperopia with Astigmatism: Cylinder Vector Magnitude at 12 Months, n = 207

	Pre	Post	IRC	SIRC	SIRC/IRC
Mean	1.46	0.45	-1.59	-1.55	0.97
Median	1.25	0.50	-1.30	-1.30	1.00
SD	0.92	0.48	1.02	0.99	
Min	0.50	0.00	-4.71	-4.97	
Max	4.00	3.25	-0.52	-0.02	

Table 3-42 — Hyperopia with Astigmatism: Cylinder Correction Efficacy Stratified by Pre-Operative Cylinder at 12 Months

Pre-Operative Cylinder	Percent Reduction of Absolute Cylinder (Not a Vector)	Achieved vs Intended Vector Magnitude Ratio (SIRC/IRC)
≤ 1.0 D	52% (0.36/0.75)	112% (-0.91/-0.81)
> 1.0 to ≤ 2.0 D	72% (0.45/1.61)	90% (-1.59/-1.76)
> 2.0 to ≤ 3.0 D	76% (0.63/2.58)	95% (-2.71/-2.86)
> 3.0 to ≤ 3.0 D	78% (0.78/3.57)	92% (-3.57/3.89)
Total	69% (0.45/1.46)	98% (-1.55/-1.59)

Pre-operatively, 47.1% of eyes had less than 1 D of astigmatic error.

The residual astigmatic error was evaluated at the point of stability (12 months). At that time, 77.9% (180/231) had less than 1 D of residual astigmatic error, and 41.9% of eyes had no residual error at 12 months post-operatively. Table 3-43 presents the residual astigmatic error at 12 months.

Table 3-43 — Hyperopia with Astigmatism (PRK): Residual Astigmatic Error at 12 Months

Residual Cylinder Magnitude	Absolute Shift in Axis						
	0	0 to ≤ 5	>5 to ≤ 10	>10 to ≤ 15	>15 to ≤ 30	>30	Total
	(n = 77)	(n = 81)	(n = 3)	(n = 11)	(n = 13)	(n = 32)	(n = 217)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
0.0	77 100 (88.8, 100)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 56.6)	0 0.0 (0.0, 29.5)	0 0.0 (0.0, 27.2)	0 0.0 (0.0, 17.3)	77 35.5 (29.1, 41.9)
>0.0 to <0.5	0 0.0 (0.0, 11.2)	19 23.5 (14.2, 32.7)	1 33.3 (0.0, 86.7)	0 0.0 (0.0, 29.5)	2 15.4 (0.0, 35.0)	6 18.8 (5.2, 32.3)	28 12.9 (8.4, 17.4)
≥ 0.5 to <1.0	0 0.0 (0.0, 11.2)	39 48.1 (37.3, 59.0)	2 66.7 (13.3, 100)	7 63.6 (35.2, 92.1)	6 46.2 (19.1, 73.3)	21 65.6 (49.2, 82.1)	75 34.6 (28.2, 40.9)
≥ 1.0 to <2.0	0 0.0 (0.0, 11.2)	21 25.8 (16.4, 35.5)	0 0.0 (0.0, 56.6)	3 27.3 (1.0, 53.6)	5 38.5 (12.0, 64.9)	5 15.6 (3.0, 28.2)	34 15.7 (10.8, 20.5)
≥ 2.0 to <3.0	0 0.0 (0.0, 11.2)	2 2.5 (0.0, 5.8)	0 0.0 (0.0, 56.6)	0 0.0 (0.0, 29.5)	0 0.0 (0.0, 27.2)	0 0.0 (0.0, 17.3)	2 0.9 (0.0, 2.2)
≥ 3.0	0 0.0 (0.0, 11.2)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 56.6)	1 9.1 (0.0, 26.1)	0 0.0 (0.0, 27.2)	0 0.0 (0.0, 17.3)	1 0.5 (0.0, 1.4)

6) Patient Symptoms

Patient questionnaires reflected the following patient symptoms after treatment.

Table 3-44—Hyperopia with Astigmatism: Patient Symptoms: Comparison of Vision After Surgery (All Eyes with a Pre-Operative Sphere ≤ 5.0 and Questionnaire, n = 206)

	6 M (n = 203)				12 M (n = 180)			
	Improve (≥ 2)*	No Change (0 \pm 1)	Worsen (≤ -2)*	NR	Improve (≥ 2)*	No Change (0 \pm 1)	Worsen (≤ -2)*	NR
	n %	n %	n %	n	n %	n %	n %	n
Sharpness and Clarity	39 19.2	157 77.3	7 3.4	0	34 18.9	135 75.0	11 6.1	0
Consistency of Vision	68 33.5	131 64.5	4 2.0	0	54 30.0	123 68.3	3 1.7	0
Sustained Close Work	26 12.9	162 80.6	13 6.5	2	23 12.8	137 76.5	19 10.6	1
Daylight Driving	55 27.4	140 69.7	6 3.0	2	56 31.3	114 63.7	9 5.0	1
Night Driving	63 31.2	133 65.8	6 3.0	1	57 32.0	115 64.6	6 3.4	2
Night Vision with Glare	74 36.8	122 60.7	5 2.5	2	62 34.8	109 61.2	7 3.9	2
Reading in Dim Light	36 17.9	157 78.1	8 4.0	2	28 15.7	134 75.3	16 9.0	1
General Vision in Dim Light	17 8.5	165 82.9	17 8.5	4	18 10.1	135 75.8	25 14.0	2
Overall Visual Comfort	178 88.6	23 11.4	0 0.0	2	148 82.7	31 17.3	0 0.0	1

* This table reflects the responses to a patient questionnaire on a scale of 1 (poor) to 5 (excellent). Responses at 6 and 12 months were compared to the pre-operative responses. The results presented reflect changes in response from baseline.

7) Adverse Events

Refer to Table 2-5 in Section 2.5.1.

Facts You Need to Know About Laser Assisted In Situ Keratomileusis (LASIK) Surgery and Photorefractive Keratectomy (PRK)

Patient Information Booklet

LASIK:

**Nearsighted Patients (0 to -14.0 diopters) with or without
-0.5 to -5.0 Diopters of Astigmatism**

PRK:

**Nearsighted Patients (-1.0 to -12.0 diopters) or
Nearsighted Patients (0 to -12.0 diopters) with
up to -4.0 Diopters of Astigmatism**

**Farsighted Patients (+1.0 to +6.0 diopters) with
no more than 1.0 Diopter of Refractive Astigmatism**

**Farsighted Patients (+0.5 to +5.0 diopters) with
+0.5 to +4.0 Diopters of Refractive Astigmatism**

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

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Introduction

The information in this booklet is to help you decide whether to have Photorefractive Keratectomy (PRK) or Laser Assisted In Situ Keratomileusis (LASIK) laser surgery. PRK may be used to correct or partly correct your nearsightedness (myopia) with or without astigmatism or farsightedness (hyperopia) with or without astigmatism. LASIK may be used to correct or partly correct your nearsightedness with or without astigmatism. Some other ways to correct nearsightedness, farsightedness, and astigmatism are glasses, contact lenses, and other kinds of refractive surgery such as radial keratotomy (RK) or automated lamellar keratectomy (ALK). LASIK and PRK are completely different from RK and ALK.

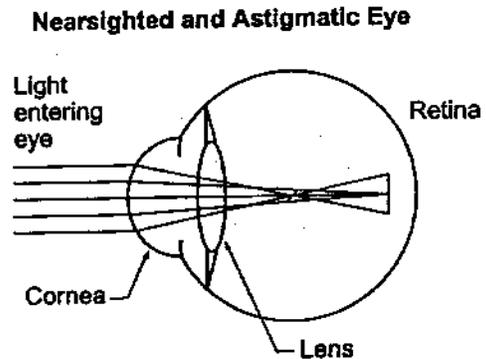
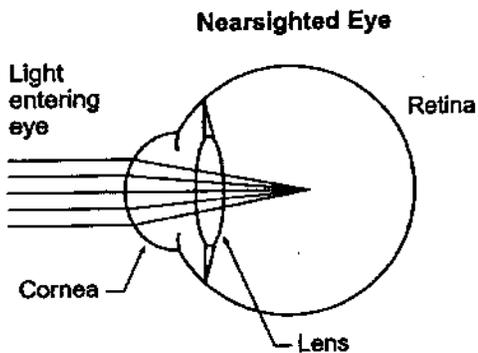
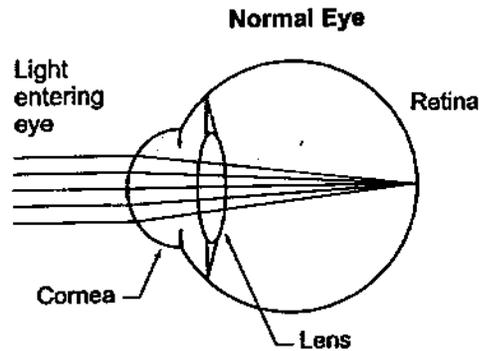
If both of your eyes are nearsighted with or without astigmatism, your doctor may recommend LASIK or PRK surgery for both eyes. If both of your eyes are farsighted with or without astigmatism, your doctor may recommend PRK surgery for both eyes. However, sometimes it is better to have LASIK or PRK done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Please read this booklet completely. Discuss any questions with your doctor before you decide if laser vision correction is right for you. Only an eye care professional trained in laser vision correction can determine whether you are a suitable candidate. Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.

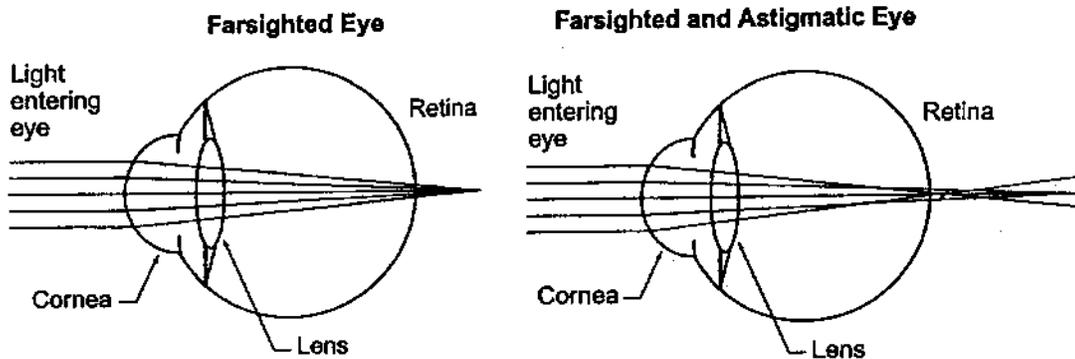
How the Eye Functions

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred. This condition is called nearsightedness, or myopia. Myopia usually starts in childhood and gets progressively worse through adolescence. It usually stops changing by the late teens, but it can sometimes continue to get worse into the mid-twenties.

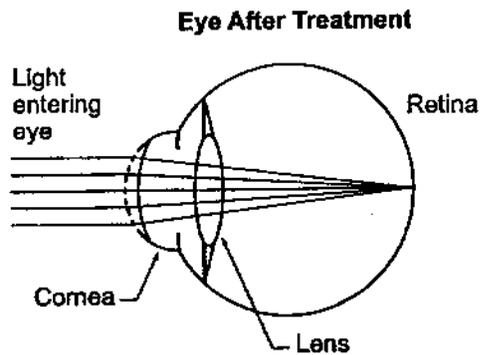
In astigmatism the image does not come to a point focus on the retina, but there are at least two points of focus that are differing distances from the retina.



In farsightedness the image focuses beyond the retina. In our youth, the innate accommodating (focusing) power of the eyes often compensates for farsightedness. But as we age, our eyes become less able to accommodate. For this reason, farsightedness most commonly becomes a problem later in life. Many farsighted eyes do not need correction until the individuals reach their forties or fifties.



Nearsightedness can be corrected by any method that reduces the total refractive power of the eye. Astigmatism correction makes all of the rays of light focus at the same distance so that they all fall right on the retina. Eyeglasses and contact lenses do this by putting in front of the eye "negative" lenses that are thicker at the edge than in the center. LASIK and PRK correct nearsightedness by flattening the central part of the cornea, and they correct astigmatism by flattening the central cornea by different amounts at different orientations to correct for the uneven focus of the rays of light.



Farsightedness can be corrected by any method that increases the total refractive power of the eye. Eyeglasses and contact lenses do this by putting in front of the eye "positive" lenses that are thicker in the center than at the edge. PRK does it by making the central part of the cornea more steeply curved, and it corrects astigmatism by steepening the central cornea by different amounts at different orientations to correct for the uneven focus of the rays of light.

During a regular eye examination, your doctor uses lenses to measure your nearsightedness, astigmatism, or farsightedness in units called diopters. The VISX STAR Excimer Laser Systems are approved for PRK treatments in correcting eyes with up to -12 diopters of nearsightedness with or without refractive astigmatism between 0.75 to 4.0 diopters. For farsightedness, the systems are approved for correcting eyes with up to +6.0 diopters of farsightedness without astigmatism, and up to +5.0 diopters of farsightedness with refractive astigmatism between 0.5 and 4.0 diopters. The VISX STAR Excimer Laser Systems are also approved for LASIK treatment in correcting eyes with up to -14 diopters of nearsightedness with or without refractive astigmatism between +0.5 and +5.0 diopters.

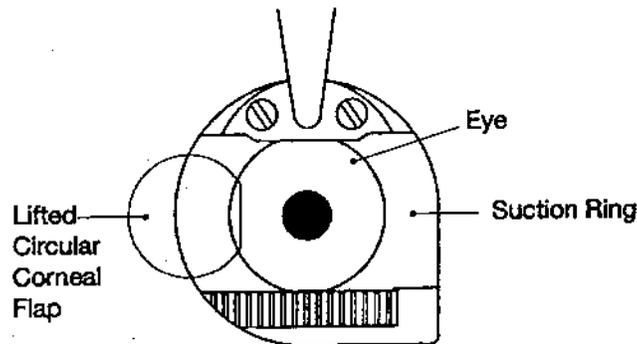
What are PRK and LASIK?

PRK is laser surgery to correct nearsightedness (myopia), nearsightedness with astigmatism, or farsightedness (hyperopia). For nearsightedness with or without astigmatism, an excimer laser beam is used to flatten the front of the cornea. The laser beam removes small amounts of tissue from the front of the cornea. For farsightedness, the excimer laser beam is used to steepen the front of the cornea. To do this, the laser beam removes small amounts of tissue from a ring-shaped area around the center of the cornea.

LASIK is laser surgery to correct nearsightedness with or without astigmatism. The surgery is similar to PRK, but does not treat or alter the front surface of the cornea. The doctor uses an instrument called a microkeratome to create a circular flap of corneal tissue. The flap is then lifted from the cornea while the doctor uses the excimer laser to remove

small amounts of underlying tissue from the exposed cornea. The corneal flap is then repositioned.

View of Microkeratome on Eye



An excimer laser produces a powerful beam of ultraviolet light. The laser is controlled by the doctor. It produces a series of rapid pulses that removes small amounts of corneal tissue. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, retina) undisturbed. PRK and LASIK differ from RK, which uses a knife to make deep cuts around the center of the cornea.

Benefits

- PRK surgery, as performed with the VISX STAR Systems, is effective in reducing nearsightedness between 0 and -12.0 diopters with or without refractive astigmatism between 0.75 and 4.0 diopters.
- LASIK surgery, as performed with the VISX STAR Systems, is effective in reducing nearsightedness between 0 and -14.0 diopters with or without refractive astigmatism between 0.5 and 5.0 diopters.
- PRK surgery, as performed with the VISX STAR Systems, is effective in reducing farsightedness between +1.0 and +6.0 diopters without astigmatism, and between +0.5 and +5.0 diopters of farsightedness with refractive astigmatism between +0.5 and +4.0 diopters.

- LASIK surgery may reduce overall nearsightedness and astigmatism, and it may also reduce or eliminate dependency upon contact lenses or glasses.
- PRK surgery may reduce overall nearsightedness, farsightedness, and astigmatism, and it may also reduce or eliminate dependency upon contact lenses or glasses.

Risks

As with any surgical procedure there are risks associated with laser vision correction. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional laser refractive surgery in the same eye.

IMPORTANT:

You may need reading glasses after laser surgery even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.

The First Week Following Surgery

- Moderate pain and discomfort may last for up to 4 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.

The First Two To Six Months Following Surgery

- Your intraocular pressure may increase due to use of anti-inflammatory medications. This is usually resolved by drug therapy or by stopping the anti-inflammatory medication.

- Your cornea may become hazy or cloudy enough to affect your vision. This haze typically disappears over time, but some patients may continue to experience haze.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail later in this booklet (see the section titled Long-Term Post-Treatment Safety Problems).

Contraindications

You should **NOT** have laser refractive surgery if:

- You have collagen vascular, autoimmune, or immunodeficiency diseases (for example, lupus or AIDS).
- You are pregnant or nursing.
- You show signs of keratoconus (corneal disease).
- You are taking one or both of the following medications:
 - Accutane* (isotretinoin).
 - Cordarone† (amiodarone hydrochloride).

Warnings

Your treatment result might not be as good with higher corrections of refractive error.

Discuss with your doctor if:

- Your nearsightedness, astigmatism, or farsightedness is changing.
- You are diabetic or have severe allergies.
- You have a history of *Herpes simplex* or *Herpes zoster* of the eye.

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

† Cordarone is a registered trademark of Sanofi.

Precautions

The PRK clinical trials included only 21 out of 200 eyes with nearsightedness between -10 and -12 diopters and 13 out of 275 eyes with farsightedness between +4 and +6 diopters. These populations were not sufficient to determine the level of effectiveness and complication rate for patients with severe nearsightedness and severe farsightedness.

If you have more than +4.0 D of farsightedness with or without astigmatism, there is a greater chance that your farsightedness may return. For patients with farsightedness with astigmatism, there is a 36% chance of being significantly (1 diopter or more) farsighted at 1 year after surgery.

The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined. Following laser refractive surgery, you may 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. If you are under age 30 or have a large pupil size and have laser refractive surgery for treatment of astigmatism, you will be more likely to experience problems with your vision under poor lighting conditions.

The safety and effectiveness of the VISX STAR Excimer Laser Systems have **NOT** been established:

- In eyes with corneal disease or abnormality (for example, scar, infection, etc.).
- In eyes with previous surgery or injury to the center of the cornea where the surgery will be performed.
- For hyperopia (farsightedness) treatment of patients with refractions less than +0.5 D.
- In eyes with progressive nearsightedness, astigmatism, or farsightedness.
- In eyes with abnormal blood vessels within 1.0 mm of the cornea area where PRK or LASIK will be performed.

- In patients under 18 years of age for mild nearsightedness and under 21 years of age for high nearsightedness with or without astigmatism and farsightedness.
- In patients over the long term. (For PRK surgery: 3 years for nearsightedness, more than 1 year for highly nearsightedness with or without astigmatism, or 1 year for farsightedness with or without astigmatism. For LASIK surgery: 6 months for nearsightedness with or without astigmatism.)
- In patients who are taking sumatriptan (Imitrex*) for migraine.
- In patients who have a tendency to form scars.
- For PRK in patients with nearsightedness greater than -12.0 D, refractive astigmatism greater than 4.0 D, or farsightedness greater than +6.0 D.
- For LASIK in patients with nearsightedness greater than -14.0 D or refractive astigmatism greater than 5.0 D.
- In patients taking hormone replacement therapy or antihistamines who may experience delayed re-epithelialization of the cornea following surgery.
- In patients who have had prior incisional refractive surgery.
- For retreatment of farsightedness with astigmatism.

Are You a Good Candidate for Laser Vision Correction?

If you are considering laser vision correction, you must:

- Be at least 18 years of age for PRK treatment of mild nearsightedness or LASIK treatment of high nearsightedness with or without astigmatism.
- Be at least 21 years of age for PRK treatment of high nearsightedness with or without astigmatism or moderate farsightedness with or without astigmatism.

* Imitrex is a registered trademark of Glaxo Group Ltd.

- Have healthy eyes that are free from eye disease or corneal abnormality (for example, scar, infection, etc.).
- Have nearsightedness (myopia) up to -12.0 diopters with or without refractive astigmatism between 0.75 and 4.0 diopters for PRK treatment.
- Have farsightedness (hyperopia) between +1.0 and +6.0 diopters without astigmatism, or farsightedness between +0.5 and +5.0 diopters with refractive astigmatism between +0.5 and +4.0 diopters for PRK treatment.
- Have nearsightedness up to -14.0 diopters with or without refractive astigmatism between 0.5 and 5.0 diopters for LASIK treatment.
- Have documented evidence that your refraction did not change by more than 0.50 diopter during the year before your pre-operative examination.
- Be informed of PRK or LASIK risks and benefits as compared to other available treatments for nearsightedness (myopia) with or without astigmatism and farsightedness (hyperopia).
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be able to keep your eye accurately on the fixation light for the entire PRK or LASIK procedure.
- Be willing to sign an informed consent form as provided by your eye care professional.

Before the Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for surgery. This will include a complete physical and eye history, and thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks before examination and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce suboptimal surgical results.

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

The Day of Surgery

Before the surgery you will be asked to listen to the sounds of the treatment so that you will be prepared for the noise the laser makes during surgery. Anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery.

The PRK surgery begins with removal of the epithelium, the top layer of the cornea. This is done either with the laser or with a small spatula.

The LASIK surgery begins with the placement of a suction ring which elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The movement of the

microkeratome in the track of the suction ring cuts a circular corneal flap. This flap of tissue will be lifted by the doctor after the suction is released. Vision will return to the eye after the suction is released.

For both PRK and LASIK surgery, the doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking red light. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the blinking red light. Small amounts of tissue will then be removed from your cornea using the VISX STAR Excimer Laser System.

PRECAUTION:

It is very important that you keep looking at the blinking red light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this red, blinking light throughout the treatment to prevent the laser vision correction from being off target.

Typically, the laser beam will be applied to your eye less than 1 minute and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drops. If PRK surgery was performed, a bandage contact lens or a patch may be placed on your eye.

When the anesthetic drops wear off (about 45 to 60 minutes), your eye may hurt moderately for 1 to 4 days if PRK surgery was performed. Most patients describe this pain as moderate to severe. In LASIK surgery, the discomfort is less severe, typically described as "a sandy sensation." Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and to lessen the risk of infection, do **NOT** rub your eyes for the first 3 to 5 days after PRK surgery and for 3 to 5 months after LASIK surgery.

IMPORTANT:

Your doctor will monitor you for any side effects if topical steroids were used. Possible side effects of prolonged topical steroid use are ocular hypertension, glaucoma, or cataract formation.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for the first 4 days. Sunglasses may make you more comfortable during this time.

Your vision should become stable within the first several weeks after surgery. However, you may experience some small changes (for example, improvement or worsening of your vision). These changes may occur up to six months or more after surgery.

A haze or cloudiness may be seen in the cornea following surgery, but usually does not affect your vision. This haze typically disappears over time, but some patients may continue to experience haze.

IMPORTANT:

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

Results from Clinical Studies

The clinical study results of the VISX STAR Excimer Laser System were:

A. PRK surgery: without the help of glasses (results at 12 months after surgery)

- 94% mildly nearsighted eyes could see 20/40 or better
- 91% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 90% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 95% moderately farsighted eyes could see 20/40 or better
- 93% moderately farsighted eyes with moderate astigmatism could see 20/40 or better

B. PRK surgery: with the help of glasses* (results at 12 months after surgery)

- 99% mildly nearsighted eyes could see 20/40 or better
- 98% mildly nearsighted eyes with astigmatism could see 20/40 or better
- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better
- 99% moderately farsighted eyes could see 20/40 or better
- 100% moderately farsighted eyes with moderate astigmatism could see 20/40 or better

C. LASIK surgery: without the help of glasses (results at 6 months after surgery)

- 97% highly nearsighted eyes with or without astigmatism could see 20/40 or better

* Data collected from eyes that could see 20/20 or better with glasses before surgery.

D. LASIK surgery: with the help of glasses (results at 6 months after surgery)

- 99% highly nearsighted eyes with or without astigmatism could see 20/40 or better

Long Term Post-Treatment Safety Problems

The following is a list of the adverse events and complications that occurred in PRK patients who are mildly nearsighted (MN), mildly nearsighted with astigmatism (MNA), highly nearsighted with or without astigmatism (HN), moderately farsighted (MF), or moderately farsighted with moderate astigmatism (MFA) at approximately 1 year after treatment:

Problems	MN (%)	MNA (%)	HN (%)	MF (%)	MFA (%)
Worsening of Best Spectacle Corrected Vision: Significant worsening of vision in the operated eye with the help of glasses (loss of more than 2 lines of vision)	0.4	3.5	2.5	0	0
Increase in Astigmatism: Uneven curving of the cornea by 1 or more diopters that may distort vision and require corrective glasses or contact lenses	3.1	NA ^a	NA	0.9	0.8

a. Not available

Patient Symptoms: Comparison of Vision After Surgery to Correct Farsightedness with Astigmatism (All Eyes with a Pre-Operative Sphere \leq 5.0 and Questionnaire, N = 206)		
	Worsen (\geq2) 6 Months (n = 203)	Worsen (\geq2) 12 Months (n = 180)
	n %	n %
Sharpness and Clarity	7 3.4	11 6.1
Consistency of Vision	4 2.0	3 1.7
Sustained Close Work	13 6.5	19 10.6
Daylight Driving	6 3.0	9 5.0
Night Driving	6 3.0	6 3.4
Night Vision with Glare	5 2.5	7 3.9
Reading in Dim Light	8 4.0	16 9.0
General Vision in Dim Light	17 8.5	25 14.0
Overall Visual Comfort	0 0.0	0 0.0

The following is a list of the adverse events and complications that occurred in LASIK patients at approximately 3 months after treatment.

LASIK Patient Findings (All Eyes) ^a		
Visual Findings	Percent of Patients Reporting	
	Before LASIK Surgery	3 Months After LASIK Surgery
Severe Glare	9%	6%
Severe Halo	9%	4%
Severe Visual Fluctuations	4%	2%

a. The following adverse events and complications occurred at a rate of less than 1% at 6 months: loss of 2 or more lines of BSCVA (0.5%), BSCVA worse than 20/40 (0.4%), BSCVA less than 20/25 when the pre-operative eye was 20/20 or better (0.4%), and wrinkling of the LASIK cap (0.3%).

Questions to Ask Your Doctor

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

- What other options are available for correcting my nearsightedness with or without astigmatism or farsightedness?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK for my amount of nearsightedness with or without astigmatism or farsightedness with or without astigmatism?
- What are the benefits of LASIK for my amount of nearsightedness with or without astigmatism?
- What vision can I expect in the first few months after surgery?
- If laser refractive surgery does not correct my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after laser surgery if I need them?

- How is laser vision correction likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having laser surgery?
- Should I have laser surgery in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have laser surgery only on one eye?

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

Self-Test

Are You an Informed and Educated Patient?

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

	TRUE	FALSE
1. Laser refractive surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. Laser surgery is the same as radial keratotomy (RK).	<input type="checkbox"/>	<input type="checkbox"/>
3. It doesn't matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
4. The laser does all the work; I just have to lie on the chair.	<input type="checkbox"/>	<input type="checkbox"/>
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	<input type="checkbox"/>	<input type="checkbox"/>
6. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk that I may lose some vision after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. It doesn't matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
9. If I have an autoimmune disease, I am still a good candidate for PRK or LASIK.	<input type="checkbox"/>	<input type="checkbox"/>

Answers to SELF-TEST are found on page 21.

Summary of Important Information

- Laser vision correction is a permanent operation to the cornea and is irreversible.
- Laser vision correction 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 laser vision correction. You will need written evidence that your nearsightedness with or without astigmatism or farsightedness has changed less than 0.50 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- Laser vision correction 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.
- PRK and LASIK are not laser versions of radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK and LASIK are completely different from RK and ALK.
- Alternatives to PRK and LASIK include, but are not limited to, glasses, contact lenses, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having RK, ALK, PRK, or LASIK.
- Before considering laser vision correction you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about the potential benefits of PRK or LASIK surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions:

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

Glossary

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

Antibiotic Medication: a drug used to treat or prevent infection.

Anti-Inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

Astigmatism: The cornea and lens focus light rays at multiple points at differing distances from the retina. The multiple focal points result in blurred distance and/or near vision.

Automated Lamellar Keratectomy (ALK): a type of surgery used to correct vision by removing a cap of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

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 or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

Contraindications: any special condition that results in the treatment being inadvisable.

Cornea: the clear front surface of the eye. Surgery such as PRK and LASIK reshape or flatten this surface to correct vision.

Corneal Epithellum: the top layer of the cornea. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

Corneal Haze: a cloudiness of the cornea that may occur after PRK and LASIK.

Corneal Ulcer: an infection of the cornea that may result in a loss of vision.

Diopter (D): a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

Farsightedness: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Hyperopia is another term for farsightedness.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object.

Herpes Simplex: a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body.

Herpes Zoster: a type of infection caused by a virus that can recur. Vesicles typically appear on only one side of the body.

Highly Nearsighted: nearsightedness greater than -6 diopters.

Hyperopia: The cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Farsightedness is another term for hyperopia.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS.

Intraocular Pressure (IOP): fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

LASIK: a type of surgery used to correct vision by raising a flap of cornea using a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

Lens: a structure inside the eye that helps to focus light onto the back of the eye.

Mildly Nearsighted: nearsightedness between -1.0 and -6.0 diopters.

Moderately Farsighted: farsightedness between +1.0 and +6.0 diopters.

Myopia: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: The cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

Ocular Hypertension: an increase in the pressure inside the eye.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the cornea using an excimer laser.

Radial Keratotomy (RK): a type of surgery used to correct vision by flattening the cornea with a scalpel.

Re-epithelialization: regrowth of the top layer of the cornea. The epithelium is removed before the PRK treatment and usually grows back within a few days after the treatment.

Regression: a decrease in the amount of vision correction after PRK or LASIK surgery.

Retina: the back surface of the eye. The retina takes focused light and transfers it to the brain.

Patient Assistance Information

Primary Eye Care Professional

Name: _____

Address: _____

Phone: _____

Laser Vision Correction Doctor

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

Laser Manufacturer:

VISX, Incorporated
3400 Central Expressway
Santa Clara, CA 95051
U.S.A.
Tel: 408.733.2020