VISX STAR S2™
Excimer Laser System

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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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 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 the Safe Operating Procedures outlined in the Operator's Manual (Section 4.5.5, Gas Cylinder 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 protective respirators, and 4) be familiar with safety procedures 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.

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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.

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.

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

2.1 Indications for Use

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 less than or equal to 0.5 D (in both cylinder and sphere components) per year for at least one year prior to the date of pre-operative examination; and
- in patients 18-20 years of age in PRK treatments for the reduction or elimination of myopia (nearsightedness) of less than or equal to -6.0 D spherical equivalent at the corneal plane with less than or equal to -1.0 D of astigmatism; or
- in patients 21 years of age or older in PRK treatments for the reduction or elimination of myopia (nearsightedness) of between 0 and -12.0 D spherical myopia at the spectacle plane with up to -4.0 D of astigmatism; or
- in patients 21 years of age or older in PRK treatments of naturally occurring hyperopia between +1.0 and +6.0 D spherical equivalent, with no more than 1.0 D of refractive astigmatism.

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.

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

2.2 Contraindications

PRK 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 PRK 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.
- PRK is not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster.*

2.4 Precautions

A. General

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

Ablation of corneal stroma to less than 200 µm from the endothelium may result in corneal ectasia.

Of the eyes treated in these 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 may not have been 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.

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

2.1% of hyperopic 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.

The effects of PRK on visual performance under poor lighting conditions have not been determined. It is possible, following PRK treatment, 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. 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 hyperopia treatment of patients with refractions less than +1.0 D.

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- In patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone.
- In patients with corneal neovascularization within 1.0 mm of the ablation zone.
- For patients under 21 years of age with myopia greater than 6.0 D and astigmatism greater than 1.0 D.
- For 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 astigmatism.
- For patients under 18 years of age.
- Over the long term: More than 3 years after surgery for low myopia; more than 1 year after surgery for high myopia with astigmatism; 1 year after surgery for hyperopia.
- In patients with a history of keloid formation.
- In patients who are taking sumatripin (Imitrex).
- In patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for PRK:

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

D. Post-Procedure

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

- Uncorrected Visual Acuity (UCVA or VA-sc).
- Manifest refraction with the Best Spectacle Corrected Visual Acuity (BSCVA or VA-cc).
- Intraocular pressure (IOP).
- Slit-lamp examination, including corneal clarity evaluation.
- Videokeratography at 6 months (sooner only if unanticipated events occur during the healing process).

- If topical steroids are used post-operatively, patients should be monitored for development of possible steroid side-effects, including but not limited to ocular hypertension, glaucoma, and/or cataract.

2.5 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: pain (24-48 hours), 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.

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.

A. Low Myopia

Nine hundred and nine (909) eyes of 676 subjects were used for safety analyses. Five hundred and forty-two 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
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:

$$\frac{\text{number of eyes with at least one occurrence observed at the specified study visit}}{\text{number of eyes examined at the specified study visit}}$$

◆ 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 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* (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
Corneal Causes	15	7.5	8	5.1
2. Pre-treatment BSCVA 20/20 or Better with a				
Post-treatment BSCVA Worse than 20/25	14	7.0	7	4.5
Post-treatment BSCVA Worse than 20/40	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. Myopic 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 — Myopic Astigmatism Adverse Events (n = 116)

Adverse Events	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
With Post-treatment BSCVA						
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:

$$\frac{\text{number of eyes with at least one occurrence observed/reported at the specified study visit}}{\text{number of eyes examined at the specified study visit}}$$

* 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.

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

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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

Adverse Events*	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	0	0	2	2.1*
Post-treatment Worse than 20/40	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.

3.0 Clinical Results

3.1 Low Myopia

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

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

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 — 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 — 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 — 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)	
Efficacy Parameter	**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 ≥+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 ≥+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 – < 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 – < 3 D	0	0.0	7	1.6	3	0.7	1	0.2	1	0.3	0	0.0	0	0.0
Hyperopia ≥ 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

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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)*

	Pre-Treatment		Before Retreatment		After Retreatment	
UCVA	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 ≥ 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	45.5	4	14.3
± 0.5 D	0	0.0	2	6.1	14	50.0
± 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 ≥ 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.

3.2 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 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 who were immunocompromised.

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 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							
	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	Total	
	(n = 87)	(n = 49)	(n = 27)	(n = 20)	(n = 10)	(n = 7)	n	(%)
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-Month (n = 199)				12-Month (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							
	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	Total	
BSCVA	(n = 71)	(n = 38)	(n = 20)	(n = 15)	(n = 7)	(n = 5)	n	(%)
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

* 6885115-2 (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-Month (n = 199)	12-Month (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

	Pre-Treatment		Pre-Retreatment		Post-Retreatment at Last Visit	
Subject ID	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.

3.3 Myopic 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 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 — Myopic Astigmatism — Cohort Pre-Operative Refractive Characteristics (n = 116)

Primary Eyes (n = 71)	Spherical Equivalent	Spherical Myopia	Astigmatism
Mean	-4.46 D	-3.64 D	-1.63 D
SD	1.39 D	1.47 D	0.74 D
Range	-1.75 – -6.63 D	-0.5 – -6.00 D	-0.75 – -4.00 D
Fellow Eyes (n = 45)			
Mean	-4.16 D	-3.33 D	-1.66
SD	1.45	1.59	0.65
Range	-1.38 – -6.50 D	0.00 – 5.75	-0.75 – -3.25 D
All Cohort Eyes (n = 116)			
Mean	-4.34 D	-3.52	-1.64 D
SD	1.41	1.52	0.71
Range	-1.38 – -6.63	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 — Myopic 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) for the primary and fellow eyes stratified by pre-operative refractive cylinder (PE = primary eye, FE = fellow eye) 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 — Myopic 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		
	PE	FE	All	PE	FE	All	PE	FE	All	PE	FE	All
≥ 20/20	6	6	12	11	7	18	2	1	3	0	0	0
< 20/20 – 20/30	7	1	8	13	6	19	2	4	6	1	0	1
< 20/30 – 20/40	2	0	2	1	3	4	0	1	1	1	0	1
< 20/40 – 20/50	0	1	1	2	0	2	0	1	1	0	0	0
< 20/50 – 20/60	0	0	0	0	0	0	0	0	0	0	0	0
< 20/60 – 20/70	0	0	0	0	0	0	0	0	0	0	0	0
< 20/70 – 20/100	0	1	1	1	0	1	0	1	1	0	0	0
< 20/100 – 20/200	0	0	0	0	0	0	0	0	0	0	0	0
< 20/200 – 20/800	0	0	0	0	0	0	0	0	0	0	0	0
CF or Worse	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	15	9	24	28	16	44	4	8	12	2	0	2

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

Table 3-22 — Myopic Astigmatism — Cylinder Magnitude and Axis (n = 116)

	6 Months (n = 106)*	12 Months (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 -0.10D. The mean pretreatment manifest refractive S.E. was -4.34D. The mean S.E. was reduced by 92.9% at the final visit.

Table 3-23 — Myopic Astigmatism — Reduction of Mean Spherical Equivalent

	6-Month (n = 106)*	12-Month (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 — Myopic 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 — Myopic 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.

3.4 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 cycloplegic refraction. 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 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	0.60	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 0.26		0.42 0.21		0.25 0.07		0.19 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 US 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.

4.0 Surgical Planning and Procedures

After reading this section, please refer to the procedures provided in Section 5, 5.1, Step-By-Step Procedure, before proceeding with surgery.

4.1 Introduction

PRK is a procedure using the energy of the excimer laser to create a superficial lamellar keratectomy of a shape designed to correct or ameliorate a specific refractive error. It is essential that the refractive information upon which this surgical procedure is based is accurate and is correctly transmitted to the laser. It is the sole responsibility of the operating doctor to ensure that the information for each individual patient is accurate.

4.2 Pre-Operative (Examination of the Patient)

A complete examination, including but not limited to cycloplegic evaluation, must be performed. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP 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. Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 30 days of PRK surgery.

Patients who wear soft contact lenses must discontinue their use for at least 2 weeks, and those who wear gas permeable or hard lenses must discontinue their use for at least 3 weeks. Failure to do so will adversely affect the end surgical result.

4.3 Peri-Operative (Anesthesia and Analgesia)

Extensive clinical experience has shown that PRK excimer surgery is well tolerated and rarely causes significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Topical anesthesia applied just before insertion of the lid speculum will provide adequate control of pain during the surgery. For those patients with a high degree of anxiety, appropriate medication may be given pre-operatively.

4.4 Removing the Epithelium

If you do not intend to remove the epithelium using the laser, do not select Epithelium from the treatment menu.

The TREAT button is disabled on the Epithelium page. To perform an epithelial procedure, you must first define a stromal treatment. When the programming is complete, press TREAT from the stromal (PRK or PTK) page to begin epithelium removal.

When the Hyperopia treatment is selected, the laser epithelium removal is disabled. You cannot combine the Hyperopia treatment with laser epithelium removal.

The system will always perform the epithelium treatment first if it is selected.

The surgeon may use one of three epithelium removal techniques:

- Laser only
- Partial laser removal (laser plus scraping) supplemented with surface scraping to ensure complete and uniform removal of the epithelial cells.
- Mechanical (no laser) removal.

4.4.1 Complete Laser Epithelium Removal

To perform complete laser epithelium removal the surgeon must be able to monitor the blue flash. Ensure that your system is equipped with the necessary optics upgrade before proceeding.[1]

To ensure complete and uniform removal of the epithelial cells using only the laser, the surgeon should compensate for the central under-ablation of the plano beam by adding a spherical refractive component to the ablation. This spherical refractive ablation may be done either before or after the plano ablation. To ensure greater patient comfort and better surgeon monitoring of the procedure, the spherical ablation is typically done before the plano ablation. The surgeon may define a plano ablation of up to 100 µm, as well as associated spherical ablation of up to -2.00 D.

- Set the sequence. Select Sphere or Plano from the Perform First box.

1. For ordering information, contact your VISX service or sales representative.

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For instructions on setting a spherical default value, see Chapter 9, Entering Treatment Data and Printing Reports, in the VISX STAR S2 Operator's Manual.

- Go to the first stromal treatment page of your procedure (PTK or PRK).
- Press the **TREAT** button to begin epithelium removal. Monitor the Ablation Status screen as the treatment progresses.

When the epithelial ablation is complete the Ablation Status screen automatically resets for the PTK or PRK treatment. **AT THIS POINT** the surgeon has an option to proceed to the stromal treatment, or to remove more epithelium.

- To proceed to the stromal treatment:
  - — Lift the footswitch, then depress it.
- To remove more epithelium:
  - — Lift the footswitch, and be careful **NOT** to depress it at this time.

WARNING! If you need to remove more epithelium, it is critically important to refrain from depressing the footswitch at this point. If you depress the footswitch at this point, the stromal treatment will begin, and you will not be able to remove more epithelium.

  - — Select **CANCEL** from the ablation status screen; the program returns to the Epithelium page.
  - — Reprogram the amount of epithelial ablation desired.

If no additional spherical ablation is desired, be sure to reprogram the sphere portion of the ablation to 0. Additional spherical ablation is subject to a total epithelial sphere limit of -2.00 D. There is no limitation on the total epithelium plano pulses.

  - — Re-select the desired PRK or PTK page and select **TREAT**. The system will prompt with **Repeat epithelium ablation?**
  - — Select **YES**, and repeat the epithelial removal process. You may repeat the process as many times as you need to, subject to the parameters in the note above.

When ready to proceed to the stromal treatment:

- If pulses remain, lift footswitch, depress it, select **SKIP**.
- If no pulses remain, lift footswitch, depress it; stromal treatment begins.

4.4.2 Partial Laser Epithelium Removal (Laser-Plus-Scrape) Technique

The surgeon uses this technique to compensate for the central under-ablation of the plano beam by manually scraping away residual epithelial tissue.

- Set plano to the desired depth.
- Set sphere to 0.0.
- Treat with laser.
- Manually remove residual epithelial elements, ensuring that Bowman's layer is uniformly exposed.
- The laser automatically adjusts to match the diameter of the largest defined treatment zone plus a margin of 0.5 mm up to a total diameter of 6.5 mm (the mechanical limit).[1, 2]

4.4.3 Mechanical Epithelium Removal

Remove the epithelium using a blunt instrument such as a Paton spatula. The region of epithelial removal should be at least 6.0 mm in diameter. Once the stromal bed is cleaned of debris, saturate a non-fragmenting sterile sponge, squeeze out, and wipe over the ablation bed.

4.4.4 Examples of Epithelium Removal Treatments

A. Example 1: Sphere Plus Plano Trans-Epithelial Removal

In this laser-epithelium-removal technique, the surgeon monitors the progress of the epithelium removal and gauges its completeness by observing the pattern of the blue fluorescence, which is produced during epithelium ablation.

- To perform this treatment use a combination of plano and spherical ablations.
  - — Enter a spherical value for the initial ablation.
  - — Enter plano depth for the second ablation.
  - — Select Sphere from the Perform First menu.
  - — Complete the initial sphere component of the ablation.
  - — Plano ablation begins automatically.
  - — Monitor the epithelial fluorescence during the plano portion of the treatment.
  - — When all the fluorescence disappears, lift the footswitch to end the treatment.
- Skip any remaining plano pulses.

1. This measurement is subject to change.
2. If no treatments have been defined, the diameter shown is not meaningful.

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Observe the pattern of the dissipating fluorescence for these characteristics to judge the accuracy of the sphere value.

- Sphere value correct: Fluorescence disappears from the entire area almost all at once, indicating a uniform ablation.
- Sphere value too small: Fluorescence first disappears in a ring at the outer diameter of the ablated area, indicating a residual central epithelium. Additional sphere may be applied.
- Sphere value too large: Fluorescence disappears from the center of the ablated area first, indicating a residual peripheral epithelium. Additional plano PTK may be applied.

B. Example 2: Plano Plus Sphere Trans-Epithelial Removal

Values entered may be similar to those in the first example, but the plano portion of the procedure is performed first.

- Monitor the fluorescence during the plano portion.
- Lift the footswitch when the fluorescence just begins to disappear in a ring at the outer diameter.
- Select SKIP to proceed to the spherical portion of the procedure.
- Complete the spherical portion of the treatment.

On completion, the program automatically proceeds to the stromal treatment page from which the epithelial removal was selected. Refer to Example 1 for fluorescence patterns.

C. Example 3: Laser Plus Scrape

- Set the sphere value to 0.
- Enter the desired plano depth (for example 45 μm).
- Treat until the desired depth is reached.
- Remove remaining epithelium mechanically.
- Alternatively, monitor the fluorescence as it dissipates from the outer epithelial ring.
- Skip remaining pulses.
- Depress footswitch and treat, or press CANCEL and do more epithelial removal.

D. Example 4: Mechanical

- Gently remove the epithelium using a blunt instrument such as a Paton spatula.
- The region of epithelial removal should have a diameter of at least 6.0 mm.
- Clean the stromal bed of debris.
- Saturate a non-fragmenting sponge with balanced sterile saline, squeeze it out, and wipe it over the ablation bed.
- Proceed to the PRK or PTK treatment.

4.5 Post-Operative

A. Patching and Antibiotics

Following completion of the excimer laser surgery, appropriate medications and a bandage contact lens should be applied to the eye in a sterile manner. A steroidal medication may be included at the time of lens insert. Daily observation is required until re-epithelialization is complete, regardless of whether or not steroids are used.

B. Handling Complications

Delayed re-epithelialization of the ablated surface may be anticipated in some patients. It is essential that these patients be monitored on a daily basis with installation of antibiotics and maintenance of a firm patch. The doctor must remain alert to the possible development of corneal infiltrates, which will require appropriate diagnostic and therapeutic measures.

5.0 VISX STAR S2 Surgical Procedures

Before proceeding, please refer to the laser preparation and shut-down procedures presented in the VISX STAR S2 System Operator's Manual, Section 6.2, Turning System On and Off.

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. However, 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 there is a possibility that healthcare personnel will approach closer than this distance from the primary beam.

The Professional Use Information Manual is to be used in conjunction with the VISX STAR S2 System Operator's Manual.

5.1 Step-by-Step Procedure

1. Power ON the system.
2. Complete all daily calibrations, as described in the VISX STAR S2 System Operator's Manual, Chapter 8, Calibrating the System.
3. Prepare a VisionKey card with patient information and parameters for the PRK procedure as described in the Operator's Manual, Chapter 9, Entering Treatment Data and Printing Reports. This may be done in advance of treatment.

Ablate a -4.0 D, 6.0 mm lens after every THIRD treatment to verify the calibration of the VISX STAR S2 System. Refer to the Operator's Manual, Chapter 8, Calibrating the System, for additional information on the calibration procedure.

4. Ensure that all persons in the operating room obey all safety regulations. Caution all attendees in the operating room against touching the laser, patient, or patient chair during the procedure. Movement of personnel in the operating room should be minimized during the procedure. It is recommended that all attendees, including the doctor, wear surgical masks and protective eyewear.

5. Allow the patient the opportunity to become familiar with the sounds of the laser during the calibration procedure.

6. Insert the VisionKey card into the card drive when prompted by the system software. Follow the system software prompts. If the card has been preprogrammed, verify that the card corresponds with the patient to be treated. Add any additional data to the PRK Auto Treatment screen. For an unprogrammed VisionKey card, enter all necessary data and the planned surgery on the PRK Auto Treatment screen.

The doctor has the option to perform a test of the patient's procedure parameters prior to the actual procedure. Refer to the Operator's Manual, Section 9.4, Patient Test Calibration. Confirm that the desired patient parameters are entered in the treatment fields, then fully depress the laser footswitch.

The patient's refraction should be entered into the system software at the spectacle plane, and the vertex distance carefully measured and entered. Accurate vertex distances are essential for the best surgical result. The importance of an accurate and thorough refractive and ophthalmological evaluation cannot be over-emphasized.

7. Power ON the video recorder.

8. Center the mechanical position of the chair using the guide marks found on the chair base.

9. Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.

10. Position the patient so the lateral canthus aligns to the mark on the headrest.

11. Place the vacuum pillow under the patient's head with the bottom portion of the "U" supporting the patient's neck. Assure that there is no head tilt or rotation present. This is accomplished by assuring that a line from the vertex of the chin through the nasion is parallel to the operating table.

12. Cover the untreated eye with an opaque shield that protects the eye and occludes vision. A post-operative surgical shield covered with electrical tape is suitable for this purpose. Instruct the patient to keep both eyes opened during the surgical procedure.

13. Monitor patient clearance while rotating the patient chair to the treatment position, then lock the patient chair in place by pressing the foot pedal in the locked position. The chair must be fully rotated and the foot pedal locked for the laser to operate. Correct positioning is confirmed by the green status bar on the computer screen, which allows the procedure to continue.

If the patient chair is not in the treatment position and securely locked, the laser will not fire. Check the interlock message on the status screen.

14. Check the surgical parameters entered into the computer against the surgical plan and confirm that all interlocks are cleared. The accuracy of the entered data is the responsibility of the doctor.

15. Instruct the patient to remove earrings prior to using the vacuum pillow. Adjust the patient's head and vacuum pillow for comfort, angle, alignment, and stability. Connect the vacuum pillow suction tubing to the suction port located on the patient chair headrest. While keeping the patient properly aligned, conform the pillow shape to the patient's head, creating support under the occiput of the skull. This is more effective than creating lateral support for the head. Holding the pillow support against the occiput, power ON the suction pump switch, which is between the two (2) tilt knobs on the headrest. After several seconds, the pillow will harden and conform to the patient's head. This creates a comfortable, stable platform for the patient. Disconnect the tubing after the pillow has hardened.

16. Position the patient with the microscope set at low zoom magnification. When the cornea is visible in the microscope, focus the image of the cornea and increase the magnification. Refer to the Operator's Manual, Section 6.5, Focusing Microscope. Instruct the patient to begin fixating on the blinking red fixation light.

17. Move the patient so the microscope reticle is centered over the patient's pupil. Chair movement is controlled by the doctor's keypad. Refer to the Operator's Manual, Section 6.3.1, Preparing Chair for Patient, for information regarding chair movement.

The microscope oculars must be properly focused to accommodate the doctor's refraction. This will assure that the microscope focal plane and the laser focal plane are coincident.

18. Continually encourage the patient to maintain fixation on the blinking red fixation light throughout the procedure.

19. Verify that all color status bars are green in the procedure screen of the system software. If a yellow status bar is displayed, you may continue with the procedure; however, a condition exists that warrants attention as soon as possible after completion of treatment. A red status bar will prevent system operation. Therefore, any interlock must be cleared prior to a treatment.

20. After verification of green system status bars, warn all attendees to stand clear of the laser, patient, and patient chair. Accidental bumping of the laser, patient, or patient chair during the surgery can cause de-centering of the treatment area. Movement in the operating room must be kept to a minimum during patient treatment.

21. Insert a closed blade speculum into the eye to hold the eyelid open. If using mechanical epithelial removal, a 6.0 or 6.5 mm marker can be used, centered over the entrance pupil and gently depressed onto the epithelial surface. If the laser scrape technique is to be used, then there is no need to mark the epithelium.

22. Epithelial removal is best performed using the ring illuminator, with the illumination on the lowest setting that allows good visualization of the epithelial surface while not causing the patient discomfort. This is accomplished by setting the ring illuminator on low power and gradually increasing illumination until the epithelial surface is comfortably in view. Visibility of the red blinking fixation light by the patient is facilitated by low operating illumination.

23. After confirming the pupillary centration of the 6.0 or 6.5 mm marker, mechanical removal is facilitated by placing one or two drops of anesthetic in the operative eye prior to commencing the surgical procedure. Many light, even strokes at a fixed site may be necessary to start the mechanical epithelial removal process. Avoid hard pressure that deforms the cornea. Use rapid, even strokes until the epithelium is completely removed. Mechanical epithelial removal can be accomplished with either a blunt spatula or a small blade such as a Beaver 64. If a sharp instrument is used, take care not to disrupt Bowman's layer. If a patient has not had adequate pre-operative topical anesthesia, place a 6.0 mm anesthetic-soaked pledget on the cornea prior to removal of the epithelium. Remove the pledget after 60 seconds. If laser scrape epithelium removal is to be used, place one or two drops of anesthetic in the operative eye prior to commencing the surgical procedure. The epithelial portion of the ablation should be set between 40 and 45 µm. The epithelium does not need to be mechanically marked if using the VISX STAR S2 system, as the reticle can be used to center the ablation over the entrance pupil. The reticle must be kept centered over the entrance pupil throughout the ablation of the epithelium. In the laser scrape procedure the foot pedal is depressed to complete the epithelial portion of the ablation, while the stromal portion is initiated only with a second foot depression. The epithelial portion of the ablation is a 6.0 mm PTK-type of ablation, while the stromal portion is PRK. After either mechanical removal or laser scrape, the surface of the cornea must be wiped with a nonfragmenting sponge that has been soaked with balanced sterile saline and then squeezed so it is moist but not saturated. For more detailed instructions on laser epithelial removal, see Section 10.1.1 in the Operator's Manual, "Complete Laser Epithelial Removal."

There should be no epithelial cells in the 6.0 mm diameter treatment zone prior to laser initiation. Avoid adding fluids to the cornea after epithelium removal has begun. Position the head so the cornea is centered within the lid speculum. This minimizes the potential for tears to touch the corneal surface during surgery.

24. If, during the epithelial removal process, the surface of the cornea appears unevenly hydrated, wipe the area with a nonfragmenting sponge that has been soaked with balanced sterile saline and then squeezed so it is moist but not saturated.

25. Patients with nystagmus or poor fixation may require external fixation.

Keep the patient relaxed by explaining the process as you go along. Use the dimmest ring illumination intensity that allows the doctor to remove the epithelium. This low illumination is more comfortable for the patient. Use the oblique halogen illumination at its lowest intensity during laser ablation.

26. Just prior to surgery, verify that the pupil is centered in the reticle and the patient is fixating on the blinking red fixation light. Instruct the patient to maintain fixation on the blinking red fixation light at all times. Switch from the ring illumination to the lowest intensity of the oblique illumination.

27. Check the system focus and adjust the oblique illumination to the lowest intensity that allows monitoring of the pupil position during surgery. Depress the laser footswitch to initiate the procedure. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration.

Make sure all laser pulses have been fired. Check the Heads-Up Display to confirm treatment completion.

28. When the surgery is complete, remove the speculum and allow the patient to close the eye which has just undergone the laser surgery. Power OFF the microscope light and relieve the vacuum in the patient pillow.

The doctor may interrupt the procedure for any reason, at any time, by releasing the laser footswitch. This may be done if the patient should move and the treatment area becomes de-centered. The doctor then realigns the eye and continues the procedure by depressing the laser footswitch again. The procedure will automatically start from the point of interruption.

29. Lower the patient chair to its lowest position, then rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.

30. Place appropriate post-operative medications in the treated eye. Following application of medication, apply a firm pressure patch to the eye.

31. Raise the chair backrest to a sitting position. Assist the patient in putting on any spectacles, and escort him or her to a waiting area.

32. Ensure that the patient is given post-operative instructions. An analgesic may be given to the patient prior to leaving the facility.

33. Review post-operative instructions, confirm the first follow-up appointment, and discharge the patient when stable.

34. Clean the debris removal nozzle with isopropanol wipes and prepare the system for the next patient.

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

Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.