VISX™ 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 Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the VISX 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 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 3.7, Chapter 3).

  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 Excimer Laser 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 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.

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I. DEVICE DESCRIPTION

The VISX Excimer Laser 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 Excimer Laser 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 (STAR, Model C) or mouse (Model B) 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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II. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS

2.1 INDICATIONS FOR USE

Photorefractive Keratectomy (PRK) procedure using the VISX Excimer Laser 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.

NOTE:
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 Excimer Laser 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

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

- For PRK treatment of astigmatism in patients with refractive cylinder of less than 0.75 D.
- 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 18 years of age.
- Over the long term: More than 3 years after surgery for low myopia and more than 1 year after surgery for high myopia with astigmatism.
- In patients with a history of keloid formation.
- In patients who are taking sumatripin (Imitrex).

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 with the same reliability as for patients with less severe myopia.

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.

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.

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 Excimer Laser 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
(n=909)†

	Adverse Event Description	1M (n=810)‡ n	(%)	3 to 6 M (n=846)‡ n	(%)	12M (n=520)‡ n	(%)	≥24M (n=542)‡ n	(%)
1.	Loss ≥2 Lines of BSCVA	113	(14.3%)*	50	(6.0%)*	11	(2.1%)	1	(0.2%)
2.	Pre-treatment BSCVA 20/20 or Better with Post-treatment BSCVA Worse than 20/25	114	(14.9%)*	52	(6.4%)*	10	(2.0%)*	7	(1.3%)
3.	Pre-treatment BSCVA 20/20 or Better with Post-treatment BSCVA Worse than 20/40	13	(1.7%)φ	7	(0.9%)*	1	(0.2%)	0	(0.0%)
4.	Overcorrection:								
	>1D	88	(11.0%)*	44	(5.2%)	6	(1.2%)	7	(1.3%)
	>2D	24	(3.0%)	9	(1.1%)	1	(0.2%)	3	(0.6%)
5.	Increase in Refractive Cylinder:								
	≥1D	36	(4.5%)*	46	(5.4%)	16	(3.1%)	16	(3.0%)
	≥2D	2	(0.2%)	3	(0.4%)	0	(0.0%)	0	(0.0%)
6.	Glare Testing: Abnormal (≥2 line loss in BSCVA with glare)	---	---	1	(1.0%)*	1	(1.6%)*	0	(0.0%)
7.	Worsening of Patient Symptoms:								
	"Double Vision"	---	---	23	(2.7%)	8	(1.5%)	7	(1.3%)
	"Sensitivity to Bright Lights"	---	---	35	(4.1%)	25	(4.8%)	16	(3.0%)
8.	Difficulty with Night Vision**	---	---	41	(4.8%)	27	(5.2%)	21	(3.9%)
9.	IOP Increase:								
	> 5 mm Hg	35	(4.4%)*	61	(7.2%)	9	(1.8%)*	19	(3.9%)*
	>10 mm Hg	2	(0.2%)	7	(0.8%)	0	(0.0%)	0	(0.0%)
10.	Corneal Haze ≥ grade 2	3	(0.4%)	11	(1.3%)	3	(0.6%)	1	(0.2%)
11.	Corneal Infection/Ulcer/Infiltrate (none lost BSCVA)	3	(0.4%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
12.	Corneal Decompensation/Edema (nonpersistent)	1	(0.1%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
13.	Lens Abnormality Post-treatment◊	1	(0.1%)	2	(0.2%)	1	(0.2%)	3	(0.6%)
14.	Secondary Surgical Intervention:								
	Single Retreatments	0	(0.0%)	1	(0.1%)	22	(4.2%)	2	(0.4%)
	Double Retreatments	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
	Other Refractive Procedures	0	(0.0%)	4	(0.5%)	14	(2.7%)	9	(1.7%)

† Last Observation - Post-retreatment data not included.

‡ For all adverse events, percentages are given as:

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

◊ Adverse Event #13: lens abnormality post-treatment counted by first occurrence.

* Reflects number of patients who reported these symptoms occurring 'often or always' post-treatment and worse than pre-treatment.

** Reflects number of patients who reported this symptom as significantly worse than pre-treatment.

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

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	0.0%	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	0.0%
> 25 mm Hg	1	0.5%	0	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 undercorrecton	0	0.0%	3	1.5%

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

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	6M (n=108)		12M (n=92)		Final Visit* (n=82)	
	n	%	n	%	n	%
1. Increased Difficulty with Night Vision•	28	25.9%	17	18.5%	19	22.6%
2. Worsening of Patient Symptoms•: "Sensitivity to Bright Lights"	18	16.7%	12	13.0%	13	15.5%
3. Loss of ≥2 lines BSCVA						
Due to Any Cause	5	4.8%	6	6.7%	7	8.5%•
Due to Corneal Causes	4	3.8%	4	4.5%	4	4.8%•
4. Pre-treatment BSCVA 20/20 or Better with Post-treatment BSCVA Worse than 20/25•	5	4.8%	4	4.5%	5	6.1%
5. Worsening of Patient Symptoms•: "Double Vision"	6	5.6%	5	5.4%	5	5.9%
6. Secondary Surgical Intervention Retreatments	0	0.0%	4	4.3%	5	5.9%
7. IOP Increase > 5 mm Hg < 10 mm Hg	8	7.4%	2	2.2%	2	2.4%
8. Corneal Haze ≥ Grade 2	2	1.9%	4	4.3%	1	1.2%
9. Pre-treatment BSCVA 20/20 or Better with Post-treatment BSCVA Worse than 20/40•	0	0.0%	2	2.2%	0	0.0%
10. Secondary Surgical Intervention Other Refractive Procedures	0	0.0%	1	1.1%	0	0.0%

Percentages of adverse events 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.**

⊗ Visual acuities were taken from the ETDRS standard and may have (+) and (-) designations.

• Reflects the number of eyes where these symptoms as occurring 'often or always' post-treatment and worse than pre-treatment. Post-retreatment data are not included.

• Reflects the number of eyes where this symptom was reported as significantly worse than pre-treatment. Post-retreatment data are not included.

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

III. 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
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 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 due to rounding.

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

1 to <2D		2 to <3D		3 to <4D		4 to <5D		5 to 6D	
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 <2D (n=37 Eyes)		2 to <3D (n=75 Eyes)		3 to <4 D (n=119 Eyes)		4 to <5D (n=128 Eyes)		5 to 6D (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 +/-1D	33	91.7%*	69	92.0%	111	93.3%	113	88.3%	106	87.6%	432*	90.2%*
(5) Dev. From Intended ≤+1D (Not Overcorrected)	36	100.0%*	74	98.7%	119	100.0%	127	99.2%	118	97.5%	474*	99.0%*
(6) Dev. From Intended ≥-1D (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 -1.0D and +0.5D *Post-treatment*	30	85.7%*	61	82.4%*	86	74.8%*	95	76.0%*	87	75.7%*	359*♦	77.4%*
(8) Spherical Equivalent >+1D	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		1M n=436		3M n=415		6M n=421		12M n=344		18M n=294		≥24M 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 ± 1D of intended) post-treatment. At 1 month post-treatment, 86.9% of the eyes were ± 1D 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 ≥+1D). 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 ≥+1D).

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

Spherical Equivalent	Preop n=480 n	(%)	1M n=434 n	(%)	3M n=411 n	(%)	6M n=419 n	(%)	12M n=342 n	(%)	18M n=294 n	(%)	≥24M n=479* n	(%)
Myopia ≥3D	368	(76.7%)	1	(0.2%)	2	(0.5%)	4	(1.0%)	1	(0.3%)	1	(0.3%)	1	(0.2%)
Myopia 2 to <3D	75	(15.6%)	3	(0.7%)	7	(1.7%)	3	(0.7%)	1	(0.3%)	2	(0.7%)	3	(0.6%)
Myopia 1 to <2D	37	(7.7%)	30	(6.9%)	41	(10.0%)	34	(8.1%)	42	(12.3%)	33	(11.2%)	61	(12.7%)
± 0.5D	0	(0.0%)	297	(68.4%)	286	(69.6%)	300	(71.6%)	254	(74.3%)	214	(72.8%)	339	(70.8%)
± 1D	1	(0.2%)	377	(86.9%)	370	(90.0%)	387	(92.4%)	309	(90.4%)	269	(91.5%)	435	(90.8%)
Hyperopia 1 to <2D	0	(0.0%)	37	(8.5%)	10	(2.4%)	7	(1.7%)	3	(0.9%)	2	(0.7%)	2	(0.4%)
Hyperopia 2 to <3D	0	(0.0%)	7	(1.6%)	3	(0.7%)	1	(0.2%)	1	(0.3%)	0	(0.0%)	0	(0.0%)
Hyperopia ≥3D	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 ±0.5D and ±1D, respectively, of attempted correction remains relatively stable throughout the 24-month period. At 2 or more years, 90.2% of cases were within ±1D of attempted correction.

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

Diopter	1M n=434 n	(%)	3M n=411 n	(%)	6M n=419 n	(%)	12M n=342 n	(%)	18M n=294 n	(%)	≥24M n=479* n	(%)
± 0.5D	261	(60.1%)	265	(64.5%)	288	(68.7%)	233	(68.1%)	203	(69.0%)	309	(64.5%)
± 1D	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 Excimer Laser 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 -4.07D was reduced to almost plano (0.08D) at 1 month following treatment. At 3 months the mean myopia is 0.19D and remains unchanged at 6, 12, 18, and 24 months. There is no statistically 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 0.5D from 12 to 24 months, only 7/247 (2.8%) of those eyes had a myopic shift of $\geq$1D.

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	# 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 0.5D.
**Undercorrection: deviation from intended correction of $\leq$0.5D.
***Haze: a grade of $\geq$1 at any time prior to retreatment.

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

UCVA	Pre-Treatment n	(%)	Before Retreatment n	(%)	After Retreatment 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 n	(%)	Before Retreatment n	(%)	After Retreatment 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 n	(%)	Before Retreatment n	(%)	After Retreatment n	(%)
Myopia > 3D	28	(84.8%)	2	(6.1%)	1	(3.6%)
Myopia > 2 to 3D	4	(12.1%)	5	(15.2%)	1	(3.6%)
Myopia > 1 to 2D	1	(3.0%)	15	(45.5%)	4	(14.3%)
± 0.5D	0	(0.0%)	2	(6.1%)	14	(50.0%)
± 1D	0	(0.0%)	10	(30.3%)	22	(78.6%)
Hyperopia > +1 to 2D	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 n	(%)	Before Retreatment n	(%)	After Retreatment 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 II.

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 to -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 immunocompromise.

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						Total n (%)
	6.1 to 7.0 n=87	7.1 to 8.0 n=49	8.1 to 9.0 n=27	9.1 to 10.0 n=20	10.1 to 11.0 n=10	11.1 to 12.0 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-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)

	Pre-Operative Sphere						
Post-Op BSCVA	6.1 to 7.0 n=71	7.1 to 8.0 n=38	8.1 to 9.0 n=20	9.1 to 10.0 n=15	10.1 to 11.0 n=7	11.1 to 12.0 n=5	Total 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 6.0D spherical equivalent with between -0.75 and -4.5D 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.

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
6M	108	106	104	106	90	87
12M	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 - Summary of Sphere, Cylinder Magnitude and Axis (n=116)

	6-Month (n=106)*		12-Month (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 degrees		10.49 degrees		11.5 degrees	
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 4.06D (SD 1.72) at 6 months, 4.15D (SD 1.60) at 12 months, and 4.03D (SD 1.64) at the final visit. The mean pretreatment cylinder was -1.64 (SD 0.71). The mean observed cylinder was -0.55D (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

	Pre-Treatment		Pre-Retreatment		Post-Retreatmentφ	
Patient	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.
φLast 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)[ξ]

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

[ξ]The refractive data for 2 eyes are not available for this visit.

6) ADVERSE EVENTS

Refer to Table 2-3 in Section 2.5.

6/

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FACTS YOU NEED TO KNOW ABOUT PHOTOREFRACTIVE KERATECTOMY (PRK) SURGERY

PATIENT INFORMATION BOOKLET

Nearsighted Patients (-1.0 to -12.0 diopters)
or
Nearsighted Patients (0 to -12.0 diopters) with 0.75 to 4.0 Diopters of 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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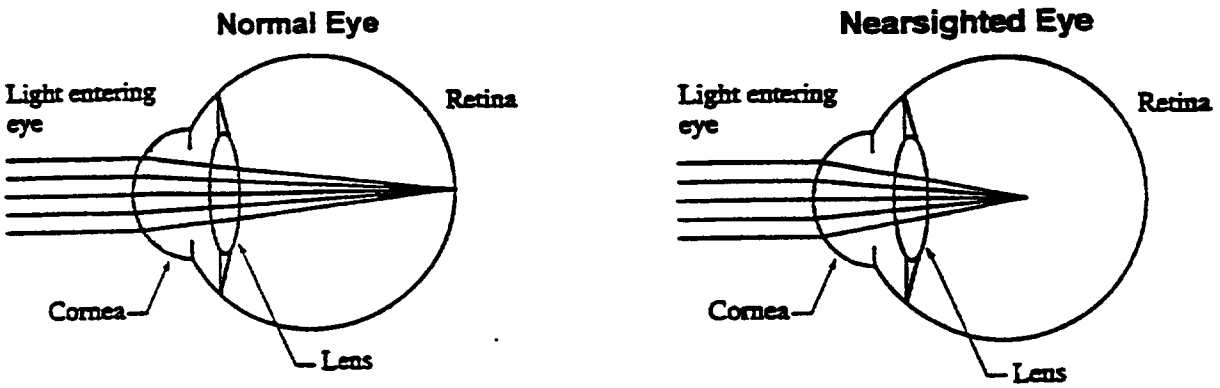
INTRODUCTION

The information in this booklet is to help you decide whether or not to have Photorefractive Keratectomy (PRK) laser surgery to correct or partly correct your nearsightedness (myopia) and/or astigmatism. Some other ways to correct nearsightedness and astigmatism are glasses, contact lenses and other kinds of refractive surgery such as radial keratotomy (RK) or automated lamellar keratectomy (ALK). PRK is a completely different type of surgery from RK or ALK.

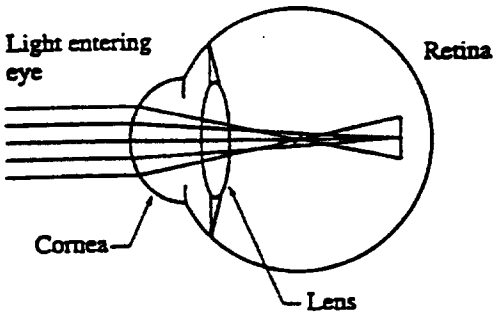
If both of your eyes are nearsighted and/or astigmatic, your doctor may recommend PRK surgery for both eyes. However, sometimes it is better to have PRK done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Please read this booklet completely. Discuss any questions with your doctor before you decide if PRK is right for you. Only an eye care professional trained and certified in PRK can determine whether or not you are a suitable candidate. The vision requirements of some occupations, such as military pilots, cannot be met by having RK, ALK, or PRK.

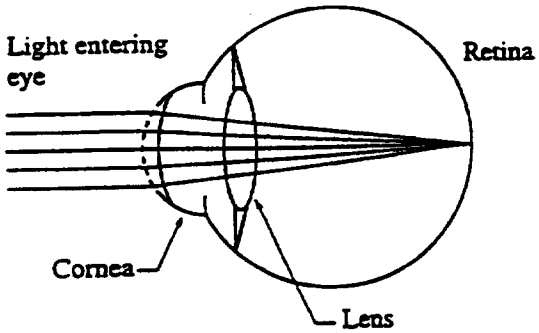
HOW THE EYE FUNCTIONS



Nearsighted and Astigmatic Eye



Eye After Treatment



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 is not evenly focused to a single point in front of the retina but the light rays are divided into two parts that focus along two lines that are different distances from the retina.

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. PRK does it by flattening the central part of the cornea. Astigmatism flattens 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 and astigmatism in units called "diopters". The VISX Excimer Laser System is approved for correcting up to 12 diopters of nearsightedness and from 0.75 to 4.0 diopters of astigmatism.

WHAT IS PRK?

PRK is laser surgery to correct nearsightedness (myopia) or nearsightedness with astigmatism, respectively. 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. This differs from RK, which uses a knife to make deep cuts around the center of the cornea.

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 surgery is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes without complications or adverse reactions. Laser surgery of the second eye is usually done three months after the first eye, if needed.

In the clinical studies of the VISX Excimer Laser System for nearsightedness and astigmatism, the results at 12 months after surgery were:

A. Without the help of glasses
- 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

B. With the help of glasses*
- 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

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

Even though their vision without glasses improved, some patients still needed glasses or contact lenses after PRK. PRK does not eliminate the need for reading glasses. NOTE: You may need reading glasses after laser surgery even if you did not wear them before.

BENEFITS

- PRK surgery, as performed with the VISX Excimer Laser System, is effective in reducing nearsightedness between 0 and -12.0 diopters and/or astigmatism between 0.75 and 4.0 diopters.

- PRK may reduce overall nearsightedness and astigmatism, while also reducing or eliminating dependency upon contact lenses or glasses.

RISKS

As with any surgical procedure there are risks associated with PRK surgery. 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 PRK surgery in the same eye.

THE FIRST WEEK FOLLOWING SURGERY

- Pain and discomfort may last for up to 3 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 continue to experience haze over 2 - 3 years.

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 PRK 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

Discuss with your doctor if:

- Your nearsightedness or astigmatism is changing.

- You are diabetic or have severe allergies.

- You have a history of *Herpes simplex* or *Herpes zoster* of the eye.

PRECAUTIONS

The safety and effectiveness of the VISX Excimer Laser System have **NOT** been established in:

- Eyes with corneal disease or abnormality (for example, scar, infection, etc.).

- Eyes with previous surgery or injury to the center of the cornea where PRK will be performed.

- Eyes with progressive nearsightedness or astigmatism.

- Eyes with abnormal blood vessels within 1.0 mm of the cornea area where PRK will be performed.

- Patients under 18 years of age for mild nearsightedness and under 21 years of age for high nearsightedness and astigmatism.

- Patients over the long term (more than 2 years after the surgery).

- Patients who are taking sumatripin (Imitrex) for migraine.

- Patients who have a tendency to form scars.

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

Because of the low numbers of patients (10.5%, 21/200) with nearsightedness 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 with the same reliability as for patients with less severe nearsightedness.

The effects of PRK on visual performance under poor lighting conditions have not been determined. Following PRK treatment, 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 and have PRK treatment of astigmatism, you will be more likely to experience problems with your vision than older people because your pupils are larger under poor lighting conditions.

ARE YOU A GOOD CANDIDATE FOR PRK?

If you are considering PRK, you must:

- Be at least 18 years of age for treatment of mild nearsightedness or 21 years of age for treatment of high nearsightedness or astigmatism.
- 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 and/or between 0.75 and 4.0 diopters of astigmatism.
- 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 risks and benefits as compared to other available treatments for nearsightedness (myopia) and astigmatism.
- Be willing to sign an informed consent form, if provided by your eye care professional.

BEFORE THE SURGERY

If you are interested in having PRK, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for PRK. This will include a complete 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.

IMPORTANT:

If you wear contact lenses, it is very important to stop wearing them 2 - 4 weeks before the evaluation. Failure to do this will produce poor 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 at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery.

The surgery begins with removal of the outermost layer of the cornea. This is done either with the laser or with a small spatula. After this has been completed, the doctor will 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 Excimer Laser.

IMPORTANT:

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

You will be under the laser less than 1 minute and, overall, the surgery takes about 10 minutes.

After the laser surgery is complete, some eye drops, a contact lens or a patch will be placed on your eye. The surgery is painless because of the anesthetic drops.

When the anesthetic drops wear off (about 45 to 60 minutes), your eye may hurt for 1 to 3 days. Most patients describe this pain as moderate to severe. Do **NOT** rub your eyes for the first 3 to 5 days. Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery.

WARNING:
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 few 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 is typically seen in the cornea following surgery, but usually does not affect your vision. This haze tends to decrease over time and usually disappears completely over a 12 to 24-month period.

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

LONG TERM POST-TREATMENT SAFETY PROBLEMS

The following is a list of the adverse events and complications that occurred in patients who are **mildly nearsighted (MN), mildly nearsighted with astigmatism (MNA), and for highly nearsighted with or without astigmatism (HN)** at approximately 1 year after treatment (the exact percentages are given in parentheses):

- **Overcorrection (by more than 1 diopter):** Farsightedness, which may need to be corrected with glasses or contact lenses (MN=1.2%; MNA=1.2%; HN=5.1%).

- **Overcorrection (by more than 2 diopters):** Farsightedness, which may need to be corrected by glasses or contact lenses (MN=0.3%; MNA=1.2%; HN= 1.9%).

- **Worsening of Best Spectacle Corrected Vision**** Significant worsening of vision in the operated eye with the help of glasses (MN=0.4%; MNA=3.5%; HN= 2.5%).

- **Double Vision:** Shadows or ghost images around objects, judged by the patient to be worse than before the surgery (MN=1.5%; MNA=5.4%; HN - not available).

- **Sensitivity to Bright Lights:** Difficulty tolerating bright lights, judged by the patient to be worse than before the surgery (MN=4.8%; MNA=13.0%; HN - not available).

- **Increase in Astigmatism:** Uneven curving of the cornea of 1 or more diopters that may distort vision and require corrective glasses or contact lenses (MN=3.1%; MNA and HN - not available).

- **Difficulty with Night Vision:** Difficulty performing visual tasks in low light or at night that are performed without difficulty during the day, judged by the patient to be worse than before the surgery (MN=5.2%; MNA=18.5%; HN - not available).

- **Increase in Intraocular Pressure:** Increase of pressure in the eye greater than 5 mm Hg that could, but may not necessarily, cause damage (MN=1.8%; MNA=2.2%; HN=0.7%).

- **Corneal Haze:** A scar or cloudy cornea surface that may affect vision (MN=0.6%; MNA=4.3%; HN=1.3%).

**Significant is defined as a loss of more than 2 lines of vision

QUESTIONS TO ASK YOUR DOCTOR

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

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

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

SELF-TEST

ARE YOU AN INFORMED AND EDUCATED PATIENT?

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

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

Answers to SELF-TEST are found at the bottom of page 12.

SUMMARY OF IMPORTANT INFORMATION

- **PRK is a permanent operation to the cornea and is irreversible.**
- **PRK does 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 PRK surgery. You will need written evidence that your nearsightedness and/or astigmatism 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 auto-immune diseases, or have a condition that makes wound healing difficult.**
- **PRK surgery 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 is not a laser version of radial keratotomy (RK) or automated lamellar keratectomy (ALK). These operations are completely different from each other.**
- **Alternatives to PRK include, but are not limited to, glasses, contact lenses, RK and ALK.**
- **The vision requirements of some occupations, such as military pilots, cannot be met by having RK or PRK.**
- **Before considering PRK surgery you should:**

  a. **Have a complete eye examination.**
  b. **Talk with one or more eye care professionals about the potential benefits of PRK surgery, and the complications, risks, and time required for healing.**

Answers to Self-Test Questions:
1. False (see Risks on page 4); 2. False (see What Is PRK? on page 2); 3. False (see Before The Surgery on page 6); 4. False (see The Day of Surgery on page 7); 5. True (see Benefits on page 3); 6. True (see What Is PRK? on page 2); 7. True (see Risks on page 4); 8. False (see Contraindications on page 4); 9. False (see Contraindications on page 4).

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PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

PRK 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