

Professional Use Information

VISX STAR S4 IR™ Excimer Laser System and WaveScan WaveFront® System

CustomVue™ Treatment

For the reduction or elimination of naturally occurring mixed astigmatism where the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs

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

This document provides information concerning the intended clinical use of the STAR S4 IR Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the STAR S4 IR 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

STAR S4 IR™ EXCIMER LASER SYSTEM

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.

GAS HANDLING: High-pressure gas cylinders are contained in a protected compartment within the STAR S4 IR™ Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with "Gas Safety" (Section 4.5) and "Gas Maintenance" (Section 14.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

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

SKIN AND EYE EXPOSURE: The STAR S4 IR System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. The fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms, including surgical instruments, is extremely low for 193 nm radiation.

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

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

ELECTROMAGNETIC FIELD (EMF): The thyatron emits an electromagnetic pulse which is shielded by the metal coverings of the STAR S4 IR™ Excimer Laser System. This metal covering reduces the EMF below the limits set by applicable standards for electromagnetic compliance.

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

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

WAVESCAN WAVEFRONT® SYSTEM

PRECAUTIONS: The WaveScan WaveFront System is a Class III accessory device. It contains a Class IIIB laser with a 780 nm output. The light levels accessible with the covers off and the interlocks defeated are potentially hazardous to skin and eyes. Avoid direct exposure to these light levels. The covers should be removed only by trained service personnel. To avoid inadvertent exposure to laser radiation, never operate the system with the covers opened or removed. Doing so may expose the user or others to stray laser radiation.

Any service requiring access to the interior of the system should be performed only by VISX® service personnel or by qualified service technicians who have received specific system training. Never try to defeat safety interlocks after removing covers. The safety interlocks are there for user protection. All power cords must be connected to the medical grade isolation transformer in the system.

Carefully read all instructions prior to use. Retain all safety and operating instructions for future use. Observe all contraindications, warnings, and precautions noted in the WaveScan WaveFront Operator's Manual.

1.1 Device Description

1.1.1 STAR S4 IR™ Excimer Laser System

The STAR S4 IR System is designed to create a superficial lamellar keratectomy on exposed corneal tissue. Corneal tissue is removed by a process known as Ablative Photodecomposition. Ablative Photodecomposition occurs when far-ultraviolet radiation reacts with organic molecules, resulting in the photochemical breakdown of the molecular bonds without a significant local thermal effect. The source of the far-ultraviolet photons is a high-efficiency, gas-discharge excimer laser that electronically excites a combination of argon and fluorine, producing an ultraviolet wavelength of 193 nm.

The STAR S4 IR Excimer Laser System combines submicron precision of tissue removal by an excimer laser with a sophisticated computer controlled delivery system. Features and components of the STAR S4 IR 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

The ActiveTrak® System, which enables the laser beam to track the patient's eye movements during the treatment, 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

A PC-compatible computer, video monitor, keyboard with touchpad for user interface (Windows® standard), printer, a floppy drive to store patient information on floppy disks, a VISX® treatment card driver, and system software.

VISX® Treatment Card

The VISX Treatment Card system comprises a card drive and treatment cards. The VISX treatment card defines the number and the types of treatments available.

1.1.2 WaveScan WaveFront® System

The WaveScan WaveFront System is a diagnostic instrument indicated for the automated measurement, analysis, and recording of refractive errors of the eye: including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, and for displaying refractive data of the eye to assist in prescribing refractive correction.

The WaveScan WaveFront System measures the refractive error and wavefront aberrations of the human eye using a Hartmann-Shack wavefront sensor. The measurements can be used to determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that cause decreased or blurry vision in the human eye.

The function of the Hartmann-Shack sensor is to measure the refractive error of the eye by evaluating the deflection of rays emanating from a small beam of light projected onto the retina. To control the natural accommodation of the eye during WaveScan imaging, the system incorporates a fogged fixation target.

The WaveScan® System optical head projects a beam of light onto the retina. The light reflects back through the optical path of the eye and into the wavefront device. The reflected beam is imaged by a lenslet array onto the charge-coupled device (CCD). Each lens of the array gathers light information (deflection information) from a different region of the pupil to form an image of the light that passes through that region of the pupil. An array of spots are imaged on the CCD sensor. The system compares the locations of the array of spots gathered from the CCD to the theoretical ideal (the ideal plane wave).

The WaveScan System software uses these data to compute the eye's refractive errors and wavefront aberrations using a polynomial expansion. The system displays the refractive errors and wavefront aberrations as the optical path difference (OPD) between the measured outgoing wavefront and the ideal plane wave. The WaveScan system software subtracts the refractive errors from the wavefront errors map and displays the higher order aberrations as OPD errors. Regions of the pupil with positive OPD are in front of the ideal plane wave and areas with negative OPD are behind the ideal plane wave.

* Windows® is a registered trademark of Microsoft Corporation.

Features and components of the WaveScan WaveFront® System include:

Computer Control

The WaveScan WaveFront® System includes software to calculate the desired laser vision correction treatment (CustomVue™ treatment) from the WavePrint® measurement. The software generates two sets of laser instructions, one for PreVue® plastic and the other for the patient procedure. Both sets of instructions are loaded on to the STAR S4 IR™ System and are used to define the patient treatment.

PC and Monitor

The computer is PC-compatible. The monitor is a flat-panel LCD display. Keyboard and mouse (or glidepad) are Windows standard.

Isolation Transformer

The medical-grade isolation transformer complies with IEC 601-1 regulations. All power cords connect to the isolation transformer.

Power Supply

The power supply provides DC power to the video cameras (CCDs), and the superluminescent diode (SLD).

LED

Yellow (D3): Indicates SLD over-power fault. Located on back panel of power supply box.

Optical Head

The optical head includes two optical units for the precompensation of sphere and astigmatism, adjusted by three stepper motors, two CCD cameras, and a light source (the SLD). A circuit continuously measures the incident power of the light source and switches the SLD off if the incident power exceeds a defined threshold.

Printer

A high resolution color printer is included with the system.

Motorized table

The motorized table supports the WaveScan WaveFront System. Electrical ratings: 120 V ~, 50/60 Hz, 6 A. Vertical position is controlled by a rocker control switch (vertical height can range from 630 mm to 1030 mm). Table top supports the PC monitor, keyboard, mouse (or glidepad), and optical head. Shelves hold PC, printer, isolation transformer, and power supply.

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

2.1.1 Indications for Use

The STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere, and the cylinder and sphere have opposite signs;
- in patients 21 years of age or older; and
- in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.



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

2.1.2 Contraindications

Laser refractive surgery is contraindicated:

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

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

† Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc.

2.1.3 Warnings

LASIK is not recommended in patients who have:

- diabetes.
- a history of *Herpes simplex* or *Herpes zoster* keratitis.
- significant dry eye that is unresponsive to treatment.
- severe allergies.

2.1.4 Precautions

A. General

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

The safety and effectiveness of this laser for LASIK correction have **NOT** been established in patients:

- with progressive myopia, hyperopia, myopic or hyperopic astigmatism; ocular disease; corneal abnormality; previous corneal or intraocular surgery; or trauma in the ablation zone.
- with a residual corneal thickness less than 250 microns at the completion of ablation.
- with a history of glaucoma.
- who are taking the medication Sumatriptan (Imitrex®).

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

Pupil size should be evaluated under mesopic illumination conditions.

Pre-operative evaluation for dry eye should be performed. Patients should be advised of the potential for dry eye post-LASIK surgery.

Pre-operative ultrasonic pachymetry measurement must be performed.

* Imitrex® is a registered trademark of GlaxoSmithKline.

The physician's adjustment of defocus has not been studied, and its effects on the safety and effectiveness outcomes of wavefront-guided LASIK are unknown.

The safety and effectiveness of wavefront-guided LASIK surgery has **ONLY** been established with an optical zone of 6 mm and an ablation zone of 9 mm for mixed astigmatism.

The WaveScan® sensor measures the higher order aberrations only over the diameter of the patient's pupil, to a maximum of 7.0 mm. No optical zone diameters other than 6 mm were studied in the U.S. wavefront-guided clinical trials.

No higher order aberrations can be measured or treated outside the wavefront measurement region. If the surgeon extends the optical zone beyond the measured wavefront diameter, the nonuniform wavefront transition zone will overlie the attempted spherocylindrical treatment. Some treatments with extended optical zones were used to establish the safety and effectiveness of wavefront-guided mixed astigmatism treatments, but the outcomes of treatments with extended optical zones were not compared to those based on a 6 mm wavefront measurement.

It is important to maintain a carefully controlled surgical environment. VISX recommends that all CustomVue™ treatments be performed in surgical environments where the humidity is between 40-45% and the temperature is between 68-72° F for best results.

The safety and effectiveness of the STAR S4 IR™ System have **NOT** been established for wavefront-guided LASIK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone.
- under 21 years of age.
- over the long term (more than 1 year after surgery).
- with prior intraocular or corneal surgery of any kind.
- For eyes with mixed astigmatism:
 - whose difference between WaveScan and manifest refraction sphere or cylinder are not within ± 0.75 D, or whose WaveScan cylinder axis is > 15 degrees different from manifest cylinder axis.
 - whose difference between manifest and cycloplegic refraction sphere or cylinder are not within ± 0.75 D, or whose manifest cylinder axis is > 15 degrees different from cycloplegic cylinder axis.
 - whose difference between WaveScan and cycloplegic refraction sphere or cylinder are not within ± 0.75 D, or whose WaveScan cylinder axis is > 15 degrees different from cycloplegic cylinder axis.
 - whose BSCVA is worse than 20/25.
 - whose WaveScan® wavefront measurement diameter is < 5 mm.

- for treatments with cylinder magnitude greater than 5.0 diopters.
- for retreatment with CustomVue™ LASIK.
- who were wearing contact lenses unless they had evidence of stability.
- with an anticipated post-op keratometry reading > 50 D in any meridian.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for CustomVue™ treatment:

- All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK).
- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assess the presence of nuclear sclerosis or any other lens opacity. 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.
- Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo laser refractive surgery.
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- Baseline evaluation of patients requesting CustomVue™ treatments should be performed within 30 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the WaveScan® refraction, BSCVA, and pupil size, as outlined in the previous section of these Precautions.

- The minimum size of the wavefront measurement diameter must be ≥ 5 mm to calculate a CustomVue treatment.
- If a PreVue® lens is used in the baseline evaluation of patients requesting CustomVue™ treatments, the vision obtained by the patient through the PreVue lens is not meant to be predictive of the end result that a patient might achieve. In situations where there is a clinical question regarding the applicability of the computer-generated treatment, a PreVue lens can be ablated to assist both the practitioner and the patient in evaluating the appropriateness of this generated treatment.
- The patient should have the ability to tolerate local or topical anesthesia.
- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the laser refractive procedure.
- The patient must be able to understand and give an informed consent.
- Patients must be clearly informed of all alternatives for the correction of myopia, hyperopia, and astigmatism. These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries.

C. Procedure

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

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

D. Post-Procedure

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

- WaveScan® measurement.
- Uncorrected Visual Acuity (UCVA or VA-sc).
- Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc).
- Manifest refraction.
- Intraocular pressure (Goldmann applanation) at 1, 3, and 6 months.
- Slit-lamp examination.
- Keratometry and videokeratography.

2.1.5 Adverse Events for Mixed Astigmatism Study

Eighty-six (86) eyes were used for safety analyses. Eighty-six (86) eyes were followed for 3 months and eighty (80) eyes were followed for 6 months.

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

Table 2-1 — Summary of Adverse Events for Mixed Astigmatism Study, N=86

Mixed Astigmatism	<1 Month (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal epithelial defect involving the keratectomy at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1*	1.6
Corneal edema at 1 month or later (specify "flap" or "bed" or both)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface with loss of 2 or more lines of BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Miscreated Flap	1†	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Melting of the flap (LASIK only)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Uncontrolled IOP >10 mm Hg or Any reading > 25 mm Hg	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease in BSCVA of > 10 letters <u>not due</u> to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0	1‡	1.3	0	0.0	0	0.0

* An epithelial defect occurred when dendritic figures were cultured for herpes at >12 months post-operatively. The culture proved negative for herpes.

† One subject experienced a free LASIK cap during surgery. Although this event occurred on the day of surgery and resolved at the 3-month visit, it is reported in the <1-month column.

‡ The subject experienced a branch retinal artery occlusion 8 months post-operatively that resolved with sequelae (hazy vision inferiorly) by the 9-month visit.

Table 2-2 — Summary of Complications for Mixed Astigmatism Study, N=86

Mixed Astigmatism	<1 Month (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
Misaligned flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema between 1 week and 1 month after procedure	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral corneal epithelial defect at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface	0	0.0	4*	4.8	4*	4.7	2	2.5	2	2.9	2	3.2
Foreign body sensation at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pain at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Diplopia (ghost images) in the operative eye	0	0.0	3	3.6	7	8.1	4	5.0	2	2.9	4	6.3

* Two (2) eyes experienced epithelium in the interface at 1 and 3 months post-retreatment.

3.1 Clinical Results

3.1.1 Mixed Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted at six U.S. centers. The refractive inclusion criteria specified that the patient have mixed astigmatism ≤ 5.0 D (at the spectacle plane) where magnitude of cylinder was greater than the magnitude of sphere, and the cylinder and sphere have opposite signs. To qualify for the study, patients also had to demonstrate agreement between the manifest, WaveScan®, and cycloplegic refraction, a BSCVA of 20/25 or better, and a wavefront measurement diameter of ≥ 5 mm. All study treatments were conducted using a 6 mm optical zone and a 9 mm ablation zone with intention of full correction to emmetropia. Eighty-six (86) eyes were evaluated for safety and effectiveness. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopy.

A. About the Study

Analyses of results were performed at 1, 3, 6, 9, and 12 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, vector analysis, and stability. Safety analyses included change in best spectacle-corrected visual acuity (BSCVA), intraocular pressure, adverse events, and complications. The post-operative spectacle/contact lens wear frequency was not assessed.

B. Patient Accountability

Eighty-six (86) eyes of 44 subjects were evaluated for safety and effectiveness. Table 3-1 presents the demographic characteristics of the patient population. Table 3-2 presents the percent accountability for all eyes treated in the study. Over 95% accountability was achieved at the 1, 3, and 6-month visits.

Table 3-1 — Demographics, N=86

Age (in years)	Average ± Standard Deviation Minimum to Maximum	41.3 ± 10.8 23 to 66	
		Number	% of Eyes
Gender	Male	57	66.3
	Female	29	33.7
Race	Caucasian	59	68.6
	African American	1	1.2
	American Indian/Aleut Eskimo	0	0.0
	Asian/Pacific Islander	2	2.3
	Hispanic	24	27.9
Eyes	Right	42	48.8
	Left	44	51.2
Contact Lens History	None	83	96.5
	Soft	3	3.5
	RGP/PMMA	0	0.0

Table 3-2 — Patient Accountability, N=86

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Available for Analysis	84	97.7	86	100	80	93.0	69	80.2	63	73.2
Discontinued*	0	0.0	0	0.0	2	2.3	6	7.0	6	7.0
Missed Visit	2	2.3	0	0.0	0	0.0	7	8.1	0	0.0
Not yet Eligible	0	0.0	0	0.0	0	0.0	0	0.0	13	15.1
Lost to Follow-Up†	0	0.0	0	0.0	4	4.7	4	4.7	4	4.7
% Accountability‡	97.7%		100%		95.2%		86.3%		94.0%	

* Eyes discontinued due to retreatment.

† Four (4) eyes were lost to follow-up due to the military deployment of 2 subjects during the study.

‡ Percent accountability = [available for analysis/(enrolled – discontinued – not yet eligible)] x 100.

C. Data Analysis and Results

1) Pre-Operative Characteristics

The mean age of the 44 subjects participating in this trial was 41.3 ± 10.8 years, and ranged from 23-66 years. There were 15 women and 29 men. Table 3-3 presents pre-operative refractive error stratified by manifest sphere and cylinder expressed in plus cylinder notation.

All refractions were measured at 8 feet and adjusted to optical infinity (by subtracting 0.41 D from the spherical component of the refraction) for data analysis and presentation. After the refractions were adjusted, 15 of the 86 eyes were no longer classified as having mixed astigmatism because their sphere power shifted from hyperopic to myopic. Fourteen of these 15 eyes received a mixed astigmatism wavefront treatment pattern. One eye received a wavefront treatment pattern that was marginally classified as myopic astigmatism.

Table 3-3 — Pre-Operative Refractive Error Stratified by Sphere and Cylinder*, N=86

Sphere	Cylinder									
	1 to ≤2 D		>2 to ≤3 D		>3 to ≤4 D		>4 to ≤5 D		Total	
	n	%	n	%	n	%	n	%	n	%
<0 to ≤-1 D	9	10.5	4	4.7	2	2.3	3	3.5	18	20.9
<-1 to ≤-2 D	14	16.3	8	9.3	5	5.8	3	3.5	30	34.9
<-2 to ≤-3 D	1	1.2	15	17.4	2	2.3	1	1.2	19	22.1
<-3 to ≤-4 D	0	0.0	0	0.0	5	5.8	8	9.3	13	15.1
<-4 to ≤-5 D	0	0.0	0	0.0	0	0.0	4	4.7	4	4.7
<-5 D	0	0.0	0	0.0	0	0.0	2	2.3	2	2.3
Total	24	27.9	27	31.4	14	16.3	21	24.4	86	100

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

2) Uncorrected Visual Acuity (UCVA)

All eyes were targeted for emmetropia. Pre-operatively, 14% (12/86) of eyes had an uncorrected visual acuity (UCVA) of 20/40 or better; at the 3 and 6 month visits, 95% and 96% (82/86 and 77/80) of these eyes had UCVA of 20/40 or better. Table 3-4 presents UCVA over time.

Table 3-4 — UCVA* Over Time, N=86

	Pre-Op (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/16 or better	0	0.0	17	20.2	20	23.3	20	25.0	18	26.1	26	41.3
20/20 or better	0	0.0	56	66.7	53	61.6	48	60.0	51	73.9	47	74.6
20/25 or better	0	0.0	71	84.5	72	83.7	68	85.0	60	87.0	55	87.3
20/32 or better	0	0.0	77	91.7	79	91.9	75	93.8	68	98.6	61	96.8
20/40 or better	12	14.0	79	94.0	82	95.3	77	96.3	68	98.6	61	96.8
20/80 or better	59	68.6	83	98.8	85	98.8	79	98.8	69	100	63	100
20/200 or better	86	100	84	100	86	100	80	100	69	100	63	100
Worse than 20/200	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	86	100	84	100	86	100	80	100	69	100	63	100

* Acuity was measured at 8 feet.

At 3 months, a sex difference in percent of patients with UCVA 20/20 or better was statistically significant (41% females, 72% males; $p = 0.0062$).

Analysis of UCVA as a measure of effectiveness is most meaningful for eyes with the ability to achieve BSCVA of at least 20/20 pre-operatively since these eyes have the capacity to achieve UCVA of 20/20 post-operatively. Seventy-three (73) out of eighty-six (86) eyes had a pre-operative BSCVA of 20/20. At 3 months, 95% (69/73) and at 6 months 96% (63/66) of these eyes had UCVA of 20/40 or better.

While pre-operatively, no eye had UCVA of 20/20 or better; at 3 months, 67% (49/73) and at 6 months 65% (45/69) of eyes had UCVA of 20/20 or better. Table 3-5 presents distance UCVA over time of eyes with a pre-operative BSCVA of 20/20 or better.

Table 3-5 — UCVA* Over Time: Eyes with Pre-Op BSCVA of 20/20 or Better, N=73

	Pre-Op (n=73)		1 Month (n=72)		3 Months (n=73)		6 Months (n=69)		9 Months (n=61)		12 Months (n=55)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/16 or better	0	0.0	17	23.6	20	27.4	20	29.0	18	29.5	25	45.5
20/20 or better	0	0.0	49	68.1	49	67.1	45	65.2	49	80.3	44	80.0
20/25 or better	0	0.0	62	86.1	64	87.7	59	85.5	56	91.8	48	87.3
20/32 or better	0	0.0	65	90.3	66	90.4	64	92.8	60	98.4	53	96.4
20/40 or better	12	16.4	67	93.1	69	94.5	66	95.7	60	98.4	53	96.4
20/80 or better	49	67.1	71	98.6	72	98.6	68	98.6	61	100	55	100
20/200 or better	73	100	72	100	73	100	69	100	61	100	55	100
Worse than 20/200	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Acuity was measured at 8 feet.

At six months, more than 56% of eyes were able to achieve a post-operative uncorrected vision that was either the same or better than their pre-operative best-corrected vision.

Table 3-6 — Post-Operative Uncorrected Visual Acuity Compared to Pre-Operative Best Spectacle-Corrected Visual Acuity*, N=86

	1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%
2 lines better	0	0.0	0	0.0	1	1.3	0	0.0	2	3.2
1 line better	18	21.4	16	18.6	11	13.8	11	15.9	15	23.8
Equal	24	28.6	28	32.6	33	41.3	30	42.5	27	42.9
1 line worse	25	29.8	25	29.1	18	22.5	20	29.0	9	14.3
2 lines worse	8	9.5	9	10.5	9	11.3	5	7.2	6	9.5
>2 lines worse	9	10.7	8	9.3	8	10.0	3	4.3	4	6.3

* Acuity was measured at 8 feet.

3) Best-Spectacle-Corrected Visual Acuity (BSCVA)

At both the 1 and 6-month visits, 1 eye (less than 2%) lost 2 lines of BSCVA, but no eye at the 1, 3, 6, 9, or 12-month visits lost more than 2 lines of BSCVA. Table 3-7 presents the change in lines of BSCVA over time.

Table 3-7 — Change in BSCVA Over Time, N=86

	1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n= 63)	
	n	%	n	%	n	%	n	%	n	%
Decrease > 2 Lines	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease > 1 to ≤ 2 Lines*	2	2.4	0	0.0	1	1.3	0	0.0	0	0.0
Decrease > 0 to ≤ 1 Line	11	13.1	11	12.8	11	13.8	11	15.9	3	4.8
No Change	36	42.9	38	44.2	29	36.3	25	36.2	22	34.9
Increase > 0 to ≤ 1 Line	33	39.3	34	39.5	34	42.5	29	42.0	31	49.2
Increase > 1 to ≤ 2 Lines	2	2.4	3	3.5	5	6.3	4	5.8	5	7.9
Increase > 2 Lines	0	0.0	0	0.0	0	0.0	0	0.0	2	3.2

* One (1) eye lost 2 lines of BSCVA at 1 month (1.2%) and at 6 months (1.3%).

4) Accuracy of Manifest Refraction

Table 3-8 — Accuracy of Manifest and WaveScan® Cylinder, N=86

	Pre-Op		1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%	n	%
Manifest Cylinder	n=86		n=84		n=86		n=80		n=69		n=63	
± 0.50 D	0	0.0	50	59.5	51	59.3	44	55.0	41	59.4	36	57.1
± 1.00 D	1	1.2	78	92.9	76	88.4	72	90.0	62	89.9	60	95.2
WaveScan Cylinder	n=86		n=81		n=86		n=77		n=65		n=54	
± 0.50 D	0	0.0	23	28.4	20	23.3	22	28.6	18	27.7	15	27.8
± 1.00 D	0	0.0	57	70.4	64	74.4	58	75.3	47	72.3	42	77.8

Table 3-9 — Accuracy of Cylinder at 3 Months, Stratified by Pre-Operative Manifest Cylinder, N=86

Manifest Cylinder	1.0 to 2.0 D		>2.0 to 3.0 D		>3.0 to 4.0 D		>4.0 to 5.0 D		Total	
	n	%	n	%	n	%	n	%	n	%
	n=24		n=27		n=14		n=21		n=86	
Cylinder ± 0.50 D	19	79.2	18	66.7	5	35.7	9	42.9	51	59.3
Cylinder ± 1.00 D	23	95.8	25	92.6	13	92.9	15	71.4	76	88.4
Cylinder ± 2.00 D	24	100	27	100	14	100	21	100	86	100

At 3 months, there was a significant sex difference in percent of patients with cylinder ± 0.5 D (38% females, 70% males; p = 0.0042).

Table 3-10 — Axis Change from Baseline for Manifest Refractive Cylinder

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Eyes with $\leq 15^\circ$ axis change from baseline	52	61.9	52	60.5	49	61.3	39	56.5	35	55.6
Eyes with $>15^\circ$ axis change from baseline and post-op cylinder ≤ 0.5 D	20	23.8	20	23.3	17	21.3	14	20.3	14	22.2
Eyes with $>15^\circ$ axis change from baseline and post-op cylinder >0.5 D	12	14.3	14	16.3	14	17.5	16	23.2	14	22.2
Available for analysis	N = 84		N = 86		N = 80		N = 69		N = 63	

Table 3-11 — Accuracy of Manifest Refraction in Pre-Op Hyperopic Meridian (For Eyes with $\leq 15^\circ$ Axis Change from Baseline)*

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Correction Error										
0.00 to ± 0.50 D	29	55.8	31	59.6	30	61.2	32	84.2	25	71.4
Undercorrected (Hyperopic)										
>0.50 to 0.99 D	8	15.4	14	26.9	11	22.4	1	2.6	4	11.4
1.00 to 1.99 D	13	25.0	5	9.6	5	10.2	3	7.9	3	8.6
≥ 2.00 D	3	5.8	0	0.0	0	0.0	0	0.0	0	0.0
Overcorrected (Myopic)										
>0.50 to 0.99 D	0	0.0	2	3.8	3	6.1	2	5.3	3	8.6
1.00 to 1.99 D	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
≥ 2.00 D	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	N = 52		N = 52		N = 49		N = 38		N = 35	

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

Table 3-12 — Accuracy of Manifest Refraction in Pre-Op Myopic Meridian (For Eyes with $\leq 15^\circ$ Axis Change from Baseline)*

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Correction Error										
0.00 to ± 0.50 D	28	53.8	33	63.5	29	59.2	23	60.5	21	60.0
Undercorrected (Myopic)										
>0.50 to 0.99 D	8	15.4	14	26.9	14	28.6	10	26.3	12	34.3
1.00 to 1.99 D	13	25.0	3	5.8	3	6.1	4	10.5	2	5.7
≥ 2.00 D	3	5.8	0	0.0	0	0.0	0	0.0	0	0.0
Overcorrected (Hyperopic)										
>0.50 to 0.99 D	0	0.0	2	3.8	3	6.1	1	2.6	0	0.0
1.00 to 1.99 D	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
≥ 2.00 D	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	N = 52		N = 52		N = 49		N = 38		N = 35	

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

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5) Accuracy of MRSE Over Time

At 3 months post-operatively, 78% (67/86) of eyes were within 0.50 D and 98% (84/86) were within 1 D of attempted MRSE. At 6 months, 67% (54/80) and 96% (77/80) were within 0.50 D and 1 D, respectively. At the 3 and 6-month visits, no eye was overcorrected by more than 1 D and no eye was undercorrected by more than 2 D. Table 3-13 presents the accuracy of MRSE over time.

Table 3-13 — Accuracy of MRSE[†] Over Time, Attempted vs. Achieved, N=86

	Pre-Op (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	22	25.6	56	66.7	67	77.9	54	67.5	53	76.8	48	76.2
± 1.00 D	52	60.5	78	92.9	84	97.7	77	96.3	68	98.6	63	100
± 2.00 D	82	95.3	84	100	86	100	80	100	69	100	63	100
Not Reported	0		0		0		0		0		0	
Overcorrected (Myopic)												
< -1.00 D			3	3.6	1	1.2	1	1.3	0	0.0	0	0.0
< -2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected (Hyperopic)												
> +1.00 D			3	3.6	1	1.2	2	2.5	1	1.4	0	0.0
> +2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

6) Stability of Outcome

a) Stability of MRSE

Stability of outcome is evaluated both by the cohort of eyes with a refraction at two consecutive visits (n = 84), as well as the cohort of eyes with a refraction at each post-operative visit (n = 67). Table 3-14 presents refractive stability data for those eyes with two consecutive visits.

Table 3-14 — Refractive Stability*: Eyes With Two Consecutive Visits, N=84

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
	n = 84	n = 80	n = 69	n = 56
Change in MRSE by ≤ 1.0 D	83	79	69	55
%	98.8	98.8	100	98.2
95% CI	(93.5, 100)	(93.2, 100)	(95.8, 100)	(90.4, 100)
Mean Change in MRSE	0.08	0.02	-0.03	-0.01
SD	0.33	0.37	0.22	0.30
95% CI	(0.01, 0.15)	(-0.06, 0.10)	(-0.08, 0.02)	(-0.09, 0.07)

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

Between the 1, 3, and 6-month visits, 98.5% (66/67) of eyes experienced a change in MRSE of ≤ 1.00 D. Refractive stability is reached at 3 months and confirmed at 6 months. Table 3-15 presents refractive stability for those eyes with exams at 1, 3, and 6 months.

Table 3-15 — Refractive Stability*: Eyes With Exams at 1, 3, 6, and 9-Month Visits, N=67

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months
Change in MRSE by ≤ 1.0 D	66	66	67
%	98.5	98.5	100
95% CI	(92.0, 100)	(92.0, 100)	(95.6, 100)
Mean Change in MRSE	0.06	0.02	-0.04
SD	0.32	0.38	0.21
95% CI	(-0.02, 0.13)	(-0.08, 0.11)	(-0.09, 0.01)

* Refractions were measured at 8 feet; results shown are adjusted for optical infinity.

b) Stability of Refractive Cylinder

Using the target outcome for refractive stability, defined as the point at which 95% of eyes experience a change of not more than 1 D between two visits, stability of refractive cylinder is also achieved at 3 months post-operatively (100%) and maintained through 12 months (100%). Table 3-16 presents the stability of refractive cylinder for those eyes with two consecutive visits.

Table 3-16 — Stability of Refractive Cylinder: Eyes with Two Consecutive Visits, N=84

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
	n = 84	n = 80	n = 69	n = 56
Change in Cylinder by ≤ 1.0 D	84	80	69	56
%	100	100	100	100
95% CI	(96.5, 100)	(96.3, 100)	(95.8, 100)	(94.8, 100)
Mean Change in Cylinder \pm SD	0.06 \pm 0.33	0.03 \pm 0.24	-0.01 \pm 0.25	+0.08 \pm 0.25
95% CI	(-0.01, 0.13)	(-0.03, 0.08)	(-0.07, 0.05)	(0.01, 0.14)

The analysis of stability was limited to the 67 eyes with follow-up exams at 1, 3, 6, and 9 months, because 65% of eyes (n=56) had data available at all exams through 12 months.

Table 3-17 — Stability of Refractive Cylinder: Eyes with Exams at 1, 3, 6, and 9 Months, N=67

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months
	n = 67	n = 67	n = 67
Change in Cylinder by ≤ 1.0 D	67	67	67
%	100	100	100
95% CI	(95.6, 100)	(95.6, 100)	(95.6, 100)
Mean Change in Cylinder \pm SD	0.06	0.03	-0.02
95% CI	(-0.01, 0.13)	(-0.02, 0.08)	(-0.07, 0.04)

c) Stability of Keratometry

Since the treatment of refractive errors was achieved by an alteration of the anterior corneal curvature, an important method to evaluate treatment stability is through keratometry. Between the 1, 3, 6, 9, and 12-month visits, more than 97% of eyes experienced a change in average keratometry of ≤ 1.0 D.

Table 3-18 presents the stability of average keratometry between the 1, 3, 6, and 9-month visits. Table 3-19 presents mean keratometry over time.

Table 3-18 — Stability of Average Keratometry: Eyes with Two Consecutive Visits, N=84

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
	n = 84	n = 80	n = 69	n = 56
Change in Avg K by ≤ 1.0 D	82	79	69	56
%	97.6	98.8	100	100
95% CI	(91.7, 99.7)	(93.2, 100)	(95.8, 100)	(94.8, 100)
Mean Change in Avg K \pm SD	-0.01 \pm 0.39	0.03 \pm 0.30	0.02 \pm 0.27	-0.05 \pm 0.28
95% CI	(-0.10, 0.07)	(-0.03, 0.10)	(-0.05, 0.08)	(-0.13, 0.02)

Table 3-19 — Mean Keratometry Over Time

	Pre-Op	1 Month	3 Months	6 Months	9 Months	12 Months
	n = 86	n = 84	n = 86	n = 80	n = 69	n = 63
Mean	43.94	43.32	43.27	43.36	43.27	43.43
SD	1.27	1.44	1.42	1.39	1.34	1.45
95% CI	(43.68, 44.21)	(43.01, 43.63)	(42.97, 43.57)	(43.06, 43.66)	(42.96, 43.59)	(43.07, 43.78)

When plotted over time, the mean manifest spherical equivalents illustrate that stability is achieved by the 3-month visit.

Figure 3-1 — Stability of MRSE Over Time (N=86)

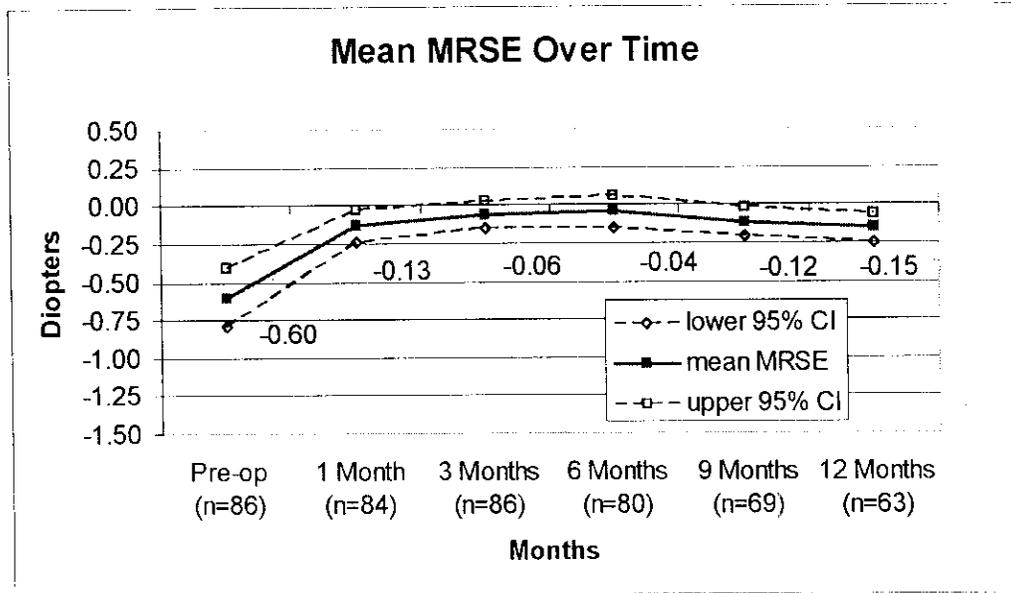
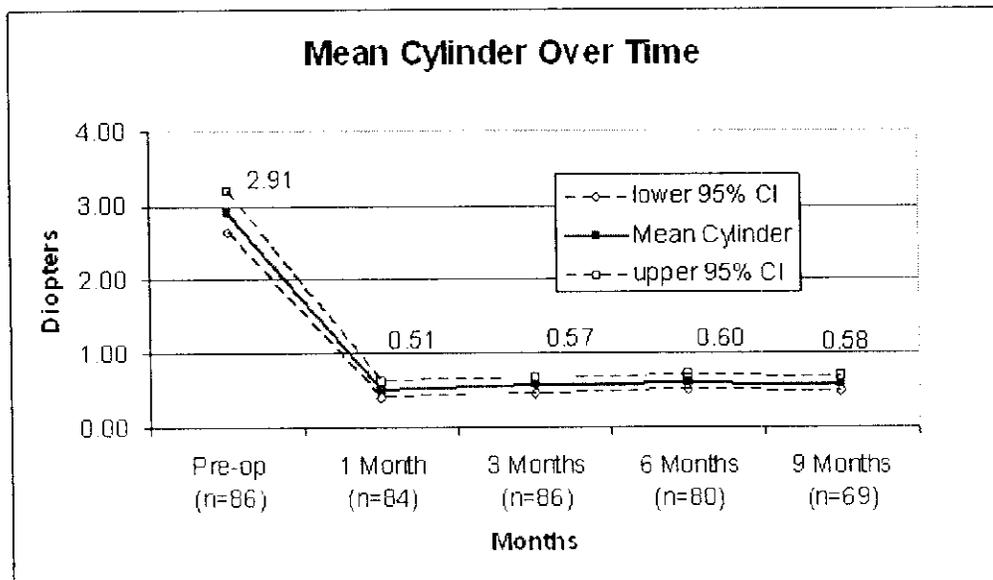


Figure 3-2 — Mean Cylinder Over Time (N=86)



7) Efficacy of Correction of Astigmatism

Efficacy of correction of astigmatism was evaluated at the point of stability (3 months). Table 3-20 presents post-operative cylinder correction stratified by diopter of pre-operative manifest refraction cylinder.

Table 3-20 — Reduction of Absolute (Non-Vector) Cylinder, N=86

Pre-Operative Cylinder	Mean % Reduction	Range
ALL (n=86)	79.3%	16.7% to 100%
1.0 to \leq 2.0 D (n=24)	77.3%	16.7% to 100%
>2.0 to \leq 3.0 D (n=27)	79.6%	45.5% to 100%
>3.0 to \leq 4.0 D (n=14)	81.4%	62.5% to 100%
>4.0 to \leq 5.0 D (n=21)	79.8%	57.9% to 100%

The correction ratio (SIRC/IRC) is an indicator of procedure effectiveness. Vector analysis was performed at the point of stability (3 months). The mean cylindrical correction ratio is 0.88. Table 3-21 reflects a summary of the Intended Refractive Change (IRC), Surgically Induced Refractive Change (SIRC), Correction Ratio (CR), and Error Ratio (ER) at the point of stability (3 months).

Table 3-21 — Summary of Vector Analysis at Stability (3 Months), N=86

Pre-Operative Cylinder	IRC*	SIRC†	CR‡	ER**
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
ALL (n=86)	-2.97 ± 1.19	-2.58 ± 1.05	0.88 ± 0.17	0.21 ± 0.15
1.0 to ≤2.0 D (n=24)	-1.64 ± 0.29	-1.50 ± 0.51	0.90 ± 0.22	0.23 ± 0.21
>2.0 to ≤3.0 D (n=27)	-2.50 ± 0.28	-2.26 ± 0.47	0.91 ± 0.17	0.21 ± 0.14
>3.0 to ≤4.0 D (n=14)	-3.57 ± 0.32	-3.17 ± 0.61	0.88 ± 0.12	0.19 ± 0.12
>4.0 to ≤5.0 D (n=21)	-4.66 ± 0.25	-3.85 ± 0.65	0.83 ± 0.13	0.21 ± 0.12

* IRC – Intended Refractive Change – vector difference between target refraction and pre-operative refractions.

† SIRC – Surgically Induced Refractive Error – difference between post-operative and pre-operative vectors.

‡ CR – Correction Ratio – ratio of achieved versus intended vector magnitude.

CR mathematical definition: |SIRC| divided by |IRC|

** ER – Error Ratio – ratio of Error Vector and IRC magnitudes

Error Vector mathematical definition: vector difference between |SIRC| and |IRC|

ER mathematical definition: |Error Vector| divided by |IRC|

8) Higher Order Aberrations

Although the WaveScan WaveFront® System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, in the clinical study for this PMA, the average higher order aberration did not decrease after CustomVue™ treatment.

Table 3-22 presents an analysis of root mean square (RMS) over time for wavefront aberrations. This analysis is limited to those eyes with a WaveScan® measurement over a minimum of 5 mm post-operatively, as aberration analysis is standardized at and calculated over a 5 mm diameter. At no point is there a clinically significant increase in any higher order aberration.

Table 3-22 — RMS Over Time, N=86

	Pre-Op Mean ± SD	1 Month Mean ± SD	3 Months Mean ± SD	6 Months Mean ± SD	9 Months Mean ± SD	12 Months Mean ± SD
	n = 86	n = 80	n = 86	n = 77	n = 63	n = 54
All Higher Order	0.16 ± 0.06	0.22 ± 0.09	0.22 ± 0.08	0.22 ± 0.09	0.23 ± 0.10	0.21 ± 0.08
Coma	0.10 ± 0.06	0.12 ± 0.07	0.12 ± 0.06	0.12 ± 0.07	0.12 ± 0.08	0.11 ± 0.06
Trefoil	0.08 ± 0.05	0.11 ± 0.07	0.11 ± 0.07	0.12 ± 0.08	0.13 ± 0.07	0.11 ± 0.07
Spherical Aberration	0.05 ± 0.03	0.05 ± 0.05	0.06 ± 0.04	0.06 ± 0.04	0.05 ± 0.04	0.05 ± 0.04
Secondary Astigmatism	0.03 ± 0.02	0.06 ± 0.04	0.07 ± 0.04	0.07 ± 0.05	0.07 ± 0.05	0.07 ± 0.05
Tetrafoil	0.03 ± 0.02	0.05 ± 0.03	0.05 ± 0.04	0.06 ± 0.03	0.06 ± 0.03	0.06 ± 0.04
5th Order	0.03 ± 0.02	0.04 ± 0.02	0.04 ± 0.02	0.04 ± 0.02	0.04 ± 0.02	0.03 ± 0.02
6th Order	0.02 ± 0.01	0.04 ± 0.02	0.03 ± 0.02	0.03 ± 0.02	0.03 ± 0.02	0.03 ± 0.02
Signed Value of Spherical Aberration	0.03 ± 0.05	0.00 ± 0.07	0.00 ± 0.07	0.00 ± 0.07	-0.01 ± 0.06	0.01 ± 0.07
Min, Max	(-0.06, 0.16)	(-0.23, 0.20)	(-0.19, 0.13)	(-0.19, 0.15)	(-0.19, 0.12)	(-0.13, 0.17)
n*	n = 86	n = 81	n = 86	n = 77	n = 65	n = 54
WaveScan SE*	-0.13 ± 0.89	0.55 ± 0.35	0.56 ± 0.39	0.55 ± 0.43	0.50 ± 0.50	0.40 ± 0.34
Astigmatism Magnitude*	3.04 ± 1.23	0.81 ± 0.44	0.81 ± 0.42	0.79 ± 0.42	0.80 ± 0.43	0.77 ± 0.42

* WaveScan spherical equivalent and astigmatism analyses are calculated over 4 mm.

9) Contrast Sensitivity Analysis

Table 3-23 presents the results of the contrast sensitivity analysis from pre-operative to 1, 3, 6, and 12 months post-operative. The data are sorted to allow for a two-tailed paired-t for the means. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease. Table 3-24 presents the change in contrast sensitivity from a baseline of more than 2 lines (>0.30 log units) at 2 or more spatial frequencies for all eyes treated in the study.

Table 3-23 — Contrast Sensitivity, N=86

CPD	Pre-Op			Change from Pre-Op to 1 Month			Change from Pre-Op to 3 Months			Change from Pre-Op to 6 Months			Change from Pre-Op to 12 Months							
	3	6	12	3	6	12	3	6	12	3	6	12	3	6	12	18				
Dim w/ Glare	n = 86																			
Mean	1.51	1.45	0.86	0.44	0.00	0.03	0.08	0.07	-0.01	0.06	0.12	0.10	0.01	0.07	0.13	0.17	0.06	0.018	0.021	0.014
(SE)	0.024	0.037	0.038	0.039	0.024	0.034	0.038	0.039	0.025	0.039	0.034	0.036	0.025	0.041	0.038	0.045	0.026	0.043	0.050	0.050
P Value ≤ *					0.953	0.456	0.050	0.093	0.740	0.114	0.001	0.009	0.622	0.108	0.001	0.000	0.025	0.000	0.000	0.006
Dim w/o Glare	n = 84																			
Mean	1.52	1.55	0.99	0.55	0.01	0.02	-0.01	0.02	0.03	0.03	0.11	0.12	0.08	0.09	0.11	0.12	0.08	0.13	0.18	0.18
(SE)	0.027	0.032	0.040	0.038	0.021	0.028	0.034	0.037	0.022	0.031	0.041	0.037	0.026	0.029	0.040	0.039	0.027	0.036	0.043	0.048
P Value ≤ *					0.575	0.406	0.825	0.565	0.252	0.408	0.007	0.002	0.002	0.002	0.006	0.004	0.005	0.001	0.000	0.000
Bright w/o Glare	n = 86																			
Mean	1.72	1.88	1.47	0.99	0.01	0.00	0.05	0.05	0.04	0.07	0.06	0.08	0.02	0.06	0.09	0.08	0.04	0.08	0.12	0.13
(SE)	0.020	0.024	0.032	0.034	0.020	0.019	0.029	0.028	0.019	0.020	0.028	0.027	0.021	0.020	0.031	0.029	0.025	0.027	0.031	0.031
P Value ≤ *					0.618	1.000	0.113	0.068	0.042	0.001	0.040	0.003	0.253	0.005	0.004	0.007	0.094	0.006	0.000	0.000

* Two-tailed paired t test for the means.

Table 3-24 — Change in Contrast Sensitivity, N=86

	3 Months, N=86			6 Months, N=80			12 Months, N=63		
	Decrease	No Change	Increase	Decrease	No Change	Increase	Decrease	No Change	Increase
Bright without Glare	3	75	8	3	68	9	1	55	7
%	3.5	87.2	9.3	3.8	85.0	11.3	1.6	87.3	11.1
Dim without Glare	6	64	16	4	58	18	3	40	20
%	7.0	74.4	18.6	5.0	72.5	22.5	4.8	63.5	31.7
Dim with Glare	4	67	15	4	63	13	3	37	23
%	4.7	77.9	17.4	5.0	78.8	16.3	4.8	58.7	36.5

10) Retreatments

Six (6) eyes (6/86, 7.0%) underwent retreatment. Two eyes were retreated after completing the 3-month visit and 4 eyes were retreated after completing the 6-month visit. Data for these eyes prior to retreatment are included in all analyses.

11) Patient Symptoms

Patient questionnaires reflected the following patient responses to symptoms and satisfaction pre-operatively and at 3 and 6 months post-operatively.

Table 3-25 — Summary of Patient Symptoms, N=86

	Never			Rarely			Sometimes			Often			Always			Not Reported		
	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M									
	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Dryness	30 34.9	10 11.6	8 10.0	24 27.9	30 34.9	28 35.0	27 31.4	27 31.4	30 37.5	5 5.8	16 18.6	14 17.5	0 0.0	3 3.5	0 0.0	0 0.0	0 0.0	0 0.0
Blurry Vision	16 18.6	13 15.1	19 23.8	31 36.0	32 37.2	34 42.5	25 29.1	29 33.7	20 25.0	7 8.1	6 7.0	3 3.8	7 8.1	6 7.0	4 5.0	0 0.0	0 0.0	0 0.0
Fluctuation of vision	25 29.1	25 29.1	31 38.8	34 39.5	29 33.7	24 30.0	19 22.1	29 33.7	21 26.3	8 9.3	3 3.5	4 5.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Glare	21 24.4	32 37.2	33 41.3	32 37.2	32 37.2	25 31.3	26 30.2	20 23.3	21 26.3	3 3.5	0 0.0	0 0.0	4 4.7	2 2.3	1 1.3	0 0.0	0 0.0	0 0.0
Halos Around Lights	25 29.1	30 34.9	34 42.5	21 24.4	29 33.7	22 27.5	29 33.7	10 11.6	13 16.3	5 5.8	10 11.6	7 8.8	6 7.0	7 8.1	4 5.0	0 0.0	0 0.0	0 0.0
Difficulty at Night W/Glare	8 9.3	30 34.9	33 41.3	35 40.7	39 45.3	35 43.8	29 33.7	8 9.3	5 6.3	10 11.6	3 3.5	3 3.8	4 4.7	6 7.0	4 5.0	0 0.0	0 0.0	0 0.0
Ghost or Double Images	53 62.4	63 73.3	60 75.0	14 16.5	8 9.3	12 15.0	12 14.1	13 15.1	3 3.8	6 7.1	0 0.0	1 1.3	0 0.0	2 2.3	4 5.0	1 1.2	0 0.0	0 0.0

Patients rated levels of symptoms on a five-category scale that consisted of the choices: never, rarely, sometimes, often, and always. In order for the scores to be rated as either "improved" or "worsened" required a change in two (2) or more levels of symptoms compared to pre-operative levels. For example, a change from "always" to "often" (one level) was rated as "no change," but a change from "always" to "sometimes" (2 levels) was rated as "improve."

Table 3-26 — Summary of Patient Symptoms: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision, N=86

Symptoms	3 Months, N=86						6 Months, N=80							
	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR
	n	%	n	%	n	%	n	n	%	n	%	n	%	n
Dryness	2	2.3	68	79.1	16	18.6	0	1	1.3	67	83.8	12	15.0	0
Blurry Vision	11	12.8	61	70.9	14	16.3	0	11	13.8	62	77.5	7	8.8	0
Fluctuation of Vision	7	8.1	73	84.9	6	7.0	0	7	8.8	67	83.8	6	7.5	0
Glare	13	15.1	65	75.6	8	9.3	0	14	17.5	59	73.8	7	8.8	0
Halos Around Lights	13	15.1	65	75.6	8	9.3	0	14	17.5	58	72.5	8	10.0	0
Difficulty at Night With Glare	24	27.9	55	64.0	7	8.1	0	25	31.3	50	62.5	5	6.3	0
Ghost or Double Images	8	9.4	70	82.4	7	8.2	1	10	12.7	64	81.0	5	6.3	1

Table 3-27 — Summary of Patient Satisfaction: Effectiveness, N=86

	Very Satisfied			Satisfied			Not Sure			Somewhat Dissatisfied			Very Dissatisfied			Not Reported		
	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M
	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n	n
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Sharpness and Clarity	10 11.6	46 53.5	49 61.3	51 59.3	25 29.1	19 23.8	11 12.8	7 8.1	7 8.8	10 11.6	4 4.7	1 1.3	4 4.7	4 4.7	4 5.0	0 0.0	0 0.0	0 0.0
Consistency of Vision	10 11.6	36 41.9	43 53.8	48 55.8	32 37.2	25 31.3	8 9.3	9 10.5	4 5.0	20 23.3	7 8.1	6 7.5	0 0.0	2 2.3	2 2.5	0 0.0	0 0.0	0 0.0
Daylight Vision	11 12.8	49 57.0	41 51.3	53 61.6	25 29.1	33 41.3	10 11.6	0 0.0	0 0.0	12 14.0	9 10.5	2 2.5	0 0.0	3 3.5	4 5.0	0 0.0	0 0.0	0 0.0
Night Vision	8 9.3	36 41.9	33 41.3	38 44.2	36 41.9	38 47.5	13 15.1	4 4.7	4 5.0	20 23.3	6 7.0	1 1.3	7 8.1	4 4.7	4 5.0	0 0.0	0 0.0	0 0.0
Night Vision with Glare	5 5.8	28 32.6	31 38.8	28 32.6	40 46.5	30 37.5	21 24.4	9 10.5	13 16.3	22 25.6	5 5.8	2 2.5	10 11.6	4 4.7	4 5.0	0 0.0	0 0.0	0 0.0

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Patients rated satisfaction on a five-category scale that consisted of the choices: very satisfied, satisfied, not sure, somewhat dissatisfied, and very dissatisfied. In order for the scores to be rated as either “improved” or “worsened” required a change in two (2) or more levels of satisfaction compared to pre-operative levels. For example, a change from “somewhat dissatisfied” to “not sure” (one level) was rated as “no change,” but a change from “somewhat dissatisfied” to “satisfied” (2 levels) was rated as “improve.”

Table 3-28 — Summary of Patient Satisfaction: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision, N=86

	3 Months, N=86						6 Months, N=80					
	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)	
	n	%	n	%	n	%	n	%	n	%	n	%
Sharpness and Clarity	12	14.0	67	77.9	7	8.1	13	16.3	63	78.8	4	5.0
Consistency of Vision	17	19.8	61	70.9	8	9.3	15	18.8	61	76.3	4	5.0
Daylight Driving	18	20.9	58	67.4	10	11.6	16	20.0	58	72.5	6	7.5
Night Driving	26	30.2	55	64.0	5	5.8	25	31.3	50	62.5	5	6.3
Night Vision with Glare	31	36.0	55	64.0	0	0.0	29	36.3	51	63.8	0	0.0

12) Summary of Key Safety and Effectiveness Variables

The key safety and effectiveness variables over time and stratified by pre-operative MRSE and pre-operative manifest cylinder are presented in Tables 3-29 and 3-30.

Table 3-29 — Summary of Key Safety and Effectiveness Variables*, N=86

Criteria	Pre-Op		1 Month		3Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%	n	%
	(95% CI)		(95% CI)		(95% CI)		(95% CI)		(95% CI)		(95% CI)	
EFFECTIVENESS VARIABLES												
N=86	n=86		n=84		n=86		n=80		n=69		n=63	
UCVA 20/20 or better	0	0.0	56	66.7	53	61.6	48	60.0	51	73.9	47	74.6
	(0.0, 3.4)		(55.5, 76.6)		(50.5, 71.9)		(48.4, 70.8)		(61.9, 83.7)		(62.1, 84.7)	
UCVA 20/40 or better	12	14.0	79	94.0	82	95.3	77	96.3	68	98.6	61	96.8
	(7.4, 23.1)		(86.7, 98.0)		(88.5, 98.7)		(89.4, 99.2)		(92.2, 100)		(89.0, 99.6)	
Sphere ± 0.50 D	0	0.0	51	60.7	57	66.3	46	57.5	44	63.8	36	57.1
	(0.0, 3.4)		(49.5, 71.2)		(55.3, 76.1)		(45.9, 68.5)		(51.3, 75.0)		(44.0, 69.5)	
Sphere ± 1.00 D	18	20.9	78	92.9	81	94.2	74	92.5	63	91.3	60	95.2
	(12.9, 31.0)		(85.1, 97.3)		(87.0, 98.1)		(84.4, 97.2)		(82.0, 96.7)		(86.7, 99.0)	
Cylinder ± 0.50 D	0	0.0	50	59.5	51	59.3	44	55.0	41	59.4	36	57.1
	(0.0, 3.4)		(48.3, 70.1)		(48.2, 69.8)		(43.5, 66.2)		(46.9, 71.1)		(44.0, 69.5)	
Cylinder ± 1.00 D	1	1.2	78	92.9	76	88.4	72	90.0	62	89.9	60	95.2
	(0.0, 6.3)		(85.1, 97.3)		(79.7, 94.3)		(81.2, 95.6)		(80.2, 95.8)		(86.7, 99.0)	
MRSE ± 0.50 D	22	25.6	56	66.7	67	77.9	54	67.5	53	76.8	48	76.2
	(16.8, 36.1)		(55.5, 76.6)		(67.7, 86.1)		(56.1, 77.6)		(65.1, 86.1)		(63.8, 86.0)	
MRSE ± 1.00 D	52	60.5	78	92.9	84	97.7	77	96.3	68	98.6	63	100
	(49.3, 70.8)		(85.1, 97.3)		(91.9, 99.7)		(89.4, 99.2)		(92.2, 100)		(95.4, 100)	
MRSE ± 2.00 D	82	95.3	84	100	86	100	80	100	69	100	63	100
	(88.5, 98.7)		(96.5, 100)		(96.6, 100)		(96.3, 100)		(95.8, 100)		(95.4, 100)	

* UCVA, sphere, cylinder, and MRSE were measured at 8 feet; results shown are adjusted for optical infinity.

Table 3-30 — Summary of Key Safety and Effectiveness Variables, N=86

Criteria	Pre-Op		1 Month		3 Months		6 Months		9 Months		12 Months	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
STABILITY VARIABLES*												
N=86	n=86		n=84		n=84		n=80		n=69		n=56	
Change \leq 1.00 D Cylinder					84	100 (96.5, 100)	80	100 (96.3, 100)	69	100 (95.8, 100)	56	100 (94.8, 100)
Mean Change in Cylinder \pm SD					0.06 \pm 0.33 (-0.01, 0.13)		0.03 \pm 0.24 (-0.03, 0.08)		-0.01 \pm 0.25 (-0.07, 0.05)		0.08 \pm 0.25 (0.01, 0.14)	
Change \leq 1.00 D MRSE					83	98.8 (93.5, 100)	79	98.8 (93.2, 100)	69	100 (95.8, 100)	55	98.2 (90.4, 100)
Mean Change in MRSE \pm SD					0.08 \pm 0.33 (0.01, 0.15)		0.02 \pm 0.37 (-0.06, 0.10)		-0.03 \pm 0.22 (-0.08, 0.02)		-0.01 \pm 0.30 (-0.09, 0.07)	
SAFETY VARIABLES												
N=86	n=86		n=84		n=86		n=80		n=69		n=63	
Loss of $>$ 2 lines BSCVA			0	0.0 (0.0, 3.5)	0	0.0 (0.0, 3.4)	0	0.0 (0.0, 3.7)	0	0.0 (0.0, 4.2)	0	0.0 (0.0, 4.6)
Loss \geq 2 lines BSCVA			1	1.2 (0.0, 6.5)	0	0.0 (0.0, 3.4)	1	1.3 (0.0, 6.8)	0	0.0 (0.0, 4.2)	0	0.0 (0.0, 4.6)
BSCVA worse than 20/25			0	0.0 (0.0, 3.5)	0	0.0 (0.0, 3.4)	0	0.0 (0.0, 3.7)	0	0.0 (0.0, 4.2)	0	0.0 (0.0, 4.6)
BSCVA worse than 20/40			0	0.0 (0.0, 3.5)	0	0.0 (0.0, 3.4)	0	0.0 (0.0, 3.7)	0	0.0 (0.0, 4.2)	0	0.0 (0.0, 4.6)

* Includes eyes with two consecutive exams, i.e., 1 and 3 months, 3 and 6 months, etc.

**Facts You Need to Know About
CustomVue™ Laser Assisted In-Situ
Keratomileusis (LASIK) Laser Treatment
Patient Information Booklet**

For Mixed Astigmatism (1 to 5 D of Cylinder)

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

Your doctor and VISX, Incorporated provide the information in this booklet to help you decide whether to have a CustomVue™ LASIK treatment. CustomVue LASIK (laser assisted *in situ* keratomileusis) may be used to correct, or partly correct, naturally occurring mixed astigmatism. Mixed astigmatism means you have two kinds of astigmatism, myopic (nearsighted) and hyperopic (farsighted) in the same eye.

Some other ways to correct your vision are by wearing glasses or contact lenses, or by undergoing other kinds of laser refractive surgery such as non-custom LASIK or PRK (photorefractive keratectomy). Other surgical procedures that do not use a laser such as RK (radial keratotomy) and ALK (automated lamellar keratectomy) may also be an option.

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

How Refractive (Wavefront) Errors Affect Your Vision

The cornea and lens of the eye focus rays of light by bending (or refracting) them to focus an image on the retina at the back of the eye, much like a camera focuses images onto film.

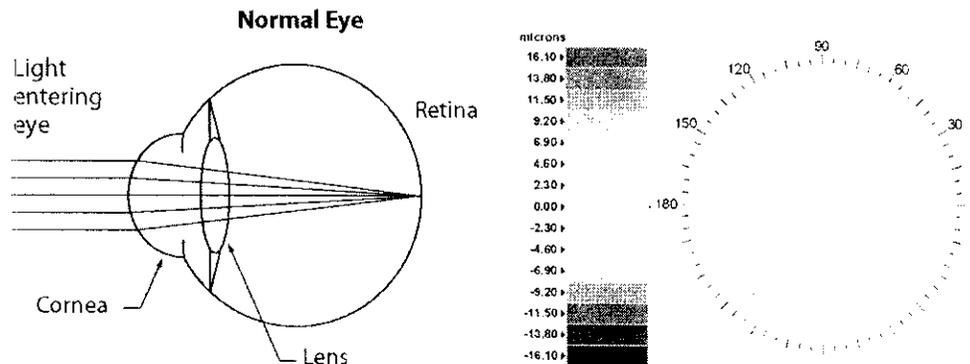


Figure 1: On the left is a diagram showing how the eye focuses light rays to create a sharp image on the retina. The corresponding wavefront map of an ideal eye is displayed on the right.

The above figure shows an ideal eye with no focusing imperfections. All of the rays of light traveling through the eye focus to a single point on the retina at the back of the eye.

In reality, all eyes have some degree of imperfections. One way to measure the focusing errors of an eye is to measure the *wavefront* of the eye. This can be done with an instrument like the VISX WaveScan WaveFront® System. The wavefront map is a picture of the rays of light as they travel through the eye. The WaveScan® System measures the wavefront errors by measuring light as it reflects out of the eye with a camera sensor.

The wavefront of a perfect eye has a flat surface because all of the light rays travel uniformly through the eye, as shown in figure 1. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others, and some rays strike different locations on the retina than others. Wavefront errors include both simple and complex focusing errors. The simple wavefront errors, which can be corrected with curved lenses (e.g., glasses or contact lenses), are also called *refractive errors* and include *mixed astigmatism*.

Astigmatism is usually caused by a misshapen cornea. Instead of being perfectly spherical, like a basketball, a cornea with astigmatism is more sharply curved in one direction than the other, like a football. The different curvatures of the cornea focus the light unequally so that they do not ever form a single point. Things look blurry because images are not ever focused clearly on the retina (the back of the eye).

There are two types of astigmatism. Hyperopic (farsighted) astigmatism causes some rays to focus behind the retina and myopic (nearsighted) astigmatism causes some rays to focus in front of the retina. Mixed astigmatism is when an eye has both types of astigmatism at the same time.

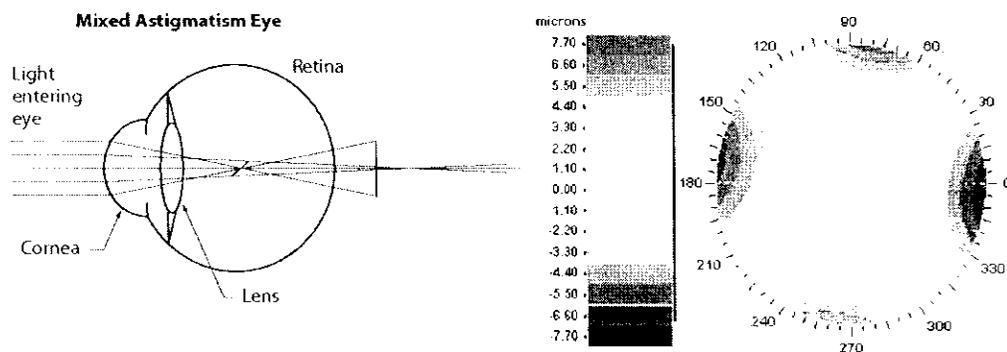


Figure 2: On the left is a diagram of an eye with mixed astigmatism showing that light entering the eye through different regions of the cornea focuses in two points, but neither point is on the retina. The corresponding wavefront map shows a surface that curves forward in one direction, and backward in the other, much like the shape of a saddle.

The WaveScan® System can also measure complex focusing errors. On the left in figure 3 is a map of all wavefront errors and on the right is a map showing just the complex errors. The combination of simple and complex wavefront errors in any eye is unique. The CustomVue™ treatment is "custom" because it includes information from the WaveScan System that is more individualized than what a doctor uses to create a non-custom treatment.

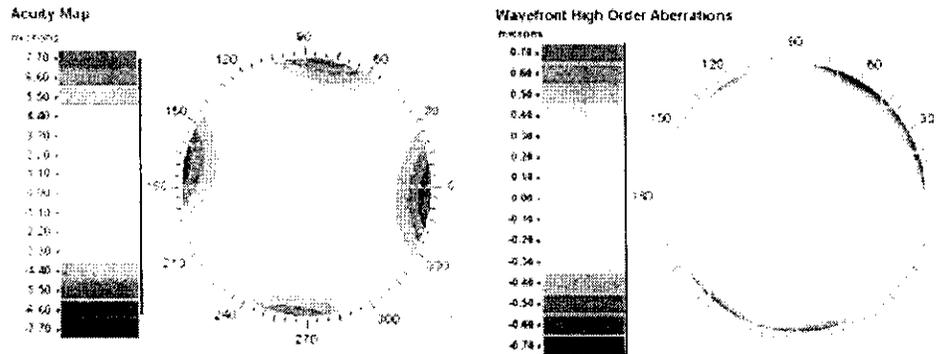


Figure 3: On the left is a wavefront map of all wavefront errors and on the right is a wavefront map showing only the complex errors.

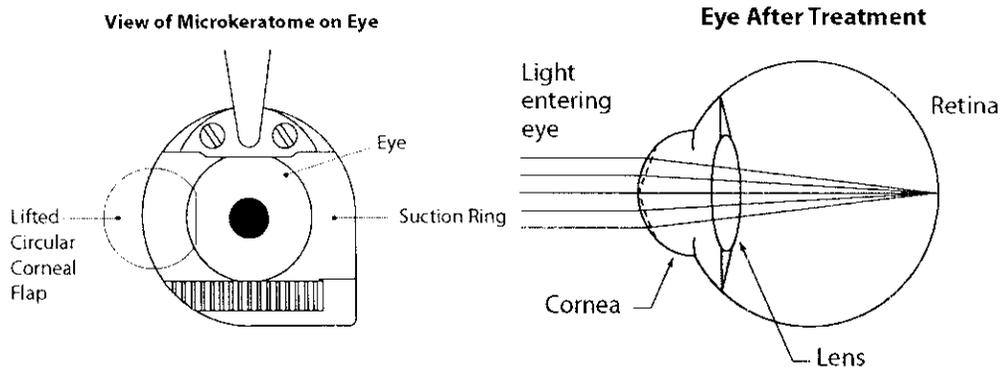
The VISX STAR S4 IR™ Excimer Laser

The excimer laser produces a beam of cool ultraviolet light. The doctor programs your information into a computer that controls the laser. The laser produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) undisturbed.

The laser also contains an auto-centering eye tracking system which will automatically align the treatment to your eye and compensate for many of your eye movements during the CustomVue™ treatment.

How the CustomVue LASIK Procedure Works

LASIK is a laser surgery technique used to correct refractive errors of the eye including nearsightedness, farsightedness, and astigmatism. Before activating the laser, the doctor creates a flap on your cornea using a *microkeratome*. A microkeratome is an instrument that creates a circular flap of tissue from the surface of the cornea using a blade or a laser. The doctor lifts the flap and folds it out of the way of the laser. After the laser treatment finishes, the doctor repositions the flap. VISX does not manufacture the microkeratome that your surgeon uses.



View (from above) of microkeratome on the eye.

Diagram of an eye after treatment showing where tissue is removed.

To correct mixed astigmatism, the cornea is flattened along one axis (e.g., vertical) and steepened along the other (e.g., horizontal). The doctor creates a unique treatment plan from the WaveScan® System to guide the laser. The laser removes tissue from the eye according to the treatment plan.

The VISX WaveScan WaveFront® System

Before your CustomVue™ LASIK treatment is programmed into the laser, you must have one or more WavePrint® measurements taken by the WaveScan® System. The WaveScan System is a tabletop diagnostic system that measures your eyes with specialized cameras. You will sit in front of the WaveScan System and look toward a light through an opening in the system while it scans your eye. Your doctor may take more than one measurement and then choose the most appropriate measurement to use as the basis for the CustomVue LASIK treatment. The doctor will also take other routine measurements of your vision to help design your treatment.

BENEFITS

CustomVue™ LASIK treatment can correct up to 5 diopters (D) of mixed astigmatism. If you have mixed astigmatism within this range, CustomVue LASIK treatment may help you to see distant objects clearly without eyeglasses or contact lenses.

Clinical Study to Evaluate Benefits

A clinical study was conducted to evaluate the benefits and risks of CustomVue LASIK for mixed astigmatism. This study involved 86 eyes of 44 patients. This study was initiated at six centers in January, 2003. The last patient in this study was treated in November 2003. The study results shown in this booklet include all the available reported outcomes on these patients through November 2004. Each table lists the number of eyes (N) for which data were available at the reported time point.

Study Patient Demographics

Table 1 lists the age, gender, race, and contact lens history of patients in this study.

Table 1 — Demographics of 86 Eyes of 44 Patients

Age	Average Range	41 ± 11 years 23 to 66 years
Gender	Male	66%
	Female	34%
Race	Caucasian	69%
	Asian/Pacific Islander	2%
	African American	1%
	Hispanic	28%
Contact Lens History	None	97%
	Soft	3%
	Hard	0%

Visual Acuity Without Glasses After Treatment

Visual acuity measures the sharpness of vision using a letter chart. Table 2 shows that six months after treatment, 60% of study patients saw 20/20 or better *without* glasses. At 12 months, 97% of study patients saw 20/40 or better. A visual acuity of 20/40 or better is the standard requirement in most states for you to drive without any glasses or contact lenses.

Table 2 — Visual Acuity *Without* Glasses After Treatment (N=86)

Time After Treatment	1 Month n=84	3 Months n=86	6 Months n=80	9 Months n=69	12 Months n=63
% of eyes with 20/20 or better	67%	62%	60%	74%	75%
% of eyes with 20/25 or better	85%	84%	85%	87%	87%
% of eyes with 20/40 or better	94%	95%	96%	99%	97%

Visual Acuity Without Glasses After Treatment and With Glasses Before Treatment

Table 3 shows that 56% of the patients saw as well or better *without* glasses 6 months after CustomVue™ treatment as *with* glasses before treatment.

Table 3 — Visual Acuity *Without* Glasses After Treatment Compared to *With* Glasses Before Treatment

Time After Treatment	1 Month n=84	3 Months n=86	6 Months n=80	9 Months n=69	12 Months n=63
% of eyes 2 lines better	0.0%	0.0%	1.3%	0.0%	3.2%
% of eyes 1 line better	21.4%	18.6%	13.8%	15.9%	23.8%
% of eyes equal	28.6%	32.6%	41.3%	42.5%	42.9%
% of eyes 1 line worse	29.8%	29.1%	22.5%	29.0%	14.3%
% of eyes 2 lines worse	9.5%	10.5%	11.3%	7.2%	9.5%
% of eyes >2 lines worse	10.7%	9.3%	10.0%	4.3%	6.3%

Patient Quality of Vision Comparison

Patients were asked to evaluate the quality of their vision both before and after the CustomVue™ treatment. Table 4 lists the patient responses reported at 3 months after treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 4 — Comparison of Quality of Vision *Without* Glasses After Treatment Compared to *With* Glasses Before Treatment

	3 Months (n=86)			6 Months (n=80)		
	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)
Sharpness and Clarity	14.0%	77.9%	8.1%	16.3%	78.8%	5.0%
Consistency of Vision	19.8%	70.9%	9.3%	18.8%	76.3%	5.0%
Daylight Driving	20.9%	67.4%	11.6%	20.0%	72.5%	7.5%
Night Driving	30.2%	64.0%	5.8%	31.3%	62.5%	6.3%
Night Vision With Glare	36.0%	64.0%	0.0%	36.3%	63.8%	0.0%

Patient Satisfaction Comparison

Patients were asked to evaluate their satisfaction with the quality of their vision both before and after the CustomVue™ treatment. Table 5 lists the patient responses reported before treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 5 — Comparison of Patient Satisfaction of Vision Before and After Treatment

	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Sharpness and clarity	71%	85%	13%	9%	16%	6%
Consistency of vision	67%	85%	9%	5%	23%	10%
Daylight vision	74%	93%	12%	0%	14%	8%
Night vision	54%	89%	15%	5%	31%	6%
Night vision with glare	38%	76%	24%	16%	37%	8%

RISKS

As with any surgical procedure there are risks associated with CustomVue™ treatments. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional laser treatment in the same eye. Your doctor may perform CustomVue LASIK for both eyes. However, sometimes it is better to have this procedure done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Some risks related to the creation of the corneal flap. Corneal flap complications include but are not limited to: cutting an incomplete, irregular flap or free flap; misalignment of the flap; and perforation of the cornea. Corneal flap complications range in severity from those that simply require the treatment to be postponed for several months, to those which create corneal irregularities resulting in permanently blurred vision.

IMPORTANT:

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

CONTRAINDICATIONS — When Can't You Have LASIK?

If you have any of the following situations or conditions you should not have LASIK because the risk is greater than the benefit:

- You are pregnant or nursing, because these conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment may improperly change the shape of your cornea.
- You have collagen vascular disease (e.g., rheumatoid arthritis), autoimmune disease (e.g., lupus), or immunodeficiency disease (e.g., AIDS), because these conditions affect the body's ability to heal.
- You show signs of keratoconus or any other condition that causes a thinning of your cornea. This condition can lead to serious corneal problems during and after LASIK surgery. It may result in need for additional surgery and may result in poor vision after LASIK.

- You are taking medications with ocular side effects, e.g., isotretinoin (Accutane®*) for acne treatment or amiodarone hydrochloride (Cordarone®†) for normalizing heart rhythm, because they may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- Your corneas are thin. If your corneas are too thin to allow your doctor to cut a proper flap in the LASIK procedure, you can't have LASIK because it is necessary to have a flap.

What Warnings and Other Information Do You Need to Know About?

Warnings

If you have more severe mixed astigmatism, your results may not be as good as those reported in this clinical study.

If you have any of the following conditions, you may have LASIK if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk.

- Diabetes. If you have diabetes, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- History of *Herpes simplex* or *Herpes zoster* infection that has affected your eyes. If you have had a *Herpes simplex* or a *Herpes zoster* infection that affected your eyes, and have an infection now, LASIK may be more risky for you.
- Symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase the dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- Severe allergies. If you have severe allergies and take medicines for them, LASIK may be more risky for you.

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

† Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc.

Precautions

The safety and effectiveness of wavefront-guided LASIK with the STAR S4 IR™ Laser for mixed astigmatism has not been established in patients:

- With unstable eyes that have changed in their prescription more than 0.5 diopter in nearsightedness, farsightedness, or astigmatism in the last 12 months, and your nearsightedness, farsightedness, or astigmatism is getting worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK.
- With corneal disease or abnormality (e.g., scar, infection, etc.). If you have an abnormal corneal condition, such as corneal scars, it may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK. If your eyes have an active disease, it is unknown whether LASIK is safe and effective under this condition.
- With history of injury or surgery to the center of the cornea (for example, surgery to correct vision such as RK, PRK, LASIK), or other surgery on the eye. If your eyes are injured or you have had surgery, it is unknown whether LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- With large pupils. Before surgery, your doctor should measure your pupil size under dim lighting conditions and review how your pupil size may affect your vision after surgery.
- With history of glaucoma or have had pressure greater than 21 mmHg inside your eyes, because it is unknown whether LASIK is safe and effective for you.
- Who use medications that might make it harder for wounds to heal, such as sumatriptan (Imitrex®*) used for migraine headaches, because it is unknown whether LASIK is safe and effective for this condition.
- Who take other medications. Let your doctor know if you are taking any prescription medicines or any medicines you bought without a prescription.

* Imitrex® is a registered trademark of GlaxoSmithKline.

- Who are younger than 21 years of age, because it is unknown whether LASIK is safe and effective for you.
- Who have astigmatism worse than 5 diopters, because it is unknown whether LASIK is safe and effective for you.
- Over the long term (more than 1 year), because the length of the clinical study was less than 1 year.
- Who are considering retreatment with this laser for LASIK, because it is unknown whether LASIK is safe and effective for repeating the LASIK procedure on the same eye.
- With undiagnosed dry eyes. Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.
- In the following conditions: dim lighting, rain, snow, fog, or bright glare. You might have difficulty seeing in dim lighting, rain, snow, fog, or bright glare. Whether you may have poor vision under these conditions is hard to predict because it has been studied so little.

Clinical Study to Evaluate Risks

In the clinical study on CustomVue™ LASIK for mixed astigmatism, visual acuity *with* glasses was the same or better for 87% of eyes treated.

Visual Acuity With Glasses After Treatment

Table 6 shows that all patients in the clinical study saw 20/25 or better *with* glasses at 1, 3, 6, and 9 months after treatment.

Table 6 — Visual Acuity *With* Glasses (Best Vision) After Treatment

	Pre-Op (n=86)	1 Month (n=84)	3 Months (n=86)	6 Months (n=80)	9 Months (n=69)	12 Months (n=63)
20/20 or better	85%	89%	93%	91%	91%	95%
20/25 or better	100%	100%	100%	100%	100%	100%
20/32 or better	100%	100%	100%	100%	100%	100%

Change in Visual Acuity With Glasses After Treatment

Table 7 shows the change in visual acuity *with* glasses at 1, 3, 6, 9, and 12 months after treatment for the patients in the clinical study.

Table 7 — Change in Visual Acuity *With* Glasses After Treatment Compared to Before Treatment

	1 Month (n=84)	3 Months (n=86)	6 Months (n=80)	9 Months (n=69)	12 Months (n=63)
Eyes with loss of >2 lines	0%	0%	0%	0%	0%
Eyes with loss of >1 to 2 lines	2%	0%	1%	0%	0%
Eyes with loss of >0 to 1 line	13%	13%	14%	16%	5%
Eyes with no change	43%	44%	36%	36%	35%
Eyes with gain of >0 to 1 line	39%	40%	43%	42%	49%
Eyes with gain of >1 to 2 lines	2%	4%	6%	6%	8%
Eyes with gain of >2 lines	0%	0%	0%	0%	3%

Contrast Sensitivity

Unlike normal vision tests that measure the ability to see a black and white eye chart, contrast sensitivity measures how well one sees in low contrast conditions such as driving in rain or fog. While most eyes in the study achieved the same or better contrast sensitivity post-operatively as they did pre-operatively, at 3 months post-operatively, 4% experienced a significant loss in bright conditions. In dim conditions, 7% experienced a similar loss, and with the addition of glare in dim conditions, 5% experienced such a loss. Table 8 shows the change in contrast sensitivity 3 months after treatment in 86 patients.

Table 8 — Change in Contrast Sensitivity 3 Months After Treatment

	3 Months (n=86)		
	% of Eyes With Loss	% of Eyes That Stay The Same	% of Eyes With Gain
Bright conditions with no glare	4%	87%	9%
Dim conditions with no glare	7%	74%	19%
Dim conditions with glare	5%	78%	17%

Adverse Events and Complications

Some patients in the clinical study experienced adverse events and complications after CustomVue™ LASIK treatment, as shown in Table 9.

Table 9 — Adverse Events and Complications

	Less than 1 Month (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
Greater than or equal to 1% of eyes had:												
Double or ghost images	0	0.0	3	3.6	7	8.1	4	5.0	2	2.9	4	6.3
Cells growing under the flap	0	0.0	4	4.8	4	4.7	2	2.5	2	2.9	2	3.2
Miscreated flap	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Scratch on outer surface of the eye	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
Blocked blood vessel in the back of the eye	0	0.0	0	0.0	0	0.0	1	1.3	0	0.0	0	0.0

Patient Symptoms After CustomVue™ Treatment

Patients were asked to evaluate the following visual symptoms without glasses after the CustomVue treatment at 3 months and again at 6 months compared to their vision with glasses before treatment. Table 10 lists the reported responses at 3 months after treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 10 — Comparison of Patient Symptoms of Vision Without Glasses After Treatment Compared to With Glasses Before Treatment

	3 Months (n=86)			6 Months (n=80)		
	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)
Dryness	2.3%	79.1%	18.6%	1.3%	83.8%	15.0%
Blurry Vision	12.8%	70.9%	16.3%	13.8%	77.5%	8.8%
Fluctuation of Vision	8.1%	84.9%	7.0%	8.8%	83.8%	7.5%
Glare	15.1%	75.6%	9.3%	17.5%	73.8%	8.8%
Halos Around Lights	15.1%	75.6%	9.3%	17.5%	72.5%	10.0%
Difficulty at Night with Glare	27.9%	64.0%	8.1%	31.3%	62.5%	6.3%
Ghost or Double Images	9.4%	82.4%	8.2%	12.7%	81.0%	6.3%

Frequency of Patient Symptoms After CustomVue™ Treatment

Patients were asked to rank the frequency of their symptoms both before and after the CustomVue treatment. Table 11 lists the patient symptoms reported before treatment (Pre-Op) on 86 eyes and at 3 months after treatment on 86 eyes.

Table 11 — Comparison of Frequency of Symptoms Before and After Treatment

Frequency	Often or Always	
Symptom	Pre-Op	3 Months
Dryness	6%	22%
Blurry vision	16%	14%
Fluctuation of vision	9%	4%
Glare	8%	2%
Halos*	13%	20%
Difficulty at night with glare	16%	11%
Ghost or double images	7%	2%

*Halos are hazy rings around bright lights.

The First Week Following Surgery

- Moderate 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 vision may fluctuate during this time period. You may also experience some dryness.

Are You A Good Candidate For CustomVue™ LASIK?

If you are considering CustomVue LASIK, you must:

- Be at least 21 years of age and have mixed astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g., scar, infection, etc.).
- Have documented evidence that your refraction did not change by more than 0.5 diopter during the year before your pre-operative examination.
- Be informed of LASIK risks and benefits as compared to other available treatments for mixed astigmatism.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign an informed consent form as provided by your eye care professional.
- Be able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

Before Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for surgery. This will include a complete medical and eye history, and thorough examination of both eyes, including WavePrint® refractions and computerized mapping of your cornea.

WARNING:

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

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

The Day of Surgery

Before the surgery, local anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery. 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 the surgery.

The surgery begins with the placement of a suction ring that elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The microkeratome creates a circular corneal flap. The doctor will lift this flap of tissue after the suction is released. Vision will return to the eye after the suction is released.

The doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking light while the laser is running. It is important to fix your gaze on the light for the entire laser procedure. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the light. Small amounts of tissue will then be removed from your cornea using the VISX STAR S4 IR™ Excimer Laser system.

PRECAUTION:

It is very important that you keep looking at the flashing fixation light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this light throughout the treatment to ensure the best results possible.

Typically, the laser beam will be applied to your eye less than 2 minutes and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drop. When the anesthetic drops wear off (about 30 to 60 minutes), your eye may hurt moderately for 1 to 2 days. The discomfort is typically described as “a sandy sensation.” Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and lessen the risk of infection, do **NOT** rub your eye after surgery.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for 1 to 2 days. Sunglasses may make you more comfortable during this time.

IMPORTANT:

Use the lubricants and eye medications as directed by your doctor. Your results depend upon you following your doctor’s instructions.

WARNING:

Your doctor will monitor you for any side effects if you need to use a topical steroid medication. Possible side effects of prolonged topical steroid use are:

- **ocular hypertension (an increase in the eye pressure).**
- **glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision).**
- **cataract formation (an opacity or clouding of the lens inside the eye that can cause a loss of vision).**

Questions to Ask Your Doctor

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

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

Discuss the cost of surgery and follow-up care requirements with your doctor, as CustomVue LASIK 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. CustomVue™ LASIK surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. It doesn't matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
3. The laser does all the work; I just have to lie on the chair.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the surgery, there is a good chance that I will be less dependent on eyeglasses.	<input type="checkbox"/>	<input type="checkbox"/>
5. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk that I may lose some vision after CustomVue LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. It doesn't matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
8. If I have an autoimmune disease, I am still a good candidate for laser vision correction.	<input type="checkbox"/>	<input type="checkbox"/>

Answers to SELF-TEST are found on page 26.

Summary of Important Information

- CustomVue™ LASIK is a permanent operation to the cornea and is irreversible.
- CustomVue LASIK may not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before CustomVue LASIK. You will need written evidence that your mixed astigmatism has changed less than 0.5 diopter.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- CustomVue LASIK may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- Alternatives to CustomVue LASIK include, but are not limited to, glasses, contact lenses, non-custom LASIK and PRK, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having CustomVue LASIK.
- Before considering laser vision correction you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about the potential benefits of laser refractive surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions

1. False (see Risks on page 10);
2. False (see Before Surgery on page 20);
3. False (see The Day of Surgery on page 21);
4. True (see Benefits on page 6);
5. True (see Risks on page 10);
6. True (see Risks on page 10);
7. False (see Contraindications on page 20);
8. False (see Contraindications on page 20).

Glossary

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

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

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

Astigmatism: The cornea and lens focus light rays from horizontal and vertical lines at different distances from the retina. The multiple focal distances result in blurred vision. Astigmatism may occur alone or along with nearsightedness, farsightedness, and other refractive errors.

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

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

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

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

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

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

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

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

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

Farsightedness: a refractive error in which the cornea and lens focus light rays from objects behind the retina, causing images of near and distant objects to appear blurry. Hyperopia is another term for farsightedness.

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

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

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

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

Hyperopia: a refractive error in which the cornea and lens focus light rays from objects behind the retina, causing images of near and distant objects to appear blurry. Farsightedness is another term for hyperopia.

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

Intraocular lens (IOL) implantation: A refractive surgery procedure that replaces the natural lens in the eye with an artificial one that has a different focusing strength.

Intracorneal ring segments: Surgical implants that correct myopia and astigmatism by deforming the cornea.

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

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

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

Lens: a structure inside the eye that helps to focus light onto the back of the eye, or an optical instrument for forming an image by focusing rays of light.

Microkeratome: an automated surgical instrument that creates a flap of tissue from the front surface of the eye.

Mixed Astigmatism: a refractive error in which the eye has both hyperopic (farsighted) astigmatism and myopic (nearsighted) astigmatism.

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

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

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

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

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

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

Refract: to bend or focus rays of light.

Refraction: the focusing power of a lens or eye.

Refractive Error: a focusing error of the eye, in which parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

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

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

Wavefront: a surface representing the cross-section of the paths that light rays follow as they travel through the eye.

Wavefront error: simple and complex focusing errors in the eye that are revealed by differences in the paths of light rays as they are bent by the eye.

WavePrint®: a color map that displays wavefront errors measured by the VISX WaveScan WaveFront® System.

WaveScan®: the VISX WaveScan WaveFront System is a diagnostic instrument to objectively measure the refractive errors of the eye.

NOTES

NOTES

Patient Assistance Information

Primary Eye Care Professional

Name:

Address:

Phone:

Laser Vision Correction Doctor

Name:

Address:

Phone:

Treatment Location

Name:

Address:

Phone:

Laser Manufacturer:

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