

# Professional Use Information

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

### CustomVue™ Treatments for Monovision in Presbyopic Patients with Low to Moderate Myopia and Myopic Astigmatism

For the monovision visual correction of presbyopic patients, achieved by targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes with myopia and myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D

**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" and "Gas Maintenance" (sections 4.5 and 15.1 of the STAR S4 IR™ System Operator's Manual) 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. The STAR S4 IR laser software also contains a refinement to the method of STAR laser beam energy control by inclusion of an ozone compensation system.

#### **Laser Beam Delivery System**

The STAR S4 IR™ laser system delivers spatially scanning ultraviolet pulses of variable diameters and slits on to the cornea. The range of diameters and slits available during treatments are 0.65 mm to 6 mm. 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. Conventional STAR treatments utilize sphere, cylinder and axis components which are entered manually into the laser by the operator to generate the ablation treatment. CustomVue™ treatment information is generated on the WaveScan® system and transferred to the STAR S4 IR Excimer Laser System. The transferred information includes patient information, eye and refraction information, image of the eye, eye alignment information, and ablation instructions to the laser for beam diameters and the exact locations of the beam on the cornea. The variable spot scanning (VSS™) feature of the laser, used for CustomVue™ treatments delivers variable diameter ultraviolet pulses to precise locations by the scanning delivery system. The VSS algorithm optimizes the ablation pattern by choosing the best combination of beam diameters and locations to achieve a target shape. VSS expands the laser capability to achieve a broader spectrum of ablation shapes than conventional treatments because the conventional algorithm optimizes only the diameter for myopic treatments and slits for hyperopic treatments.

#### **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. Wavefront-guided treatments using the STAR S4 IR™ and WaveScan Systems utilize an automated iris registration system. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the WaveScan image to the same features located in the image of the iris taken using the STAR S4 IR camera. The treatment is rotated to align precisely with the rotation of the patient's eye under the laser.

#### **Computer Control**

A PC-compatible computer, video monitor, keyboard with touchpad for user interface (Windows®<sup>1</sup> standard), printer, a floppy drive to store patient information on floppy disks, a USB port, 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. Fourier analysis is used to construct the

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<sup>1</sup> Windows® is a registered trademark of Microsoft Corporation.

ablation target that defines the laser treatment. Spherical adjustments can be made to the wavefront-defined ablation target to deviate from an emmetropic outcome.

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® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes:

- 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision,
- with myopic astigmatism up to -6.00 D MRSE, with cylinder up to -3.00 D, and minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia,
- 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; and
- with a successful preoperative trial of monovision or history of monovision experience.



*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®<sup>2</sup>); Amiodarone hydrochloride (Cordarone®<sup>3</sup>).

<sup>2</sup> Accutane® is a registered trademark of Hoffmann-La Roche Inc.

<sup>3</sup> 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 ( $\mu\text{m}$ ) of corneal stroma should not be violated.

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<sup>®4</sup>).

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. Patients with large mesopic pupil size ( $\geq 6.6$  mm) should be advised of the potential for negative effects on vision after surgery, such as increased frequency of glare and halos, and decreased satisfaction at night under conditions with glare, such as night driving.

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.

The safety and effectiveness of wavefront-guided LASIK surgery has **ONLY** been established with a minimum optical zone of 6 mm and an ablation zone of 8 mm.

WaveScan<sup>®</sup> System software version 3.80 (and later) contains a compensation for chromatic aberration and associated algorithm adjustments, and consequently does not allow the calculation of treatments from WaveScan<sup>®</sup> System exams taken by earlier software versions.

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

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<sup>4</sup>Imitrex<sup>®</sup> is a registered trademark of GlaxoSmithKline.

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.

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 monovision LASIK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone.
- under 40 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 myopia or myopic astigmatism:
  - whose difference between WaveScan and manifest sphere or cylinder powers is more than  $\pm 0.50$  diopters, or whose difference between WaveScan and manifest cylinder axes is  $>15$  degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose difference between manifest and cycloplegic sphere powers is more than  $\pm 0.50$  diopters, or whose difference between manifest and cycloplegic cylinder axes is  $>15$  degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose difference between WaveScan and cycloplegic sphere or cylinder powers is more than  $\pm 0.50$  diopters, or whose difference between WaveScan and cycloplegic cylinder axes is  $>15$  degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose BSCVA is worse than 20/20.
  - whose WaveScan® wavefront measurement diameter is  $< 5$  mm.
  - for treatments greater than -6 diopters of MRSE or greater than -3 diopters of astigmatism.
  - for targeted residual myopia of greater than -2 D.
  - for retreatment with CustomVue™ LASIK.
  - who were wearing contact lenses unless they had evidence of stability.
  - with anticipated postoperative keratometry reading  $< 33$  diopters. Anticipated postoperative keratometry values can be calculated by multiplying the MRSE by 0.8, and subtracting that value from the average pre-operative keratometry value. In other words,  $[(K1 + K2) \times 0.5] - (MRSE \times 0.8) > 33$  D.
  - without a successful preoperative trial of monovision or history of monovision experience.

## B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for CustomVue™ monovision 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 assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.
- Preoperative assessment of the patient's acceptance of monovision visual symptoms. Patients new to monovision should undergo a one-week contact lens trial with their individualized monovision prescription. Patients should evaluate their vision over a range of vision tasks during the trial period.
- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for hard lenses. Prior to treatment and after at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard (PMMA) lenses must have 3 central keratometry readings and manifest refractions taken at 1 week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.
- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo 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 60 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the WaveScan<sup>®</sup> refraction, BSCVA, and pupil size, as outlined in the previous section of these Precautions.

- The minimum size of the wavefront measurement must be  $\geq 5$  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.
- Presbyopic patients must be clearly informed of all alternatives for the correction of myopic 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, and at 1, 3, and 6 months:

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

## 2.1.5 Adverse Events

Two hundred ninety-six (296) treated eyes were used for safety analyses. A summary of adverse events are provided in Table 2-1. There were no deaths in this study. There were twelve (12) instances of DLK, eleven (11) that occurred prior to the 1-month visit, one corneal infiltrate and two instances of elevated IOP, also prior to the 1-month visit. Complications are presented in Table 2-2.

**Table 2-1: Summary of Adverse Events**

	<1 Month (n=296)		1 Month (n=294)		3 Months (n=290)		6 Months (n=292)		9 Months (n=284)		12 Months (n=281)	
	n	%	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	1	0.3	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	0	0.0
Corneal edema at 1 month or later (specify "flap" or "bed" or both)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Diffuse Lamellar Keratitis <sup>5</sup>	11	3.7	0	0.0	0	0.0	0	0.0	1	0.4	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	0	0.0	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	2	0.7	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 letter <u>not due to irregular astigmatism</u> 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

<sup>5</sup> Overall, 4.1% eyes (12/296) experienced DLK.

**Table 2-2: Summary of Complications**

Percentage of Eyes	<1 Month (n=296)		1 Month (n=294)		3 Months (n=290)		6 Months (n=292)		9 Months (n=284)		12 Months (n=281)	
	n	%	n	%	n	%	n	%	n	%	n	%
Misaligned flap	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema between 1 week and 1 month after the 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	1	0.3	0	0.0	0	0.0
Epithelium in the interface <sup>6</sup>	1	0.3	0	0.0	2	0.7	0	0.0	0	0.0	0	0.0
Foreign body sensation at 1 month or later	0	0.0	0	0.0	2	0.7	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
Percentage of Subjects	<1 Month (n=160)		1 Month (n=159)		3 Months (n=157)		6 Months (n=158)		9 Months (n=152)		12 Months (n=149)	
†Ghost images <sup>7</sup>	0	0.0	14	8.8	8	5.1	10	6.3	9	5.9	7	4.7
†Diplopia	0	0.0	3	1.9	1	0.6	1	0.6	1	0.7	2	1.3

† These results represent data accumulated from the subjective binocular questionnaire and /or subject complaints. These complications were not consistently recorded as pertaining to one or both eyes, and are therefore reported by subject, rather than eye.

The reports of ghost images and diplopia complications, at six months or later, are limited to the eyes of 17 subjects (17/160, 10.6%). Of these, 11 cases of ghosting and 2 cases of diplopia resolved with no further intervention, one subject received a retreatment to improve near vision which successfully reduced visual symptoms of ghosting, and 5 subjects continued to experience ghosting or diplopia at their last visit.

Subjects reported the frequency of both ghost (or shadow) images and diplopia (two distinct images) on their periodic questionnaire. The frequency at which the eight subjects with complications at 12 months reported experiencing these symptoms, as a percentage of the study population, is presented in Table 2-3. No subjects with diplopia reported the diplopia as occurring "often" or "always". Ghost images were reported as occurring "often" by four subjects and "always" by one subject. 5 subjects continued to experience these Complications at their last visit. For these 5 subjects with persisting Complications, no subjects reported diplopia as occurring "often" or "always" while 4 subjects reported ghost (or shadow) images as occurring "often" or "always".

<sup>6</sup> Overall, 1.0% of eyes (3/296) experienced epithelium in the interface.

<sup>7</sup> Overall 17.5% of subjects (28/160) were reported with the Complication of ghost images or diplopia for at least one visit.

**Table 2-3: Frequency of ghost images and diplopia in subjects with complications at 12 months postoperatively (n=8), as a percentage of the study population (n=149)**

	Ghost images		Diplopia	
Sometimes	2	1.4%	2	1.4%
Often	4	2.7%	0	0.0%
Always	1	0.7%	0	0.0%

## 3.1 Clinical Results

### 3.1.1 Monovision LASIK for Presbyopic Patients with Myopic Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have myopic astigmatism with up to -6.00 D MRSE and cylinder up to -3.0 D. To qualify for the study, patients also had to demonstrate agreement between the manifest and WaveScan® refraction, a wavefront measurement size  $\geq 5$  mm and acceptance of monovision visual symptoms as demonstrated by questionnaire results after a one-week monovision contact lens trial. All study treatments were conducted using a 6 mm minimum optical zone and an 8 mm ablation zone with intention of full correction of the dominant eye to emmetropia. The non-dominant eye was targeted for retention of between approximately -1.25 and -2.0 D of myopia as required for near vision. Investigators used site-specific nomogram adjustments, ranging from -0.25 to -0.45 D spherical adjustments, based on their prior experience with CustomVue™ treatment of low myopia. Two hundred and ninety-six (296) eyes of one hundred sixty (160) subjects comprised the cohort used for both safety and effectiveness evaluations. One hundred thirty-seven (137) non-dominant eyes that were targeted for residual myopia constituted the investigational cohort, and the results of the non-dominant eyes with spherical (n=83) and myopic astigmatism (n=54) are presented separately. Spherical myopia is defined as  $\leq 0.5$  D of astigmatism by manifest refraction. One hundred fifty-nine (159) dominant eyes received non-investigational CustomVue™ treatment targeted for emmetropia. Twenty-four (24) subjects received a treatment in only one eye because the preoperative refraction in their fellow eye was close enough to the desired refractive endpoint that treatment was not indicated. Results from dominant and non-dominant eyes are presented separately, except for these cases where binocular vision was tested. 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, reading acuity, and stability. Safety analyses included change in best spectacle-corrected visual acuity (BSCVA), change in intraocular pressure, adverse events, and complications. The frequency of pre- and post-operative use of corrective lenses was also assessed.

## B. Patient Accountability

Two hundred and ninety-six (296) eyes of 160 subjects treated at seven centers in the United States were evaluated for safety and effectiveness. The mean age of the 160 subjects participating in this trial was  $50.2 \pm 5.1$  years (range 40 to 65). There were 104 women and 56 men. Table 3-1 presents the demographic characteristics of the patient population. Table 3-2 presents the accountability for all eyes treated in the study. Over 97% accountability was achieved at the 1, 3, 6, 9, and 12-month visits.

**Table 3-1 Demographic Characteristics All Subjects (N=160)**

Category	Classification	N	%
Gender	Male	56	35.0
	Female	104	65.0
Race	Caucasian	131	81.9
	African American	8	5.0
	Native American/ Alaskan Native	2	1.3
	Asian	7	4.4
	Other*	12	7.5
Dominant Eyes	Right	114	71.3
	Left	46	28.8
Contact Lens History**	None	35	22.3
	Soft	114	72.6
	RGP/PMMA	8	5.1
Monovision History	Prior Monovision Contact Lens Use	67	41.9
	No Prior Monovision Contact Lens Use	93	58.1
Age (in Years)	Mean	50.2	
	SD	$\pm 5.1$	
	Min	40	
	Max	65	

\*Other classification of "race" included: Hispanic

\*\*Contact Lens History was not available for three subjects. The percentage for this portion of the analysis is based on non-missing values.

**Table 3-2 Subject Accountability**

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
<b>Dominant Eyes (N=159)</b>										
Available for Analysis	158	99.4	156	98.1	157	98.7	151	95.0	148	93.1
Discontinued <sup>†</sup>	0	0.0	0	0.0	0	0.0	4	2.5	7	4.4
Missed Visit	1	0.6	2	1.3	1	0.6	3	1.9	3	1.9
Not yet eligible	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lost to Follow-Up	0	0.0	1	0.6	1	0.6	1	0.6	1	0.6
<b>% Accountability*</b>	<b>99.4%</b>		<b>98.1%</b>		<b>98.7%</b>		<b>97.4%</b>		<b>98.2%</b>	
<b>Non-Dominant Eyes (N=137)</b>										
Available for Analysis	136	99.3	134	97.8	135	98.5	133	97.1	133	97.1
Discontinued <sup>†</sup>	0	0.0	0	0.0	0	0.0	1	0.7	1	0.7
Missed Visit	1	0.7	2	1.5	1	0.7	2	1.5	2	1.5
Not yet eligible	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lost to Follow-Up	0	0.0	1	0.7	1	0.7	1	0.7	1	0.7
<b>% Accountability*</b>	<b>99.3%</b>		<b>97.8%</b>		<b>98.5%</b>		<b>97.8%</b>		<b>99.0%</b>	
<b>Subjects (N=160)</b>										
Available for Analysis	159	99.4	157	98.1	158	98.8	152	95.0	149	93.1
Discontinued <sup>†</sup>	0	0.0%	0	0.0%	0	0.0%	4	2.5%	7	4.4%
Missed Visit	1	0.6%	2	1.3%	1	0.6%	3	1.9%	3	1.9%
Not yet eligible	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Lost to Follow-Up	0	0.0%	1	0.6%	1	0.6%	1	0.6%	1	0.6%
<b>% Accountability*</b>	<b>99.4%</b>		<b>98.1%</b>		<b>98.8%</b>		<b>97.4%</b>		<b>97.4%</b>	

\*%Accountability= [Available for Analysis/(enrolled-discontinued-not yet eligible)] x100

<sup>†</sup>5 eyes of 4 subjects underwent retreatment after the 6-month visit, and 3 eyes of 3 subjects underwent retreatment after the 9-month visit.

### C. Data Analysis and Results

#### 1) Pre-Operative Characteristics

All refractions were tested at four meters and converted to optical infinity for data analysis and presentation. Pre-operative refractive error stratified by manifest spherical equivalent and cylinder, for dominant eyes and non-dominant eyes that underwent treatment, is presented in Tables 3-3 and 3-4, respectively.

**Table 3-3 Pre-Op Refractive Error Stratified by Manifest Spherical Equivalent and Cylinder Dominant Eyes (N=159)**

Cylinder \ MRSE	0 to -0.5 D		<-0.5 to -1 D		<-1 to -2 D		<-2 to -3 D		<-3 to -4 D		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
<0 to -1 D	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
<-1 to -2 D	10	6.3	1	0.6	1	0.6	0	0.0	0	0.0	12	7.5
<-2 to -3 D	19	11.9	8	5.0	7	4.4	0	0.0	0	0.0	34	21.4
<-3 to -4 D	25	15.7	10	6.3	5	3.1	0	0.0	0	0.0	40	25.2
<-4 to -5 D	17	10.7	18	11.3	8	5.0	0	0.0	1	0.6	44	27.7
<-5 to -6 D	12	7.5	7	4.4	5	3.1	0	0.0	0	0.0	24	15.1
<-6 D	2	1.3	2	1.3	0	0.0	0	0.0	0	0.0	4	2.5
Total	86	54.1	46	28.9	26	16.4	0	0.0	1	0.6	159	100

**Table 3-4 Pre-Op Refractive Error Stratified by Manifest Spherical Equivalent and Cylinder Non-Dominant Eyes (N=137)**

Cylinder \ MRSE	0 to -0.5 D		<-0.5 to -1 D		<-1 to -2 D		<-2 to -3 D		Total	
	n	%	n	%	n	%	n	%	n	%
<0 to -1 D	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
<-1 to -2 D	0	0.0	0	0.0	1	0.7	0	0.0	1	0.7
<-2 to -3 D	18	13.1	2	1.5	5	3.6	0	0.0	25	18.2
<-3 to -4 D	26	19.0	8	5.8	7	5.1	0	0.0	41	29.9
<-4 to -5 D	22	16.1	8	5.8	6	4.4	2	1.5	38	27.7
<-5 to -6 D	15	10.9	7	5.1	6	4.4	1	0.7	29	21.2
<-6 D	2	1.5	0	0.0	1	0.7	0	0.0	3	2.2
Total	83	60.6	25	18.2	26	19.0	3	2.2	137	100

## 2) Uncorrected Visual Acuity (UCVA)

All dominant eyes were targeted for emmetropia, and non-dominant eyes were targeted for retention of up to -2.0 D of myopia, determined by their near add requirement. Uncorrected distance visual acuity (UCDVA) was measured under photopic lighting conditions in the subject's dominant eye and binocularly at 4 meters, without any lens correction, using the VectorVision CSV-1000 ETDRS test face. Uncorrected near visual acuity (UCNVA) was measured under photopic lighting conditions in the subject's non-dominant eye and binocularly at 16 inches without any lens correction, using the ETDRS 40 cm near card for acuity testing. Uncorrected intermediate visual acuity (UCIVA) was measured under photopic lighting conditions binocularly at 60 centimeters without any lens correction, using the ETDRS acuity test for 60 cm.

At the 6-month visit, 86.7% (137/160) of subjects achieved binocular UCDVA of 20/20 or better, and 100% achieved 20/40 or better (Table 3-5). 88.0% of subjects achieved binocular UCNVA of 20/20 or better, and 100% achieved 20/40 or better (Table 3-6). 79.7% of subjects achieved simultaneous binocular UCDVA and UCNVA (Table 3-7) of 20/20 or better. Table 3-8 presents binocular UCIVA for all subjects. Table 3-9 presents monocular UCDVA over time for dominant eyes, and Tables 3-10 through 3-12 present monocular UCNVA for the cohorts of all non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism, respectively.

**Table 3-5 Binocular Uncorrected Distance Visual Acuity All Subjects (N=160)**

	Pre-Op (n=160)	1 Month (n=159)	3 Months (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
Acuity	n % (95% CI)					
20/12.5 or better	0 0.0% (0.0, 1.9)	19 11.9% (7.4, 18.0)	28 17.8% (12.2, 24.7)	28 17.7% (12.1, 24.6)	36 23.7% (17.2, 31.3)	29 19.5% (13.4, 26.7)
20/16 or better	1 0.6% (0.0, 3.4)	101 63.5% (55.5, 71.0)	105 66.9% (58.9, 74.2)	112 70.9% (63.1, 77.8)	105 69.1% (61.1, 76.3)	103 69.1% (61.0, 76.4)
20/20 or better	1 0.6% (0.0, 3.4)	137 86.2% (79.8, 91.1)	138 87.9% (81.7, 92.6)	137 86.7% (80.4, 91.6)	142 93.4% (88.2, 96.8)	138 92.6% (87.2, 96.3)
20/25 or better	1 0.6% (0.0, 3.4)	156 98.1% (94.6, 99.6)	153 97.5% (93.6, 99.3)	151 95.6% (91.1, 98.2)	146 96.1% (91.6, 98.5)	145 97.3% (93.3, 99.3)
20/32 or better	2 1.3% (0.2, 4.4)	159 100% (98.1, 100)	155 98.7% (95.5, 99.8)	156 98.7% (95.5, 99.8)	151 99.3% (96.4, 100)	148 99.3% (96.3, 100)
20/40 or better	4 2.5% (0.7, 6.3)	159 100% (98.1, 100)	156 99.4% (96.5, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	148 99.3% (96.3, 100)
20/80 or better	21 13.1% (8.3, 19.4)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/100 or better	49 30.6% (23.6, 38.4)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
Worse than 20/100	111 69.4% (61.6, 76.4)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)

**Table 3-6 Binocular Uncorrected Near Visual Acuity All Subjects (N=160)**

	Pre-Op (n=160)	1 Month (n=159)	3 Months (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
Acuity	n % (95% CI)					
20/12.5 or better	2 1.3% (0.2, 4.4)	9 5.7% (2.6, 10.5)	12 7.6% (4.0, 13.0)	13 8.2% (4.5, 13.7)	17 11.2% (6.7, 17.3)	14 9.4% (5.2, 15.3)
20/16 or better	30 18.8% (13.0, 25.7)	69 43.4% (35.6, 51.5)	79 50.3% (42.2, 58.4)	71 44.9% (37.0, 53.0)	74 48.7% (40.5, 56.9)	66 44.3% (36.2, 52.7)
20/20 or better	55 34.4% (27.1, 42.3)	138 86.8% (80.5, 91.6)	140 89.2% (83.2, 93.6)	139 88.0% (81.9, 92.6)	136 89.5% (83.5, 93.9)	137 91.9% (86.4, 95.8)
20/25 or better	74 46.3% (38.3, 54.3)	155 97.5% (93.7, 99.3)	151 96.2% (91.9, 98.6)	153 96.8% (92.8, 99.0)	148 97.4% (93.4, 99.3)	147 98.7% (95.2, 99.8)
20/32 or better	82 51.3% (43.2, 59.2)	158 99.4% (96.5, 100)	155 98.7% (95.5, 99.8)	158 100% (98.1, 100)	151 99.3% (96.4, 100)	148 99.3% (96.3, 100)
20/40 or better	97 60.6% (52.6, 68.2)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	151 99.3% (96.4, 100)	149 100% (98.0, 100)
20/80 or better	140 87.5% (81.4, 92.2)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/100 or better	152 95.0% (90.4, 97.8)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/125 or better	155 96.9% (92.9, 99.0)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/160 or better	157 98.1% (94.6, 99.6)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/200 or better	159 99.4% (96.6, 100)	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
Worse than 20/200	1 0.6% (0.0, 3.4)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)

**Table 3-7 Binocular Simultaneous Uncorrected Distance and Uncorrected Near Visual Acuity All Subjects (N=160)**

	Pre-Op (n=160)	1 Month (n=159)	3 Months (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
	n % (95% CI)					
20/20 or better near and 20/20 or better distance	0 0.0% (0.0, 1.9)	121 76.1% (68.7, 82.5)	126 80.3% (73.2, 86.2)	126 79.7% (72.6, 85.7)	131 86.2% (79.7, 91.2)	128 85.9% (79.3, 91.1)
20/25 or better near and 20/25 or better distance	0 0.0% (0.0, 1.9)	152 95.6% (91.1, 98.2)	148 94.3% (89.4, 97.3)	146 92.4% (87.1, 96.0)	144 94.7% (89.9, 97.7)	144 96.6% (92.3, 98.9)
20/32 or better near and 20/32 or better distance	1 0.6% (0.0, 3.4)	158 99.4% (96.5, 100)	153 97.5% (93.6, 99.3)	156 98.7% (95.5, 99.8)	150 98.7% (95.3, 99.8)	147 98.7% (95.2, 99.8)
20/40 or better near and 20/40 or better distance	4 2.5% (0.7, 6.3)	159 100% (98.1, 100)	156 99.4% (96.5, 100)	158 100% (98.1, 100)	151 99.3% (96.4, 100)	148 99.3% (96.3, 100)
Worse than 20/40 at both distance and near	156 97.5% (93.7, 99.3)	0 0.0% (0.0, 1.9)	1 0.6% (0.0, 3.5)	0 0.0% (0.0, 1.9)	1 0.7% (0.0, 3.6)	1 0.7% (0.0, 3.7)

**Table 3-8 Binocular Uncorrected Intermediate Visual Acuity All Subjects (N=160)**

	1 Month (n=159)	3 Months (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
Acuity	n % (95% CI)				
20/12.5 or better	17 10.7% (6.4, 16.6)	20 12.7% (8.0, 19.0)	13 8.2% (4.5, 13.7)	14 9.2% (5.1, 15.0)	18 12.1% (7.3, 18.4)
20/16 or better	65 40.9% (33.2, 48.9)	75 47.8% (39.7, 55.9)	79 50.0% (42.0, 58.0)	84 55.3% (47.0, 63.3)	77 51.7% (43.4, 59.9)
20/20 or better	123 77.4% (70.1, 83.6)	122 77.7% (70.4, 84.0)	134 84.8% (78.2, 90.0)	135 88.8% (82.7, 93.3)	132 88.6% (82.4, 93.2)
20/25 or better	148 93.1% (88.0, 96.5)	146 93.0% (87.8, 96.5)	152 96.2% (91.9, 98.6)	147 96.7% (92.5, 98.9)	145 97.3% (93.3, 99.3)
20/32 or better	155 97.5% (93.7, 99.3)	153 97.5% (93.6, 99.3)	156 98.7% (95.5, 99.8)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/40 or better	156 98.1% (94.6, 99.6)	156 99.4% (96.5, 100)	156 98.7% (95.5, 99.8)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/80 or better	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
20/100 or better	159 100% (98.1, 100)	157 100% (98.1, 100)	158 100% (98.1, 100)	152 100% (98.0, 100)	149 100% (98.0, 100)
Worse than 20/100	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)

**Table 3-9 Monocular Uncorrected Distance Visual Acuity *Dominant Eyes* (N=159)**

	Pre-Op (n=159)	1 Month (n=158)	3 Months (n=156)	6 Months (n=157)	9 Months (n=151)	12 Months (n=148)
Acuity	n % (95% CI)					
20/12.5 or better	0 0.0% (0.0, 1.9)	19 12.0% (7.4, 18.1)	25 16.0% (10.6, 22.7)	23 14.6% (9.5, 21.2)	28 18.5% (12.7, 25.7)	29 19.6% (13.5, 26.9)
20/16 or better	0 0.0% (0.0, 1.9)	87 55.1% (47.0, 63.0)	99 63.5% (55.4, 71.0)	103 65.6% (57.6, 73.0)	97 64.2% (56.0, 71.9)	97 65.5% (57.3, 73.2)
20/20 or better	0 0.0% (0.0, 1.9)	134 84.8% (78.2, 90.0)	134 85.9% (79.4, 90.9)	138 87.9% (81.7, 92.6)	136 90.1% (84.1, 94.3)	132 89.2% (83.0, 93.7)
20/25 or better	0 0.0% (0.0, 1.9)	154 97.5% (93.6, 99.3)	151 96.8% (92.7, 99.0)	150 95.5% (91.0, 98.2)	145 96.0% (91.6, 98.5)	143 96.6% (92.3, 98.9)
20/32 or better	0 0.0% (0.0, 1.9)	157 99.4% (96.5, 100)	154 98.7% (95.4, 99.8)	154 98.1% (94.5, 99.6)	150 99.3% (96.4, 100)	147 99.3% (96.3, 100)
20/40 or better	0 0.0% (0.0, 1.9)	158 100% (98.1, 100)	156 100% (98.1, 100)	156 99.4% (96.5, 100)	151 100% (98.0, 100)	148 100% (98.0, 100)
20/80 or better	13 8.2% (4.4, 13.6)	158 100% (98.1, 100)	156 100% (98.1, 100)	157 100% (98.1, 100)	151 100% (98.0, 100)	148 100% (98.0, 100)
20/100 or better	31 19.5% (13.6, 26.5)	158 100% (98.1, 100)	156 100% (98.1, 100)	157 100% (98.1, 100)	151 100% (98.0, 100)	148 100% (98.0, 100)
Worse than 20/100	128 80.5% (73.5, 86.4)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)

**Table 3-10 Monocular Uncorrected Near Visual Acuity Non-Dominant Eyes (N=137)**

	Pre-Op (n=137)	1 Month (n=136)	3 Months (n=134)	6 Months (n=135)	9 Months (n=133)	12 Months (n=133)
Acuity	n % (95% CI)					
20/12.5 or better	0 0.0% (0.0, 2.2)	7 5.1% (2.1, 10.3)	7 5.2% (2.1, 10.5)	9 6.7% (3.1, 12.3)	9 6.8% (3.1, 12.5)	8 6.0% (2.6, 11.5)
20/16 or better	10 7.3% (3.6, 13.0)	46 33.8% (25.9, 42.4)	62 46.3% (37.6, 55.1)	58 43.0% (34.5, 51.8)	58 43.6% (35.0, 52.5)	49 36.8% (28.6, 45.6)
20/20 or better	25 18.2% (12.2, 25.7)	102 75.0% (66.9, 82.0)	113 84.3% (77.0, 90.0)	109 80.7% (73.1, 87.0)	116 87.2% (80.3, 92.4)	114 85.7% (78.6, 91.2)
20/25 or better	44 32.1% (24.4, 40.6)	128 94.1% (88.7, 97.4)	127 94.8% (89.5, 97.9)	129 95.6% (90.6, 98.4)	129 97.0% (92.5, 99.2)	130 97.7% (93.5, 99.5)
20/32 or better	54 39.4% (31.2, 48.1)	133 97.8% (93.7, 99.5)	130 97.0% (92.5, 99.2)	135 100% (97.8, 100)	133 100% (97.8, 100)	130 97.7% (93.5, 99.5)
20/40 or better	63 46.0% (37.4, 54.7)	136 100% (97.8, 100)	133 99.3% (95.9, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	132 99.2% (95.9, 100)
20/80 or better	100 73.0% (64.7, 80.2)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
20/100 or better	114 83.2% (75.9, 89.0)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
20/125 or better	126 92.0% (86.1, 95.9)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
20/160 or better	130 94.9% (89.8, 97.9)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
20/200 or better	136 99.3% (96.0, 100)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
Worse than 20/200	1 0.7% (0.0, 4.0)	0 0.0% (0.0, 2.2)				
Not Reported	0	0	0	0	0	0

**Table 3-11 Monocular Uncorrected Near Visual Acuity *Non-Dominant Eyes with Spherical Myopia (N=83)***

	Pre-Op (n=83)	1 Month (n=82)	3 Months (n=82)	6 Months (n=82)	9 Months (n=83)	12 Months (n=81)
Acuity	n % (95% CI)					
20/12.5 or better	0 0.0% (0.0, 3.5)	4 4.9% (1.3, 12.0)	5 6.1% (2.0, 13.7)	6 7.3% (2.7, 15.2)	6 7.2% (2.7, 15.1)	4 4.9% (1.4, 12.2)
20/16 or better	8 9.6% (4.3, 18.1)	26 31.7% (21.9, 42.9)	39 47.6% (36.4, 58.9)	35 42.7% (31.8, 54.1)	34 41.0% (30.3, 52.3)	29 35.8% (25.4, 47.2)
20/20 or better	19 22.9% (14.4, 33.4)	65 79.3% (68.9, 87.4)	70 85.4% (75.8, 92.2)	68 82.9% (73.0, 90.3)	71 85.5% (76.1, 92.3)	69 85.2% (75.6, 92.1)
20/25 or better	35 42.2% (31.4, 53.5)	78 95.1% (88.0, 98.7)	78 95.1% (88.0, 98.7)	79 96.3% (89.7, 99.2)	80 96.4% (89.8, 99.2)	79 97.5% (91.4, 99.7)
20/32 or better	39 47.0% (35.9, 58.3)	81 98.8% (93.4, 100)	81 98.8% (93.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	79 97.5% (91.4, 99.7)
20/40 or better	41 49.4% (38.2, 60.6)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
20/80 or better	58 69.9% (58.8, 79.5)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
20/100 or better	67 80.7% (70.6, 88.6)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
20/125 or better	75 90.4% (81.9, 95.7)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
20/160 or better	78 94.0% (86.5, 98.0)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
20/200 or better	82 98.8% (93.5, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
Worse than 20/200	1 1.2% (0.0, 6.5)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.5)	0 0.0% (0.0, 3.6)
Not Reported	0	0	0	0	0	0

**Table 3-12 Monocular Uncorrected Near Visual Acuity *Non-Dominant Eyes with Myopic Astigmatism (N=54)***

	Pre-Op (n=54)	1 Month (n=54)	3 Months (n=52)	6 Months (n=53)	9 Months (n=50)	12 Months (n=52)
Acuity	n % (95% CI)					
20/12.5 or better	0 0.0% (0.0, 5.4)	3 5.6% (1.2, 15.4)	2 3.8% (0.5, 13.2)	3 5.7% (1.2, 15.7)	3 6.0% (1.3, 16.5)	4 7.7% (2.1, 18.5)
20/16 or better	2 3.7% (0.5, 12.7)	20 37.0% (24.3, 51.3)	23 44.2% (30.5, 58.7)	23 43.4% (29.8, 57.7)	24 48.0% (33.7, 62.6)	20 38.5% (25.3, 53.0)
20/20 or better	6 11.1% (4.2, 22.6)	37 68.5% (54.4, 80.5)	43 82.7% (69.7, 91.8)	41 77.4% (63.8, 87.7)	45 90.0% (78.2, 96.7)	45 86.5% (74.2, 94.4)
20/25 or better	9 16.7% (7.9, 29.3)	50 92.6% (82.1, 97.9)	49 94.2% (84.1, 98.8)	50 94.3% (84.3, 98.8)	49 98.0% (89.4, 99.9)	51 98.1% (89.7, 100)
20/32 or better	15 27.8% (16.5, 41.6)	52 96.3% (87.3, 99.5)	49 94.2% (84.1, 98.8)	53 100% (94.5, 100)	50 100% (94.2, 100)	51 98.1% (89.7, 100)
20/40 or better	22 40.7% (27.6, 55.0)	54 100% (94.6, 100)	51 98.1% (89.7, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	51 98.1% (89.7, 100)
20/80 or better	42 77.8% (64.4, 88.0)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
20/100 or better	47 87.0% (75.1, 94.6)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
20/125 or better	51 94.4% (84.6, 98.8)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
20/160 or better	52 96.3% (87.3, 99.5)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
20/200 or better	54 100% (94.6, 100)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
Worse than 20/200	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 5.4)	0 0.0% (0.0, 5.6)	0 0.0% (0.0, 5.5)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 5.6)

At 6-months postoperatively, 63.9% of subjects achieved the same or better binocular uncorrected distance vision as they achieved preoperatively with best spectacle correction, and 50.9% achieved the same or better binocular uncorrected distance vision as they achieved preoperatively with best spectacle correction. On average, subjects achieved within one line of their preoperative best corrected vision and could see 20/20 at or better for both distance and near at 6 months postoperatively, regardless of their degree of postoperative anisometropia.

**Table 3-13: Post-Operative Binocular UCNVA Compared to Pre-Operative Binocular BCNVA All Subjects (N=160)**

	1 Month (n=159)	3 Month (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
	n % 95% CI				
>2 lines better	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)
2 lines better	2 1.3% (0.2, 4.5)	2 1.3% (0.2, 4.5)	3 1.9% (0.4, 5.4)	3 2.0% (0.4, 5.7)	3 2.0% (0.4, 5.8)
1 line better	12 7.5% (4.0, 12.8)	17 10.8% (6.4, 16.8)	17 10.8% (6.4, 16.7)	20 13.2% (8.2, 19.6)	16 10.7% (6.3, 16.9)
<1 line change	61 38.4% (30.8, 46.4)	66 42.0% (34.2, 50.2)	60 38.0% (30.4, 46.0)	61 40.1% (32.3, 48.4)	59 39.6% (31.7, 47.9)
1 line worse	62 39.0% (31.4, 47.0)	45 28.7% (21.7, 36.4)	49 31.0% (23.9, 38.8)	44 28.9% (21.9, 36.8)	46 30.9% (23.6, 39.0)
2 lines worse	16 10.1% (5.9, 15.8)	22 14.0% (9.0, 20.4)	25 15.8% (10.5, 22.5)	19 12.5% (7.7, 18.8)	23 15.4% (10.0, 22.3)
>2 lines worse	6 3.8% (1.4, 8.0)	5 3.2% (1.0, 7.3)	4 2.5% (0.7, 6.4)	5 3.3% (1.1, 7.5)	2 1.3% (0.2, 4.8)

**Table 3-14: Post-Operative Binocular UCDVA Compared to Pre-Operative Binocular BCDVA All Subjects (N=160)**

	1 Month (n=159)	3 Month (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
	n % 95% CI				
>2 lines better	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)
2 lines better	0 0.0% (0.0, 1.9)	1 0.6% (0.0, 3.5)	1 0.6% (0.0, 3.5)	0 0.0% (0.0, 2.0)	2 1.3% (0.2, 4.8)
1 line better	19 11.9% (7.4, 18.0)	24 15.3% (10.0, 21.9)	26 16.5% (11.0, 23.2)	33 21.7% (15.4, 29.1)	27 18.1% (12.3, 25.3)
<1 line change	71 44.7% (36.8, 52.7)	69 43.9% (36.0, 52.1)	74 46.8% (38.9, 54.9)	67 44.1% (36.0, 52.4)	64 43.0% (34.9, 51.3)
1 line worse	48 30.2% (23.2, 38.0)	45 28.7% (21.7, 36.4)	35 22.2% (15.9, 29.4)	37 24.3% (17.8, 32.0)	43 28.9% (21.7, 36.8)
2 lines worse	16 10.1% (5.9, 15.8)	12 7.6% (4.0, 13.0)	15 9.5% (5.4, 15.2)	8 5.3% (2.3, 10.1)	8 5.4% (2.3, 10.3)
>2 lines worse	5 3.1% (1.0, 7.2)	6 3.8% (1.4, 8.1)	7 4.4% (1.8, 8.9)	7 4.6% (1.9, 9.3)	5 3.4% (1.1, 7.7)

**Table 3-15 Binocular Reading Acuity: Pre-Op Monovision Contact Lens Corrected Visual Acuity and Post-Op Uncorrected Visual Acuity All Subjects (N=160)**

	Pre-Op (n=159)	1 Month (n=155)	3 Months (n=154)	6 Months (n=153)	9 Months (n=149)	12 Months (n=112)
Reading acuity	n %	n %	n %	n %	n %	n %
20/12.5 or better	12 7.5	18 11.6	16 10.4	21 13.7	13 8.7	12 10.7
20/16 or better	49 30.8	61 39.4	60 39.0	66 43.1	64 43.0	47 42.0
20/20 or better	116 73.0	122 78.7	126 81.8	129 84.3	115 77.2	82 73.2
20/25 or better	142 89.3	143 92.3	143 92.9	149 97.4	140 94.0	106 94.6
20/32 or better	155 97.5	150 96.8	150 97.4	152 99.3	146 98.0	109 97.3
20/40 or better	157 98.7	155 100	153 99.4	153 100	149 100	110 98.2
20/80 or better	159 100	155 100	154 100	153 100	149 100	112 100
20/100 or better	159 100	155 100	154 100	153 100	149 100	112 100
Worse than 20/100	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Not Reported	1	4	3	5	3	0

### 3) Accuracy of MRSE

At 6 months post-operatively, 88.5% (139/157) of dominant eyes were within 0.50 D and 98.1% (154/157) were within 1.0 D of attempted correction. Tables 3-16 presents the accuracy of MRSE over time for dominant eyes.

**Table 3-16 Accuracy of MRSE: Intended vs. Achieved Outcome *Dominant Eyes (N=159)***

	Pre-Op (n=159)	1 Month (n=158)	3 Months (n=156)	6 Months (n=157)	9 Months (n=151)	12 Months (n=148)
MRSE	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	0 0.0% (0.0, 1.9)	141 89.2% (83.3, 93.6)	137 87.8% (81.6, 92.5)	139 88.5% (82.5, 93.1)	135 89.4% (83.4, 93.8)	133 89.9% (83.8, 94.2)
± 1.00 D 95% CI	1 0.6% (0.0, 3.5)	156 98.7% (95.5, 99.8)	155 99.4% (96.5, 100)	154 98.1% (94.5, 99.6)	150 99.3% (96.4, 100)	147 99.3% (96.3, 100)
± 2.00 D 95% CI	13 8.2% (4.4, 13.6)	158 100% (98.1, 100)	156 100% (98.1, 100)	157 100% (98.1, 100)	151 100% (98.0, 100)	148 100% (98.0, 100)
Not Reported	0	0	0	0	0	0
<b>Overcorrected</b>						
> 1.00 D 95% CI		2 1.3% (0.2, 4.5)	0 0.0% (0.0, 1.9)	2 1.3% (0.2, 4.5)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)
> 2.00 D 95% CI		0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)
<b>Undercorrected</b>						
< -1.00 D 95% CI		0 0.0% (0.0, 1.9)	1 0.6% (0.0, 3.5)	1 0.6% (0.0, 3.5)	1 0.7% (0.0, 3.6)	1 0.7% (0.0, 3.7)
< -2.00 D 95% CI		0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 1.9)	0 0.0% (0.0, 2.0)	0 0.0% (0.0, 2.0)

At 6 months post-operatively, 87.5% (118/135) of non-dominant eyes were within 0.50 D and 99.3% (134/135) were within 1.0 D of attempted correction. Tables 3-17 to 3-19 present the accuracy of MRSE over time for all non-dominant eyes, and non-dominant eyes with spherical and myopic astigmatism.

**Table 3-17 Accuracy of MRSE: Intended vs. Achieved Outcome *Non-Dominant Eyes* (N=137)**

	Pre-Op (n=137)	1 Month (n=136)	3 Months (n=134)	6 Months (n=135)	9 Months (n=133)	12 Months (n=133)
MRSE	n %	n %	n %	n %	n %	n %
± 0.25 D 95% CI				83 61.5% (52.7, 69.7)		
± 0.50 D 95% CI	0 0.0% (0.0, 2.2)	120 88.2% (81.6, 93.1)	120 89.6% (83.1, 94.2)	118 87.4% (80.6, 92.5)	117 88.0% (81.2, 93.0)	115 86.5% (79.5, 91.8)
± 1.00 D 95% CI	10 7.3% (3.6, 13.0)	135 99.3% (96.0, 100)	132 98.5% (94.7, 99.8)	134 99.3% (95.9, 100)	132 99.2% (95.9, 100)	130 97.7% (93.5, 99.5)
± 2.00 D 95% CI	58 42.3% (33.9, 51.1)	136 100% (97.8, 100)	134 100% (97.8, 100)	135 100% (97.8, 100)	133 100% (97.8, 100)	133 100% (97.8, 100)
Not Reported	0	0	0	0	0	0
<b>Overcorrected</b>						
> 1.00 D 95% CI		0 0.0% (0.0, 2.2)	0 0.0% (0.0, 2.2)	0 0.0% (0.0, 2.2)	0 0.0% (0.0, 2.2)	1 0.8% (0.0, 4.1)
> 2.00 D 95% CI		0 0.0% (0.0, 2.2)				
<b>Undercorrected</b>						
< -1.00 D 95% CI		1 0.7% (0.0, 4.0)	2 1.5% (0.2, 5.3)	1 0.7% (0.0, 4.1)	1 0.8% (0.0, 4.1)	2 1.5% (0.2, 5.3)
< -2.00 D 95% CI		0 0.0% (0.0, 2.2)				

**Table 3-18 Accuracy of MRSE: Intended vs. Achieved Outcome Non-Dominant Eyes with Spherical Myopia (N=83)**

	Pre-Op (n=83)	1 Month (n=82)	3 Months (n=82)	6 Months (n=82)	9 Months (n=83)	12 Months (n=81)
MRSE	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	0 0.0% (0.0, 3.5)	73 89.0% (80.2, 94.9)	72 87.8% (78.7, 94.0)	68 82.9% (73.0, 90.3)	72 86.7% (77.5, 93.2)	70 86.4% (77.0, 93.0)
± 1.00 D 95% CI	5 6.0% (2.0, 13.5)	82 100% (96.4, 100)	81 98.8% (93.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	80 98.8% (93.3, 100)
± 2.00 D 95% CI	40 48.2% (37.1, 59.4)	82 100% (96.4, 100)	82 100% (96.4, 100)	82 100% (96.4, 100)	83 100% (96.5, 100)	81 100% (96.4, 100)
Not Reported	0	0	0	0	0	0
<b>Overcorrected</b>						
> 1.00 D 95% CI		0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.5)	1 1.2% (0.0, 6.7)
> 2.00 D 95% CI		0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.5)	0 0.0% (0.0, 3.6)
<b>Undercorrected</b>						
< -1.00 D 95% CI		0 0.0% (0.0, 3.6)	1 1.2% (0.0, 6.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.5)	0 0.0% (0.0, 3.6)
< -2.00 D 95% CI		0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.6)	0 0.0% (0.0, 3.5)	0 0.0% (0.0, 3.6)

**Table 3-19 Accuracy of MRSE: Intended vs. Achieved Outcome *Non-Dominant Eyes with Myopic Astigmatism (N=54)***

	Pre-Op (N=54)	1 Month (N=54)	3 Months (n=52)	6 Months (n=53)	9 Months (n=50)	12 Months (n=52)
MRSE	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	0 0.0% (0.0, 5.4)	47 87.0% (75.1, 94.6)	48 92.3% (81.5, 97.9)	50 94.3% (84.3, 98.8)	45 90.0% (78.2, 96.7)	45 86.5% (74.2, 94.4)
± 1.00 D 95% CI	5 9.3% (3.1, 20.3)	53 98.1% (90.1, 100)	51 98.1% (89.7, 100)	52 98.1% (89.9, 100)	49 98.0% (89.4, 99.9)	50 96.2% (86.8, 99.5)
± 2.00 D 95% CI	18 33.3% (21.1, 47.5)	54 100% (94.6, 100)	52 100% (94.4, 100)	53 100% (94.5, 100)	50 100% (94.2, 100)	52 100% (94.4, 100)
Not Reported	0	0	0	0	0	0
<b>Overcorrected</b>						
> 1.00 D 95% CI		0 0.0% (0.0, 5.4)	0 0.0% (0.0, 5.6)	0 0.0% (0.0, 5.5)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 5.6)
> 2.00 D 95% CI		0 0.0% (0.0, 5.4)	0 0.0% (0.0, 5.6)	0 0.0% (0.0, 5.5)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 5.6)
<b>Undercorrected</b>						
< -1.00 D 95% CI		1 1.9% (0.0, 9.9)	1 1.9% (0.0, 10.3)	1 1.9% (0.0, 10.1)	1 2.0% (0.1, 10.6)	2 3.8% (0.5, 13.2)
< -2.00 D 95% CI		0 0.0% (0.0, 5.4)	0 0.0% (0.0, 5.6)	0 0.0% (0.0, 5.5)	0 0.0% (0.0, 5.8)	0 0.0% (0.0, 5.6)

The predictability of induced anisometropia was calculated, and over 90% of eyes achieved anisometropia within 0.50 D of intended outcome at 6 months, as shown in Table 3-20.

**Table 3-20 Accuracy of MRSE: Attempted vs. Achieved Anisometropia All Subjects (N=160)**

	Pre-Op (n=160)	1 Month (n=159)	3 Months (n=157)	6 Months (n=158)	9 Months (n=152)	12 Months (n=149)
Anisometropia	n %	n %	n %	n %	n %	n %
± 0.50 D	10 6.3	142 89.3	139 88.5	145 91.8	137 90.1	138 92.6
± 1.00 D	48 30.0	158 99.4	157 100	158 100	151 99.3	148 99.3
± 2.00 D	154 96.3	159 100	157 100	158 100	152 100	149 100
Not Reported	0	0	0	0	0	0
Overcorrected						
> 0.50 D	NA	5 3.1	7 4.5	3 1.9	6 3.9	5 3.4
> 1.00 D	NA	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
> 2.00 D	NA	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Undercorrected						
< -0.50 D	NA	12 7.5	11 7.0	10 6.3	9 5.9	6 4.0
< -1.00 D	NA	1 0.6	0 0.0	0 0.0	1 0.7	1 0.7
< -2.00 D	NA	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

#### 4) Stability of Outcome

Stability of outcome was evaluated both by the cohort of eyes with a refraction at each visit (n=164), as well as the cohort of eyes who were available for two consecutive visits, but not for all visits. Refractive stability is reached at 6 months and confirmed at the 9-month visit. Tables 3-21 and 3-22 present refractive stability over time for all cohorts. Stability was achieved by 6-months postoperatively.

**Table 3-21 Stability of MRSE: Eyes with Two Consecutive Visits All Cohorts**

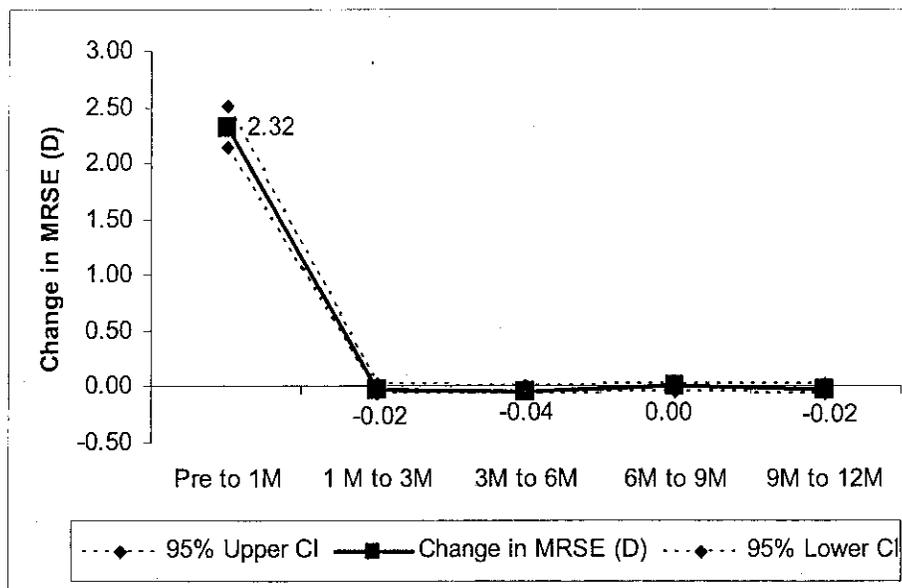
	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
<b>Dominant Eyes</b>	<b>(N=155)</b>	<b>(N=155)</b>	<b>(N=150)</b>	<b>(N=108)</b>
Change in MRSE by $\leq 0.5$ D	148 95.5%	150 96.8%	150 100%	108 100%
Change in MRSE by $\leq 1.0$ D	155 100%	155 100%	150 100%	108 100%
Mean Change in MRSE $\pm$ SD	-0.08 $\pm$ 0.25	-0.03 $\pm$ 0.23	-0.02 $\pm$ 0.18	0.01 $\pm$ 0.18
95% CI	(-0.12, -0.04)	(-0.07, 0.00)	(-0.05, 0.01)	(-0.03, 0.04)
<b>All Non-Dominant Eyes (NDE)</b>	<b>(N=133)</b>	<b>(N=133)</b>	<b>(N=132)</b>	<b>(N=102)</b>
Change in MRSE by $\leq 0.5$ D	128 96.2%	132 99.2%	131 99.2%	100 98.0%
Change in MRSE by $\leq 1.0$ D	132 99.2%	133 100%	132 100%	102 100%
Mean Change in MRSE $\pm$ SD	-0.02 $\pm$ 0.26	-0.03 $\pm$ 0.21	0.00 $\pm$ 0.19	-0.02 $\pm$ 0.21
95% CI	(-0.06, 0.03)	(-0.07, 0.01)	(-0.03, 0.04)	(-0.06, 0.02)
<b>NDE w/ Spherical Myopia</b>	<b>(N=81)</b>	<b>(N=81)</b>	<b>(N=82)</b>	<b>(N=66)</b>
Change in MRSE by $\leq 0.5$ D	79 97.5%	80 98.8%	81 98.8%	65 98.5%
Change in MRSE by $\leq 1.0$ D	81 100%	81 100%	82 100%	66 100%
Mean Change in MRSE $\pm$ SD	-0.03 $\pm$ 0.23	-0.01 $\pm$ 0.21	0.02 $\pm$ 0.20	-0.07 $\pm$ 0.19
95% CI	(-0.08, 0.02)	(-0.06, 0.04)	(-0.02, 0.07)	(-0.11, -0.02)
<b>NDE w/ Myopic Astigmatism</b>	<b>(N=52)</b>	<b>(N=52)</b>	<b>(N=50)</b>	<b>(N=36)</b>
Change in MRSE by $\leq 0.5$ D	49 94.2%	52 100%	50 100%	35 97.2%
Change in MRSE by $\leq 1.0$ D	51 98.1%	52 100%	50 100%	36 100%
Mean Change in MRSE $\pm$ SD	0.00 $\pm$ 0.31	-0.06 $\pm$ 0.20	-0.03 $\pm$ 0.18	0.06 $\pm$ 0.22
95% CI	(-0.09, 0.09)	(-0.12, -0.01)	(-0.08, 0.02)	(-0.01, 0.13)

**Table 3-22 Stability of MRSE: Eyes with 1, 3, 6, 9, and 12-Month exams All Cohorts**

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
<b>Dominant Eyes (n=106)</b>				
Change in MRSE by $\leq 0.5$ D	101 95.3%	102 96.2%	106 100%	106 100%
Change in MRSE by $\leq 1.0$ D	106 100%	106 100%	106 100%	106 100%
Mean Change in MRSE $\pm$ SD	-0.06 $\pm$ 0.25	-0.04 $\pm$ 0.24	-0.03 $\pm$ 0.19	0.01 $\pm$ 0.18
95% CI	(-0.11, -0.01)	(-0.09, 0.00)	(-0.07, 0.00)	(-0.03, 0.04)
<b>Non-Dominant Eyes (n=100)</b>				
Change in MRSE by $\leq 0.5$ D	96 96.0%	99 99.0%	99 99.0%	98 98.0%
Change in MRSE by $\leq 1.0$ D	99 99.0%	100 100%	100 100%	100 100%
Mean Change in MRSE $\pm$ SD	-0.02 $\pm$ 0.28	-0.03 $\pm$ 0.21	-0.01 $\pm$ 0.21	-0.02 $\pm$ 0.21
95% CI	(-0.08, 0.03)	(-0.07, 0.01)	(-0.05, 0.03)	(-0.06, 0.02)
<b>Non-Dominant Eyes with Spherical Myopia (n=65)</b>				
Change in MRSE by $\leq 0.5$ D	63 96.9%	64 98.5%	64 98.5%	64 98.5%
Change in MRSE by $\leq 1.0$ D	65 100%	65 100%	65 100%	65 100%
Mean Change in MRSE $\pm$ SD	-0.02 $\pm$ 0.24	0.00 $\pm$ 0.20	0.02 $\pm$ 0.22	-0.07 $\pm$ 0.19
95% CI	(-0.08, 0.03)	(-0.05, 0.05)	(-0.03, 0.07)	(-0.11, -0.02)
<b>Non-Dominant Eyes with Myopic Astigmatism (n=35)</b>				
Change in MRSE by $\leq 0.5$ D	33 94.3%	35 100%	35 100%	34 97.1%
Change in MRSE by $\leq 1.0$ D	34 97.1%	35 100%	35 100%	35 100%
Mean Change in MRSE $\pm$ SD	-0.02 $\pm$ 0.34	-0.08 $\pm$ 0.22	-0.06 $\pm$ 0.19	0.06 $\pm$ 0.22
95% CI	(-0.14, 0.10)	(-0.16, -0.01)	(-0.12, 0.01)	(-0.01, 0.14)

When plotted over time, the mean manifest spherical equivalents illustrate that stability is achieved by the 6-month visit.

**Figure 3-1 — Stability Plot: Change in MRSE Over Time for Eyes with Visits at 1, 3, 6, 9, and 12-Months (N=100)**



### 5) Efficacy of Correction of Astigmatism

Efficacy of correction of astigmatism was evaluated at the point of stability (6 months) for eyes with myopic astigmatism. Table 3-23 displays the mean percent reduction of cylinder for eyes with myopic astigmatism, stratified by pre-operative cylinder.

**Table 3-23 — Reduction of Absolute (Non-Vector) Cylinder at 6 Months: Non-Dominant Eyes with Myopic Astigmatism, N=53**

Pre-Operative Cylinder	Mean % Reduction	Range
All (n=53)	76.9%	-33.3% to 100.0%
<-0.5 to -1.0D (n=24)	65.3%	-33.3% to 100.0%
<-1.0 to -2.0D (n=26)	87.0%	37.4% to 100.0%
<-2.0 to -3.0D (n=3)	81.8%	77.8% to 90.0%

Table 3-24 presents a summary of the vector analysis which includes mean Intended Refractive Change (IRC), Surgically Induced Refractive Cylinder (SIRC), Correction Ratio (CR), Error Vector (EV) and Error Ratio (ER), at the point of stability (6 months).

**Table 3-24 6 Month Vector Analysis Summary Table *Non-Dominant Eyes with Myopic Astigmatism (N=53)***

Preoperative Cylinder	n	IRC  Mean ± SD	SIRC  Mean ± SD	EV  Mean ± SD	CR Mean ± SD	ER Mean ± SD
All (N= 53)	53	1.09 ± 0.41	1.06 ± 0.40	0.23 ± 0.30	0.98 ± 0.21	0.24 ± 0.37
>0.5D to ≤1.0D	24	0.72 ± 0.10	0.73 ± 0.23	0.26 ± 0.34	1.00 ± 0.27	0.36 ± 0.50
>1.0D to ≤2.0D	26	1.32 ± 0.20	1.29 ± 0.27	0.19 ± 0.28	0.97 ± 0.15	0.14 ± 0.18
>2.0D to ≤3.0D	3	2.07 ± 0.12	1.71 ± 0.25	0.40 ± 0.13	0.83 ± 0.07	0.19 ± 0.07

## 6) Wavefront Aberrations

Table 3-25 presents higher order aberration root-mean-square (RMS) over time for all treated dominant and non-dominant eyes. This analysis is limited to those eyes with a wavefront measurement with a 5 mm minimum diameter, as aberration analysis is standardized at and calculated over a 5 mm diameter.

**Table 3-25: Higher Order Aberration RMS Over Time**

	Pre-Op Mean ± SD	1 Month Mean ± SD	3 Months Mean ± SD	6 Months Mean ± SD	9 Months Mean ± SD	12 Months Mean ± SD
<b>Dominant Eyes</b>	n=155	n=144	n=148	n=142	n=139	n=133
All higher order	0.19 ±0.06	0.22 ±0.07	0.22 ±0.06	0.22 ±0.06	0.22 ±0.07	0.21 ± 0.06
Coma	0.11 ±0.06	0.13 ±0.06	0.13 ±0.07	0.12 ±0.06	0.13 ±0.07	0.13 ± 0.06
Trefoil	0.09 ±0.05	0.09 ±0.05	0.10 ±0.05	0.10 ±0.05	0.10 ±0.05	0.09 ± 0.05
Spherical Aberration	0.07 ±0.04	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08 ± 0.05
Secondary Astigmatism	0.04 ±0.02	0.05 ±0.03	0.05 ±0.02	0.05 ±0.02	0.05 ±0.03	0.05 ± 0.02
Tetrafoil	0.04 ±0.02	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ± 0.03
5 <sup>th</sup> order	0.03 ±0.02	0.05 ±0.03	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ± 0.02
6 <sup>th</sup> order	0.02 ±0.02	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	0.06 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07±0.06	0.07 ±0.06	0.07 ± 0.06
Min, Max	(-0.16,0.22)	(-0.13,0.21)	(-0.11,0.22)	(-0.12,0.20)	(-0.08,0.24)	(-0.10,0.22)
<b>Non-Dominant Eyes</b>	n=134	n=124	n=123	n=126	n=122	n=122
All higher order	0.20 ±0.06	0.20 ±0.08	0.20 ±0.07	0.20 ±0.06	0.20 ±0.06	0.20±0.06
Coma	0.11 ±0.06	0.11 ±0.07	0.10 ±0.06	0.11 ±0.06	0.11 ±0.06	0.10±0.06
Trefoil	0.10 ±0.05	0.09 ±0.05	0.09 ±0.05	0.08 ±0.05	0.09 ±0.05	0.09±0.05
Spherical Aberration	0.07 ±0.05	0.07 ±0.04	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08±0.05
Secondary Astigmatism	0.04 ±0.02	0.05 ±0.03	0.04 ±0.03	0.05 ±0.03	0.05 ±0.02	0.04±0.02
Tetrafoil	0.04 ±0.02	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05±0.02
5 <sup>th</sup> order	0.03 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04±0.02
6 <sup>th</sup> order	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03±0.02
Signed Value of Spherical Aberration	0.06 ±0.06	0.06 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07 ±0.06
Min, Max	(-0.15,0.20)	(-0.09,0.22)	(-0.10,0.22)	(-0.09,0.27)	(-0.08,0.24)	(-0.11,0.26)

Table 3-26 presents a paired analysis of the change in wavefront aberrations in treated non-dominant eyes with pre-operative and 6 month visits. There were no significant changes in higher order aberrations.

**Table 3-26: Change in Higher Order Aberration RMS from Pre-Op to 6 Months *Dominant and Non-Dominant Eyes***

	Mean change	95% CI of mean
<b>Dominant Eyes (n=140)</b>		
All higher order	0.03 ± 0.08	(0.01, 0.04)
Coma	0.02 ± 0.08	(0.00, 0.03)
Trefoil	0.00 ± 0.06	(-0.01, 0.01)
Spherical Aberration	0.01 ± 0.04	(0.00, 0.02)
Secondary Astigmatism	0.01 ± 0.03	(0.01, 0.02)
Tetrafoil	0.01 ± 0.03	(0.01, 0.02)
5 <sup>th</sup> order	0.01 ± 0.02	(0.01, 0.01)
6 <sup>th</sup> order	0.01 ± 0.02	(0.00, 0.01)
<b>Non-Dominant Eyes (n=126)</b>		
All higher order	0.00 ± 0.06	(-0.01, 0.01)
Coma	0.00 ± 0.07	(-0.02, 0.01)
Trefoil	-0.02 ± 0.06	(-0.03, -0.01)
Spherical Aberration	0.00 ± -0.03	(0.00, 0.01)
Secondary Astigmatism	0.01 ± 0.03	(0.01, 0.02)
Tetrafoil	0.01 ± 0.03	(0.01, 0.02)
5 <sup>th</sup> order	0.01 ± 0.02	(0.00, 0.01)
6 <sup>th</sup> order	0.00 ± 0.02	(0.00, 0.01)

Table 3-27 presents the stability of wavefront aberrations in dominant and non-dominant eyes with two consecutive visits.

**Table 3-27: Stability of Eyes with 5mm Wavefront Measurements at Two Consecutive Visits**

	1 and 3 Months	3 and 6 Months	6 and 9 Months	9 and 12 Months
<b>Dominant Eyes</b>				
<b>Total High Order RMS</b>	n=137	n=137	n=130	n=126
Mean change	0.00	0.00	0.01	-0.01
SD	0.05	0.05	0.05	0.04
95% CI	(-0.01, 0.01)	(-0.01, 0.00)	(-0.00, 0.02)	(-0.01, 0.00)
<b>Spherical Aberration RMS</b>	n=137	n=137	n=130	n=126
Mean change	0.00	0.00	0.00	0.00
SD	0.03	0.03	0.03	0.03
95% CI	(-0.01, 0.01)	(-0.00, 0.01)	(-0.01, 0.00)	(0.00, 0.01)
<b>Coma RMS</b>	n=137	n=137	n=130	n=126
Mean change	0.01	-0.01	0.00	0.00
SD	0.06	0.05	0.05	0.04
95% CI	(-0.00, 0.01)	(-0.02, 0.00)	(-0.01, 0.01)	(-0.01, 0.01)
<b>Non-Dominant Eyes</b>				
Total High Order RMS	n=116	n=116	n=118	n=114
Mean change	0.00	0.00	0.01	0.00
SD	0.06	0.05	0.05	0.05
95% CI	(-0.01, 0.01)	(-0.01, 0.01)	(-0.00, 0.01)	(-0.01, 0.01)
Spherical Aberration RMS	n=116	n=116	n=118	n=114
Mean change	0.00	0.00	0.00	0.00
SD	0.03	0.03	0.03	0.03
95% CI	(-0.00, 0.01)	(-0.01, 0.00)	(-0.00, 0.01)	(-0.00, 0.01)
Coma RMS	n=116	n=116	n=118	n=114
Mean change	0.00	0.00	0.00	0.00
SD	0.06	0.05	0.05	0.05
95% CI	(-0.01, 0.01)	(-0.01, 0.01)	(-0.01, 0.01)	(-0.01, 0.01)

Table 3-28 presents WaveScan® System-derived spherical equivalent and cylinder over time for all treated dominant and non-dominant eyes. This analysis is limited to those eyes with a wavefront measurement with a 4 mm minimum diameter, as wavefront refraction analysis is standardized at and calculated over a 4 mm diameter.

**Table 3-28: WaveScan Spherical Equivalent and Cylinder Over Time *Dominant and Non-Dominant Eyes***

	Pre-Op Mean ± sd	1 Month Mean ± sd	3 Months Mean ± sd	6 Months Mean ± sd	9 Months Mean ± sd	12 Months Mean ± sd
<b>Dominant Eyes</b>	n=158	n=154	n=156	n=152	n=149	n=144
WaveScan Spherical Equivalent	-3.40±1.23	0.52 ±0.39	0.47 ±0.41	0.40 ±0.42	0.36 ±0.39	0.38 ± 0.42
Astigmatism Magnitude	0.75 ±0.52	0.42 ±0.24	0.41 ±0.25	0.43 ±0.25	0.40 ±0.23	0.41 ± 0.25
<b>Non-Dominant Eyes</b>	n=137	n=135	n=131	n=133	n=130	n=131
WaveScan Spherical Equivalent	-3.7±1.10	-1.2±0.44	-1.2±0.44	-1.3±0.47	-1.3±0.47	-1.3 ±0.51
Astigmatism Magnitude	0.76±0.56	0.41±0.24	0.41±0.24	0.42±0.24	0.42±0.24	0.41 ±0.25

**7) Best Spectacle-Corrected Distance and Near Visual Acuity**

No eye lost more than 2 lines of BSCVA at any visit. Table 3-29 presents the change in lines of BCDVA over time, and Table 3-30 presents the change in lines of BCNVA over time.

**Table 3-29 Change in BCDVA Over Time All Eyes (N=296)**

	1 Month	3 Months	6 Months	9 Months	12 Months
Change in Acuity	n % (95% CI)				
Decrease >2 Lines	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.1)
Decrease = 2 Lines	3 1.0% (0.2, 3.0)	1 0.3% (0.0, 1.9)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.1)
Decrease >1 to ≤ 2 Lines	4 1.4% (0.4, 3.4)	1 0.3% (0.0, 1.9)	2 0.7% (0.1, 2.5)	1 0.4% (0.0, 1.9)	1 0.4% (0.0, 2.0)
Decrease >0 to ≤ 1 Lines	39 13.3% (9.6, 17.7)	25 8.6% (5.7, 12.5)	26 8.9% (5.9, 12.8)	24 8.5% (5.5, 12.3)	22 7.8% (5.0, 11.6)
No change	148 50.3% (44.5, 56.2)	129 44.5% (38.7, 50.4)	119 40.8% (35.1, 46.6)	110 38.7% (33.0, 44.7)	122 43.4% (37.5, 49.4)
Increase >0 to ≤ 1 Lines	95 32.3% (27.0, 38.0)	124 42.8% (37.0, 48.7)	135 46.2% (40.4, 52.1)	139 48.9% (43.0, 54.9)	125 44.5% (38.6, 50.5)
Increase >1 to ≤ 2 Lines	8 2.7% (1.2, 5.3)	11 3.8% (1.9, 6.7)	10 3.4% (1.7, 6.2)	10 3.5% (1.7, 6.4)	11 3.9% (2.0, 6.9)
Increase >2 Lines	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.1)
Not Reported	0	0	0	0	0
Total Reported	294	290	292	284	281

**Table 3-30 Change in BCNVA Over Time All Eyes (N=296)**

	1 Month	3 Months	6 Months	9 Months	12 Months
Change in Acuity	n % (95% CI)				
Decrease >2 Lines	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.1)
Decrease = 2 Lines	4 1.4% (0.4, 3.4)	1 0.3% (0.0, 1.9)	1 0.3% (0.0, 1.9)	2 0.7% (0.1, 2.5)	0 0.0% (0.0, 1.1)
Decrease >1 to ≤ 2 Lines	7 2.4% (1.0, 4.8)	2 0.7% (0.1, 2.5)	1 0.3% (0.0, 1.9)	2 0.7% (0.1, 2.5)	1 0.4% (0.0, 2.0)
Decrease >0 to ≤ 1 Lines	39 13.3% (9.6, 17.7)	35 12.1% (8.6, 16.4)	38 13.0% (9.4, 17.4)	22 7.7% (4.9, 11.5)	31 11.0% (7.6, 15.3)
No change	170 57.8% (52.0, 63.5)	138 47.6% (41.7, 53.5)	126 43.2% (37.4, 49.0)	142 50.0% (44.0, 56.0)	129 45.9% (40.0, 51.9)
Increase >0 to ≤ 1 Lines	72 24.5% (19.7, 29.8)	105 36.2% (30.7, 42.0)	111 38.0% (32.4, 43.9)	101 35.6% (30.0, 41.4)	106 37.7% (32.0, 43.7)
Increase >1 to ≤ 2 Lines	6 2.0% (0.8, 4.4)	10 3.4% (1.7, 6.2)	15 5.1% (2.9, 8.3)	16 5.6% (3.3, 9.0)	13 4.6% (2.5, 7.8)
Increase >2 Lines	0 0.0% (0.0, 1.0)	0 0.0% (0.0, 1.0)	1 0.3% (0.0, 1.9)	1 0.4% (0.0, 1.9)	1 0.4% (0.0, 2.0)
Not Reported	0	0	0	0	0
Total Reported	294	290	292	284	281

### 8) Near Stereopsis

Stereopsis was measured with the Landolt Rings stereo test, which tests fine depth discrimination with a series of nine steps, each at an increasing level of sensitivity, ranging from 800 seconds of arc (least sensitive) to 40 seconds of arc (most sensitive). The mean difference (within subject) between preoperative stereopsis with correction and 6-month postoperative without correction was 94.8 seconds of arc. The preoperative study mean of  $45.5 \pm 11.1$  seconds of arc decreased to  $145.3 \pm 141.3$  seconds of arc 6-months postoperatively. Eyes with less than 1.50 D anisometropia at 6-months experienced an average decrease of 76.8 seconds of arc, compared to a decrease of 98.8 seconds of arc in eyes with 1.5 D or greater anisometropia, but this difference is not statistically significant ( $p=0.3693$ ). See Table 3-31.

**Table 3-31 Difference in Stereopsis (Seconds of arc) Between Pre-Op with BSCNVA and 6 Months with UCNVA, Stratified by 6 Months Anisometropia All Subjects (N=160)**

Anisometropia	N	Mean	Std Dev	Minimum	Maximum
All	155	94.8	143.3	-40	760
<1.5D	28	76.8	107.7	-20	360
≥1.5	127	98.8	150.1	-40	760

**9) Binocular Contrast Sensitivity Analysis**

Patient responses to the spatial frequencies (1.5 (near only), 3, 6, 12, and 18 cycles per degree (CPD)) were measured with the patient's binocular vision using the VectorVision CSV-1000 and converted from contrast levels to log units. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease. Table 3-32 and 3-33 present the results of the binocular best-corrected contrast sensitivity analysis including mean change, standard error, and p-value from paired t-test.

**Table 3-32 Best-Corrected Binocular Distance Contrast Sensitivity at Pre-Op and 6 Months All Subjects (N=160)**

CPD	Pre-Op				Change from Pre-Op to 6 Months			
	3	6	12	18	3	6	12	18
<b>Photopic</b>								
	n=160	n=160	n=160	n=160	n=156	n=156	n=156	n=156
Mean	1.82	2.04	1.69	1.22	0.02	0.03	0.05	0.05
(SE)	0.012	0.015	0.018	0.019	0.013	0.016	0.018	0.020
P-Value	-	-	-	-	0.179	0.114	0.011	0.008
<b>Mesopic</b>								
	n=160	n=160	n=160	n=160	n=156	n=156	n=156	n=156
Mean	1.67	1.75	1.27	0.76	0.02	0.01	0.03	0.05
(SE)	0.015	0.023	0.032	0.035	0.016	0.023	0.031	0.033
P-Value	-	-	-	-	0.221	0.591	0.393	0.164
<b>Mesopic with Glare</b>								
	n=160	n=160	n=160	n=160	n=156	n=156	n=156	n=156
Mean	1.65	1.67	1.15	0.69	-0.01	0.05	0.07	0.10
(SE)	0.015	0.022	0.034	0.034	0.018	0.023	0.034	0.035
P-Value	-	-	-	-	0.740	0.050	0.030	0.006

**Table 3-33 Binocular Best-Corrected Near Contrast Sensitivity at Pre-Op and 6 Months All Subjects (N=160)**

CPD	Pre-Op					Change from Pre-Op to 6 Months				
	1.5	3	6	12	18	1.5	3	6	12	18
	n=160	n=160	n=160	n=160	n=157	n=155	n=155	n=155	n=155	n=149
Mean (SE)	1.72 0.014	1.95 0.013	1.99 0.015	1.67 0.018	1.32 0.022	0.03 0.015	0.00 0.015	0.00 0.018	0.02 0.020	0.02 0.023
P-Value	-	-	-	-	-	0.035	0.932	0.856	0.395	0.388

Table 3-34 presents the change in contrast sensitivity from baseline of more than 2 lines (>0.30 log levels) at 2 or more spatial frequencies, at 3, 6, and 12 months post-operatively for all eyes.

**Table 3-34 Change in Best-Corrected Binocular Contrast Sensitivity from Pre-Op to 6 Months, at Distance and Near All Subjects (N=160)**

	Decrease		No Change		Increase		Not Reported
	n	%	n	%	n	%	n
Distance Photopic	2	1.3	147	94.2	7	4.5	2
Distance Mesopic	16	10.3	126	80.8	14	9.0	2
Distance Mesopic w/Glare	16	10.3	117	75.0	23	14.7	2
Near Photopic	8	5.2	137	88.4	10	6.5	3

Binocular uncorrected contrast sensitivity was measured at 24 months postoperatively for a subset of subjects (n=30), and compared to preoperative best corrected contrast sensitivity, as presented in Tables 3-35, 3-36 and 3-37.

**Table 3-35: Mean Binocular Contrast Sensitivity (n=30)**

CPD	Mean Preop (best-corrected)					Change Pre to 24 Months (uncorrected)				
	1.5	3	6	12	18	1.5	3	6	12	18
Distance Photopic										
Mean		1.83	2.03	1.61	1.15		0.02	-0.02	0.03	-0.02
SE		0.02	0.03	0.04	0.04		0.03	0.04	0.04	0.04
P Value* <							0.55	0.72	0.43	0.65
Distance Mesopic										
Mean		1.62	1.65	1.05	0.53		0.06	0.08	0.05	0.15
SE		0.03	0.05	0.06	0.07		0.03	0.07	0.10	0.08
P Value* <							0.09	0.25	0.59	0.07
Distance Mesopic with Glare										
Mean		1.61	1.61	0.98	0.55		0.01	0.03	0.05	0.02
SE		0.03	0.05	0.07	0.06		0.05	0.06	0.07	0.08
P Value* <							0.80	0.67	0.50	0.79
Near Photopic <sup>^</sup>										
Mean	1.71	1.92	1.97	1.63	1.34	0.01	0.02	0.02	0.02	-0.06
SE	0.03	0.03	0.03	0.04	0.05	0.04	0.03	0.04	0.06	0.07
P Value* <						0.74	0.50	0.64	0.73	0.39

\*Two tailed paired t-test for the means.

<sup>^</sup>One subject did not have preoperative near photopic testing at 18 cpd.

Table 3-36 presents the percentage of subjects who experienced a change of more than 2 lines (>0.30 log units) in contrast sensitivity (CS) at 2 or more spatial frequencies."

**Table 3-36: Binocular Contrast Sensitivity, Pre-Op (best-corrected) Compared to 24-Month (uncorrected) (n=30)**

	> 2 line Decrease	Change ≤ 2 lines	> 2 line Increase
	n %	n %	n %
Dist Photopic	1 3	28 93	1 3
Dist Mesopic	8 27	17 57	5 17
Dist Meso w/ Glare	9 30	17 57	4 13
Near Photopic <sup>^</sup>	4 13	26 87	0 0

<sup>^</sup>One subject did not have preoperative near photopic testing at 18 cpd.

**Table 3-37: Binocular Contrast Sensitivity Pre-Op (best-corrected) Compared to 24-Month (uncorrected), Stratified by Anisometropia (n=30)**

	Subjects with < 1.50 D Anisometropia (n=13)			Subjects with ≥ 1.50 D Anisometropia (n=17)		
	> 2 line Decrease	Change ≤ 2 lines	> 2 line Increase	> 2 line Decrease	Change ≤ 2 lines	> 2 line Increase
	n %	n %	n %	n %	n %	n %
Dist Photopic	0 0	13 100	0 0	1 6	15 88	1 6
Dist Mesopic	2 15	8 62	3 23	6 35	9 53	2 12
Dist Meso w/ Glare	3 23	8 62	2 15	6 35	9 53	2 12
Near Photopic <sup>^</sup>	1 8	12 92	0 0	3 18	14 82	0 0

<sup>^</sup>One subject did not have preoperative near photopic testing at 18 cpd.

### 10) Retreatments

At the time of database closure, 8 eyes (8/296, 2.7%) had undergone retreatment in the study. Five eyes were retreated after completing the 6-month visit, and 3 eyes were retreated after completing the 9-month visit. Data for these eyes prior to retreatment are included in all analyses.

### 11) Patient Symptoms and Satisfaction

Patient questionnaires reflected the following patient responses pre-operatively and at 6 months post-operatively. Table 3-38 presents a summary of patient symptoms. Change in symptoms is presented in Table 3-39. Table 3-40 presents summary of overall patient satisfaction with monovision, and Table 3-41 presents a summary of satisfaction with visual quality for all subjects. Table 3-42 presents change in satisfaction with visual quality. Patients rated their vision on a 5-level scale. An improvement or worsening represents a change of at least 2 levels.

Table 3-38 Summary of Visual Symptoms All Subjects (N=160)

Symptoms	Never			Rarely			Sometimes			Often			Always		
	Pre* n=155 %	6M n=157 %	12M n=112 %												
Dryness	15.5	15.3	16.1	34.2	33.8	43.6	43.9	39.5	33.6	5.8	9.6	6.0	0.6	1.9	0.7
Blurry vision	30.3	28.0	33.6	33.5	46.5	50.3	33.5	22.3	14.1	1.9	1.9	2.0	0.6	1.3	0.0
Fluctuation of vision	35.5	42.0	43.6	33.5	36.9	36.9	28.4	19.1	17.4	2.6	1.9	2.0	0.0	0.0	0.0
Glare	26.5	42.7	42.3	38.1	33.1	40.3	32.3	19.7	14.1	1.9	2.5	3.4	1.3	1.9	0.0
Halos around lights	34.8	47.1	51.0	32.9	22.9	28.9	24.5	19.7	14.8	6.5	8.3	3.4	1.3	1.9	2.0
Difficulty at night	14.8	33.8	34.2	45.2	28.7	32.2	27.1	28.0	26.8	9.0	6.4	3.4	3.9	3.2	3.4
Ghosting or shadowing of images	65.2	68.8	77.9	25.2	21.0	14.8	7.7	6.4	3.4	1.9	1.9	3.4	0.0	1.9	0.7
Double images	89.7	86.6	91.3	9.0	9.6	5.4	0.6	2.5	2.7	0.6	1.3	0.0	0.0	0.0	0.7
Things appear distorted	85.2	83.4	87.2	11.0	13.4	8.1	3.2	3.2	4.7	0.6	0.0	0.0	0.0	0.0	0.0
My vision makes me dizzy	83.9	95.5	94.6	12.9	4.5	5.4	3.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
My vision gives me headaches	68.4	91.1	87.9	23.2	7.0	9.4	7.1	1.9	2.7	1.3	0.0	0.0	0.0	0.0	0.0

\*5 subjects did not complete a preoperative questionnaire.

**Table 3-39 Change in Visual Symptoms from Pre-Op with Correction to Post-Op without Correction All Subjects (N=155\*)**

	6 Months (n=152)				12 Months (n=145)			
	Improve	No Change	Worsen	NR	Improve	No Change	Worsen	NR
	%	%	%	%	%	%	%	%
Dryness	9.2	77.0	13.8	0	9.0	84.1	6.9	0
Blurry vision	5.9	89.5	4.6	0	9.0	88.3	2.8	0
Fluctuation of vision	11.8	83.6	4.6	0	10.3	84.8	4.8	0
Glare	9.2	82.9	7.9	0	9.7	85.5	4.8	0
Halos around lights	11.8	77.0	11.2	0	15.2	76.6	8.3	0
Difficulty at night	13.8	75.7	10.5	0	15.2	77.2	7.6	0
Ghosting or shadowing of images	5.9	88.2	5.9	0	4.8	91.0	4.1	0
Double images	1.3	96.7	2.0	0	1.4	96.6	2.1	0
Things appear distorted	2.6	94.1	3.3	0	2.8	92.4	4.8	0
My vision makes me dizzy	2.6	97.4	0.0	0	2.8	97.2	0.0	0
My vision gives me headaches	4.6	94.7	0.7	0	4.1	95.2	0.7	0

\*5 subjects did not complete a preoperative questionnaire and are excluded from this analysis.

**Table 3-40 Overall Satisfaction with Monovision Treatment All Subjects (N=160)**

Percentage of subjects who would elect to undergo Monovision LASIK treatment again	6 Months (n=157)			12 Months (n=149)		
	Yes	No	Not Sure	Yes	No	Not Sure
	n %	n %	n %	n %	n %	n %
	152 96.8	0 0.0	5 3.2	146 98.0	1 0.7	2 1.3

Table 3-41 Summary of Satisfaction with Visual Quality All Subjects (N=160)

Activity	Very Satisfied			Satisfied			Not Sure			Somewhat Dissatisfied			Very Dissatisfied		
	Pre* n=155	6M n=157	12M n=149	Pre* n=155	6M n=157	12M n=149	Pre* n=155	6M n=157	12M n=149	Pre* n=155	6M n=157	12M n=149	Pre* n=155	6M n=157	12M n=149
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Intermediate Vision	23.9	69.4	75.2	57.4	24.2	20.1	0.0	1.3	1.3	15.5	4.5	2.7	3.2	0.6	0.7
Depth Perception	36.8	71.3	72.5	53.5	26.8	26.2	0.6	0.0	0.7	9.0	1.3	0.7	0.0	0.6	0.0
Peripheral Vision	35.5	72.0	72.5	49.0	24.8	25.5	3.2	0.6	1.3	10.3	1.9	0.7	1.9	0.6	0.0
Near Vision (Sustained)	21.3	58.6	63.1	54.2	34.4	32.2	1.3	1.9	0.0	14.8	4.5	3.4	8.4	0.6	1.3
Near Vision (Brief)	26.5	71.3	68.5	49.0	24.2	28.2	1.9	1.3	0.0	17.4	1.9	2.7	5.2	1.3	0.7
Near Vision (Small Print)	14.8	42.7	50.3	38.1	42.7	35.6	8.4	4.5	2.7	24.5	7.0	8.7	14.2	3.2	2.7
Distance Vision at Night	13.5	37.6	45.0	58.1	46.5	36.9	5.8	5.7	6.0	20.0	7.0	10.7	2.6	3.2	1.3
Distance Vision at Night W/ Glare	8.4	38.2	38.9	54.8	43.3	41.6	9.7	5.7	6.0	22.6	11.5	11.4	4.5	1.3	2.0
Distance Vision at Dusk	16.8	48.4	55.0	61.3	40.8	37.6	9.0	2.5	1.3	11.6	6.4	4.7	1.3	1.9	1.3
Distance Vision Under Active Conditions	27.3	68.6	74.5	46.8	25.0	22.8	3.2	1.3	1.3	18.8	3.2	1.3	3.9	1.9	0.0
Overall Satisfaction	16.8	66.9	71.1	49.0	26.8	25.5	5.2	2.5	0.7	27.1	3.8	2.0	1.9	0.0	0.7

\*5 subjects did not complete a preoperative questionnaire.

Table 3-42 Change in Satisfaction with Visual Quality All Subjects (N=155)

	6 Months(n=152)				12 Months(n=145)			
	Improve	No Change	Worsen	Not Reported	Improve	No Change	Worsen	Not Reported
	n %	n %	n %	n	n %	n %	n %	n
Intermediate Vision	26 17.1	119 78.3	7 4.6	0	27 18.6	114 78.6	4 2.8	0
Depth Perception	14 9.2	135 88.8	3 2.0	0	13 9.0	131 90.3	1 0.7	0
Peripheral Vision	21 13.8	129 84.9	2 1.3	0	20 13.8	124 85.5	1 0.7	0
Near Vision (Sustained)	33 21.7	115 75.7	4 2.6	0	32 22.1	109 75.2	4 2.8	0
Near Vision (Brief)	35 23.0	115 75.7	2 1.3	0	36 24.8	106 73.1	3 2.1	0
Near Vision (Small Print)	59 38.8	87 57.2	6 3.9	0	48 33.1	94 64.8	3 2.1	0
Distance Vision at Night	26 17.1	117 77.0	9 5.9	0	25 17.2	110 75.9	10 6.9	0
Distance Vision at Night W/ Glare	34 22.4	107 70.4	11 7.2	0	29 20.0	108 74.5	8 5.5	0
Distance Vision at Dusk	21 13.8	121 79.6	10 6.6	0	19 13.1	123 84.8	3 2.1	0
Distance Vision Under Active Conditions*	37 24.5	109 72.2	5 3.3	1	37 25.7	106 73.6	1 0.7	1
Overall Satisfaction	46 30.3	102 67.1	4 2.6	0	45 31.0	99 68.3	1 0.7	0

<sup>^</sup>5 subjects did not complete a pre-op questionnaire.

\*One subject did not respond to this question.

**12) Spectacle Use**

Wavefront-guided Monovision LASIK treatment reduced overall use of corrective lenses postoperatively.

**Table 3-43 Frequency of Use of Corrective Lenses Over Time All Subjects (n=160)**

	Pre-Op (n=155*)		6 Months (n=157)		12 Months (n=112)	
	n	%	n	%	n	%
Never	2	1.3	132	84.1	69	61.6
Rarely	0	0.0	11	7.0	19	17.0
Sometimes	1	0.6	10	6.4	16	14.3
Often	16	10.3	3	1.9	8	7.1
Always	136	87.7	1	0.6	0	0.0

\*5 subjects did not complete a preoperative questionnaire.

**Table 3-44 Change in Use of Corrective Lenses from Pre-Op All Subjects (n=155\*)**

6 Months (n=152)			12 Months (n=145)		
Decrease in Use	No Change	Increase in Use	Decrease in Use	No Change	Increase in Use
n %	n %	n %	n %	n %	n %
146 96.1	6 3.9	0 0.0	132 91.0	12 8.3	1 0.7

\*5 subjects did not complete a preoperative questionnaire and are excluded from this analysis.

### **13) Summary of Key Safety and Effectiveness Variables**

The key safety and effectiveness variables over time for dominant eyes are presented in Table 3-45. Key safety and effectiveness variables for all non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism are presented in Table 3-46 through 3-48. The key effectiveness variables at the point of stability, stratified by pre-operative manifest refraction spherical equivalent, are presented in Tables 3-49, 3-51, 3-53 and 3-55. Key safety variables, stratified by pre-operative manifest refraction spherical equivalent are presented in Tables 3-50, 3-52, 3-54 and 3-56, for the various treatment cohorts.

**Table 3-45 Summary of Safety and Effectiveness Dominant Eyes (N=159)**

	1 Month n % (95% CI)	3 Months n % (95% CI)	6 Months n % (95% CI)	9 Months n % (95% CI)	12 Months n % (95% CI)
<b>Effectiveness Variables</b>	<b>n=158</b>	<b>n=156</b>	<b>n=157</b>	<b>n=151</b>	<b>n=148</b>
UCVA 20/20 or better	134 84.8 (78.2, 90.0)	134 85.9 (79.4, 90.9)	138 87.9 (81.7, 92.6)	136 90.1 (84.1, 94.3)	132 89.2 (83.0, 93.7)
UCVA 20/40 or better	158 100 (98.1, 100)	156 100 (98.1, 100)	156 99.4 (96.5, 100)	151 100 (98.0, 100)	148 100 (98.0, 100)
MRSE $\pm$ 0.50 D	141 89.2 (83.3, 93.6)	137 87.8 (81.6, 92.5)	139 88.5 (82.5, 93.1)	135 89.4 (83.4, 93.8)	133 89.9 (83.8, 94.2)
MRSE $\pm$ 1.00 D	156 98.7 (95.5, 99.8)	155 99.4 (96.5, 100)	154 98.1 (94.5, 99.6)	150 99.3 (96.4, 100)	147 99.3 (96.3, 100)
Sphere $\pm$ 0.50 D	138 87.3 (81.1, 92.1)	137 87.8 (81.6, 92.5)	141 89.8 (84.0, 94.1)	136 90.1 (84.1, 94.3)	130 87.8 (81.5, 92.6)
Sphere $\pm$ 1.00 D	153 96.8 (92.8, 99.0)	154 98.7 (95.4, 99.8)	155 98.7 (95.5, 99.8)	149 98.7 (95.3, 99.8)	148 100 (98.0, 100)
<b>Stability of MRSE<sup>^</sup></b>		<b>n=155</b>	<b>n=155</b>	<b>n=150</b>	<b>n=145</b>
Change $\leq$ 1.00 D MRSE		155 100 (98.1, 100)	155 100 (98.1, 100)	150 100 (98.0, 100)	145 100 (98.0, 100)
Mean Change in MRSE $\pm$ SD		-0.08 $\pm$ 0.25 (-0.12, -0.04)	-0.03 $\pm$ 0.23 (-0.07, 0.00)	-0.02 $\pm$ 0.18 (-0.05, 0.01)	0.00 $\pm$ 0.18 (-0.03, 0.03)
<b>Safety Variables</b>	<b>n=158</b>	<b>n=156</b>	<b>n=157</b>	<b>n=151</b>	<b>n=148</b>
Loss of >2 lines BSCVA	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
Loss of $\geq$ 2 lines BSCVA	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
BSCVA worse than 20/25	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
BSCVA worse than 20/40	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
Loss of >2 lines BCNVA	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
Loss of $\geq$ 2 lines BCNVA	1 1.6 (0.0, 3.5)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	1 0.7 (0.0, 3.6)	0 0.0 (0.0, 2.0)
BCNVA worse than 20/25	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
BCNVA worse than 20/40	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)
Increase of >2 D cylinder	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 1.9)	0 0.0 (0.0, 2.0)	0 0.0 (0.0, 2.0)

<sup>^</sup>Analysis of stability is limited to eyes with two consecutive visits.

**Table 3-46 Summary of Safety and Effectiveness Non-Dominant Eyes (N=137)**

	1 Month n % (95% CI)	3 Months n % (95% CI)	6 Months n % (95% CI)	9 Months n % (95% CI)	12 Months n % (95% CI)
<b>Effectiveness Variables</b>	<b>(n=136)</b>	<b>(n=134)</b>	<b>(n=135)</b>	<b>(n=133)</b>	<b>n=133</b>
UCNVA 20/20 or better	102 75.0 (66.9, 82.0)	113 84.3 (77.0, 90.0)	109 80.7 (73.1, 87.0)	116 87.2 (80.3, 92.4)	114 85.7 (78.6, 91.2)
UCNVA 20/40 or better	136 100 (97.8, 100)	133 99.3 (95.9, 100)	135 100 (97.8, 100)	133 100 (97.8, 100)	132 99.2 (95.9, 100)
MRSE* ± 0.50 D	120 88.2 (81.6, 93.1)	120 89.6 (83.1, 94.2)	118 87.4 (80.6, 92.5)	117 88.0 (81.2, 93.0)	115 86.5 (79.5, 91.8)
MRSE* ± 1.00 D	135 99.3 (96.0, 100)	132 98.5 (94.7, 99.8)	134 99.3 (95.9, 100)	132 99.2 (95.9, 100)	130 97.7 (93.5, 99.5)
Sphere* ± 0.50 D	123 90.4 (84.2, 94.8)	121 90.3 (84.0, 94.7)	121 89.6 (83.2, 94.2)	121 91.0 (84.8, 95.3)	121 91.0 (84.8, 95.3)
Sphere* ± 1.00 D	135 99.3 (96.0, 100)	132 98.5 (94.7, 99.8)	134 99.3 (95.9, 100)	131 98.5 (94.7, 99.8)	131 98.5 (94.7, 99.8)
<b>Stability of MRSE<sup>^</sup></b>		<b>n=133</b>	<b>n=133</b>	<b>n=132</b>	<b>n=131</b>
Change ≤1.00 D MRSE		132 99.2 (95.9, 100)	133 100 (97.8, 100)	132 100 (97.8, 100)	131 100 (97.7, 100)
Mean Change in MRSE ± SD		-0.02 ± 0.26 (-0.06, 0.03)	-0.03 ± 0.21 (-0.07, 0.01)	0.00 ± 0.19 (-0.03, 0.04)	-0.03 ± 0.23 (-0.07, 0.01)
<b>Safety Variables</b>	<b>n=136</b>	<b>n=134</b>	<b>n=135</b>	<b>n=133</b>	<b>n=133</b>
Loss of >2 lines BSCVA	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
Loss of ≥ 2 lines BSCVA	3 2.2 (0.5, 6.3)	1 0.7 (0.0, 4.1)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
BSCVA worse than 20/25	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
BSCVA worse than 20/40	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
Loss of >2 lines BCNVA	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
Loss of ≥2 lines BCNVA	3 2.2 (0.5, 6.3)	1 0.7 (0.0, 4.1)	1 0.7 (0.0, 4.1)	1 0.8 (0.0, 4.1)	0 0.0 (0.0, 2.2)
BCNVA worse than 20/25	1 0.7 (0.0, 4.1)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
BCNVA worse than 20/40	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)
Increase >2 D cylinder	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.2)

<sup>^</sup>Analysis of stability is limited to eyes with two consecutive visits.

**Table 3-47 Summary of Safety and Effectiveness Non-Dominant Eyes with Spherical Myopia (N=83)**

	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)
<b>Effectiveness Variables</b>	<b>n=82</b>	<b>n=82</b>	<b>n=82</b>	<b>n=83</b>	<b>n=81</b>
UCNVA 20/20 or better	65 79.3 (68.9, 87.4)	70 85.4 (75.8, 92.2)	68 82.9 (73.0, 90.3)	71 85.5 (76.1, 92.3)	69 85.2 (75.6, 92.1)
UCNVA 20/40 or better	82 100 (96.4, 100)	82 100 (96.4, 100)	82 100 (96.4, 100)	83 100 (96.5, 100)	81 100 (96.4, 100)
MRSE* ± 0.50 D	73 89.0 (80.2, 94.9)	72 87.8 (78.7, 94.0)	68 82.9 (73.0, 90.3)	72 86.7 (77.5, 93.2)	70 86.4 (77.0, 93.0)
MRSE* ± 1.00 D	82 100 (96.4, 100)	81 98.8 (93.4, 100)	82 100 (96.4, 100)	83 100 (96.5, 100)	80 98.8 (93.3, 100)
Sphere* ± 0.50 D	76 92.7 (84.8, 97.3)	73 89.0 (80.2, 94.9)	70 85.4 (75.8, 92.2)	73 88.0 (79.0, 94.1)	74 91.4 (83.0, 96.5)
Sphere* ± 1.00 D	82 100 (96.4, 100)	81 98.8 (93.4, 100)	82 100 (96.4, 100)	82 98.8 (93.5, 100)	80 98.8 (93.3, 100)
<b>Stability of MRSE<sup>A</sup></b>		<b>n=81</b>	<b>n=81</b>	<b>n=82</b>	<b>n=81</b>
Change ≤1.00 D MRSE		81 100 (96.4, 100)	81 100 (96.4, 100)	82 100 (96.4, 100)	81 100 (96.4, 100)
Mean Change in MRSE ± SD		-0.03 ± 0.23 (-0.08, 0.02)	-0.01 ± 0.21 (-0.06, 0.04)	0.02 ± 0.20 (-0.02, 0.07)	-0.07 ± 0.21 (-0.12, -0.03)
<b>Safety Variables</b>	<b>n=82</b>	<b>n=82</b>	<b>n=82</b>	<b>n=83</b>	<b>n=81</b>
Loss of >2 lines BSCVA	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
Loss of ≥ 2 lines BSCVA	2 2.4 (0.3, 8.5)	1 1.2 (0.0, 6.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
BSCVA worse than 20/25	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
BSCVA worse than 20/40	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
Loss of >2 lines BCNVA	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
Loss of ≥2 lines BCNVA	2 2.4 (0.3, 8.5)	1 1.2 (0.0, 6.6)	1 1.2 (0.0, 6.6)	1 1.2 (0.0, 6.5)	0 0.0 (0.0, 3.6)
BCNVA worse than 20/25	1 1.2 (0.0, 6.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
BCNVA worse than 20/40	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)
Increase >2 D cylinder	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.6)	0 0.0 (0.0, 3.5)	0 0.0 (0.0, 3.6)

\* MRSE and Sphere values are compared to the surgical intended outcome.

<sup>A</sup>Analysis of stability is limited to eyes with two consecutive visits.

**Table 3-48 Summary of Safety and Effectiveness Non-Dominant Eyes with Myopic Astigmatism (N=54)**

	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)
<b>Effectiveness Variables</b>	<b>n=54</b>	<b>n=52</b>	<b>n=53</b>	<b>n=50</b>	<b>n=52</b>
UCNVA 20/20 or better	37 68.5 (54.4, 80.5)	43 82.7 (69.7, 91.8)	41 77.4 (63.8, 87.7)	45 90.0 (78.2, 96.7)	45 86.5 (74.2, 94.4)
UCNVA 20/40 or better	54 100 (94.6, 100)	51 98.1 (89.7, 100)	53 100 (94.5, 100)	50 100 (94.2, 100)	51 98.1 (89.7, 100)
MRSE* ± 0.50 D	47 87.0 (75.1, 94.6)	48 92.3 (81.5, 97.9)	50 94.3 (84.3, 98.8)	45 90.0 (78.2, 96.7)	45 86.5 (74.2, 94.4)
MRSE* ± 1.00 D	53 98.1 (90.1, 100)	51 98.1 (89.7, 100)	52 98.1 (89.9, 100)	49 98.0 (89.4, 99.9)	50 96.2 (86.8, 99.5)
Sphere* ± 0.50 D	47 87.0 (75.1, 94.6)	48 92.3 (81.5, 97.9)	51 96.2 (87.0, 99.5)	48 96.0 (86.3, 99.5)	47 90.4 (79.0, 96.8)
Sphere* ± 1.00 D	53 98.1 (90.1, 100)	51 98.1 (89.7, 100)	52 98.1 (89.9, 100)	49 98.0 (89.4, 99.9)	51 98.1 (86.7, 100)
<b>Stability of MRSE<sup>^</sup></b>		<b>n=52</b>	<b>n=52</b>	<b>n=50</b>	<b>n=50</b>
Change ≤1.00 D MRSE		51 98.1 (89.7, 100)	52 100 (94.4, 100)	50 100 (94.2, 100)	50 100 (94.2, 100)
Mean Change in MRSE ± SD		0.00 ± 0.31 (-0.09, 0.09)	-0.06 ± 0.20 (-0.12, -0.01)	-0.03 ± 0.18 (-0.08, 0.02)	0.05 ± 0.24 (-0.02, 0.12)
<b>Safety Variables</b>	<b>n=54</b>	<b>n=52</b>	<b>n=53</b>	<b>n=50</b>	<b>n=52</b>
Loss of >2 lines BSCVA	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
Loss of ≥ 2 lines BSCVA	1 1.9 (0.0, 9.9)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
BSCVA worse than 20/25	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
BSCVA worse than 20/40	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
Loss of >2 lines BCNVA	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
Loss of ≥2 lines BCNVA	1 1.9 (0.0, 9.9)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
BCNVA worse than 20/25	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
BCNVA worse than 20/40	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)
Increase of 2 D cylinder	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.6)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 5.6)

\* MRSE and Sphere values are compared to the surgical intended outcome.

<sup>^</sup>Analysis of stability is limited to eyes with two consecutive visits.

Table 3-49 Summary of Key Effectiveness Variables at 6 Months Stratified by Pre-Operative MRSE Dominant Eyes (N=157)

	<0 to -1 D (n=1)	<-1 to -2 D (n=12)	<-2 to -3 D (n=34)	<-3 to -4 D (n=39)	<-4 to -5 D (n=43)	<-5 to -6 D (n=24)	<-6 D (n=4)	Total (n=157)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
<b>Effectiveness Variables</b>								
UCVA 20/20 or better	1 100 (5.0, 100)	10 83.3 (51.6, 7.9)	31 91.2 (76.3, 8.1)	33 84.6 (69.5, 4.1)	37 86.0 (72.1, 4.7)	22 91.7 (73.0, 9.0)	4 100 (47.3, 100)	138 87.9 (81.7, 92.6)
UCVA 20/40 or better	1 100 (5.0, 100)	12 100 (77.9, 100)	34 100 (91.6, 100)	39 100 (92.6, 100)	42 97.7 (87.7, 99.9)	24 100 (88.3, 100)	4 100 (47.3, 100)	156 99.4 (96.5, 100)
MRSE $\pm$ 0.50 D	1 100 (5.0, 100)	11 91.7 (61.5, 99.8)	31 91.2 (76.3, 98.1)	34 87.2 (72.6, 95.7)	37 86.0 (72.1, 94.7)	21 87.5 (67.6, 97.3)	4 100 (47.3, 100)	139 88.5 (82.5, 93.1)
MRSE $\pm$ 1.00 D	1 100 (5.0, 100)	12 100 (77.9, 100)	34 100 (91.6, 100)	38 97.4 (86.5, 99.9)	41 95.3 (84.2, 99.4)	24 100 (88.3, 100)	4 100 (47.3, 100)	154 98.1 (94.5, 99.6)
Sphere $\pm$ 0.50 D	1 100 (5.0, 100)	12 100 (77.9, 100)	31 91.2 (76.3, 98.1)	34 87.2 (72.6, 95.7)	37 86.0 (72.1, 94.7)	22 91.7 (73.0, 99.0)	4 100 (47.3, 100)	141 89.8 (84.0, 94.1)
Sphere $\pm$ 1.00 D	1 100 (5.0, 100)	12 100 (77.9, 100)	34 100 (91.6, 100)	38 97.4 (86.5, 99.9)	42 97.7 (87.7, 99.9)	24 100 (88.3, 100)	4 100 (47.3, 100)	155 98.7 (95.5, 99.8)
<b>Stability of MRSE</b>								
Change $\leq$ 1.00 D MRSE	1 100 (5.0, 100)	12 100 (77.9, 100)	34 100 (91.6, 100)	39 100 (92.6, 100)	41 100 (93.0, 100)	24 100 (88.3, 100)	4 100 (47.3, 100)	155 100 (98.1, 100)

Table 3-50 Summary of Key Safety Variables at 6 Months Stratified by Pre-Operative MRSE Dominant Eyes (N=157)

	<0 to -1 D (n=1)	<-1 to -2 D (n=12)	<-2 to -3 D (n=34)	<-3 to -4 D (n=39)	<-4 to -5 D (n=43)	<-5 to -6 D (n=24)	<-6 D (n=4)	Total (n=157)
Safety Variables	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
Loss of >2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
Loss of ≥2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
BSCVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
BSCVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
Loss of >2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
Loss of ≥2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
BCNVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
BCNVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)
Increase >2 D cylinder	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 8.4)	0 0.0 (0.0, 7.4)	0 0.0 (0.0, 6.7)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 1.9)

Table 3-51 Summary of Key Effectiveness Variables at 6 Months Stratified by Pre-Operative MRSE All Non-Dominant Eyes (N=135)

	<0 to -1 D (n=0)	<-1 to -2 D (n=1)	<-2 to -3 D (n=25)	<-3 to -4 D (n=40)	<-4 to -5 D (n=37)	<-5 to -6 D (n=29)	<-6 D (n=3)	Total (n=135)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
<b>Effectiveness Variables</b>								
UCNVA 20/20 or better		0 0.0 (0.0, 95.0)	20 80.0 (59.3, 93.2)	27 67.5 (50.9, 81.4)	33 89.2 (74.6, 97.0)	26 89.7 (72.6, 97.8)	3 100 (36.8, 100)	109 80.7 (73.1, 87.0)
UCNVA 20/40 or better		1 100 (5.0, 100)	25 100 (88.7, 100)	40 100 (92.8, 100)	37 100 (92.2, 100)	29 100 (90.2, 100)	3 100 (36.8, 100)	135 100 (97.8, 100)
MRSE $\pm$ 0.50 D		1 100 (5.0, 100)	23 92.0 (74.0, 99.0)	35 87.5 (73.2, 95.8)	31 83.8 (68.0, 93.8)	25 86.2 (68.3, 96.1)	3 100 (36.8, 100)	118 87.4 (80.6, 92.5)
MRSE $\pm$ 1.00 D		1 100 (5.0, 100)	25 100 (88.7, 100)	40 100 (92.8, 100)	36 97.3 (85.8, 99.9)	29 100 (90.2, 100)	3 100 (36.8, 100)	134 99.3 (95.9, 100)
Sphere $\pm$ 0.50 D		1 100 (5.0, 100)	24 96.0 (79.6, 99.9)	35 87.5 (73.2, 95.8)	31 83.8 (68.0, 93.8)	27 93.1 (77.2, 99.2)	3 100 (36.8, 100)	121 89.6 (83.2, 94.2)
Sphere $\pm$ 1.00 D		1 100 (5.0, 100)	25 100 (88.7, 100)	40 100 (92.8, 100)	36 97.3 (85.8, 99.9)	29 100 (90.2, 100)	3 100 (36.8, 100)	134 99.3 (95.9, 100)
<b>Stability of MRSE</b>								
Change $\leq$ 1.00 D MRSE		1 100 (5.0, 100)	25 100 (88.7, 100)	40 100 (92.8, 100)	37 100 (92.2, 100)	27 100 (89.5, 100)	3 100 (36.8, 100)	133 100 (97.8, 100)

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Table 3-52 Summary of Key Safety Variables at 6 Months Stratified by Pre-Operative MRSE All Non-Dominant Eyes (N=135)

	<0 to -1 D (n=0)	<-1 to -2 D (n=1)	<-2 to -3 D (n=25)	<-3 to -4 D (n=40)	<-4 to -5 D (n=37)	<-5 to -6 D (n=29)	<-6 D (n=3)	Total (n=135)
Safety Variables	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
Loss of >2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
Loss of ≥2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
BSCVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
BSCVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
Loss of >2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
Loss of ≥2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	1 2.5 (0.1, 13.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	1 0.7 (0.0, 4.1)
BCNVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
BCNVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)
Increase >2 D cylinder	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 11.3)	0 0.0 (0.0, 7.2)	0 0.0 (0.0, 7.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 63.2)	0 0.0 (0.0, 2.2)

**Table 3-53 Summary of Key Effectiveness Variables at 6 Months Stratified by Pre-Operative MRSE Non-Dominant Eyes with Spherical Myopia (N=82)**

	<0 to -1 D (n=0)	<-1 to -2 D (n=0)	<-2 to -3 D (n=18)	<-3 to -4 D (n=26)	<-4 to -5 D (n=21)	<-5 to -6 D (n=15)	<-6 D (n=2)	Total (n=82)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
<b>Effectiveness Variables</b>								
UCNVA 20/20 or better			15 83.3 (58.6, 96.4)	17 65.4 (44.3, 82.8)	20 95.2 (76.2, 99.9)	14 93.3 (68.1, 99.8)	2 100 (22.4, 100)	68 82.9 (73.0, 90.3)
UCNVA 20/40 or better			18 100 (84.7, 100)	26 100 (89.1, 100)	21 100 (86.7, 100)	15 100 (81.9, 100)	2 100 (22.4, 100)	82 100 (96.4, 100)
MRSE $\pm$ 0.50 D			16 88.9 (65.3, 98.6)	22 84.6 (65.1, 95.6)	16 76.2 (52.8, 91.8)	12 80.0 (51.9, 95.7)	2 100 (22.4, 100)	68 82.9 (73.0, 90.3)
MRSE $\pm$ 1.00 D			18 100 (84.7, 100)	26 100 (89.1, 100)	21 100 (86.7, 100)	15 100 (81.9, 100)	2 100 (22.4, 100)	82 100 (96.4, 100)
Sphere $\pm$ 0.50 D			17 94.4 (72.7, 99.9)	22 84.6 (65.1, 95.6)	16 76.2 (52.8, 91.8)	13 86.7 (59.5, 98.3)	2 100 (22.4, 100)	70 85.4 (75.8, 92.2)
Sphere $\pm$ 1.00 D			18 100 (84.7, 100)	26 100 (89.1, 100)	21 100 (86.7, 100)	15 100 (81.9, 100)	2 100 (22.4, 100)	82 100 (96.4, 100)
<b>Stability of MRSE</b>								
Change $\leq$ 1.00 D MRSE			18 100 (84.7, 100)	26 100 (89.1, 100)	21 100 (86.7, 100)	14 100 (80.7, 100)	2 100 (22.4, 100)	81 100 (96.4, 100)

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**Table 3-54 Summary of Key Safety Variables at 6 Months Stratified by Pre-Operative MRSE Non-Dominant Eyes with Spherical Myopia (N=82)**

	<0 to -1 D (n=0)	<-1 to -2 D (n=0)	<-2 to -3 D (n=18)	<-3 to -4 D (n=26)	<-4 to -5 D (n=21)	<-5 to -6 D (n=15)	<-6 D (n=2)	Total (n=82)
Safety Variables	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
Loss of >2 lines BSCVA			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
Loss of ≥2 lines BSCVA			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
BSCVA worse than 20/25			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
BSCVA worse than 20/40			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
Loss of >2 lines BCNVA			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
Loss of ≥2 lines BCNVA			0 0.0 (0.0, 15.3)	1 3.8 (0.1, 19.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	1 1.2 (0.0, 6.6)
BCNVA worse than 20/25			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
BCNVA worse than 20/40			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)
Increase >2 D cylinder			0 0.0 (0.0, 15.3)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 18.1)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.6)

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**Table 3-55 Summary of Key Effectiveness Variables at 6 Months Stratified by Pre-Operative MRSE Non-Dominant Eyes with Myopic Astigmatism (N=53)**

	<0 to -1 D (n=0)	<-1 to -2 D (n=1)	<-2 to -3 D (n=7)	<-3 to -4 D (n=14)	<-4 to -5 D (n=16)	<-5 to -6 D (n=14)	<-6 D (n=1)	Total (n=53)
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
<b>Effectiveness Variables</b>								
UCNVA 20/20 or better		0 0.0 (0.0, 95.0)	5 71.4 (29.0, 96.3)	10 71.4 (41.9, 91.6)	13 81.3 (54.4, 96.0)	12 85.7 (57.2, 98.2)	1 100 (5.0, 100)	41 77.4 (63.8, 87.7)
UCNVA 20/40 or better		1 100 (5.0, 100)	7 100 (65.2, 100)	14 100 (80.7, 100)	16 100 (82.9, 100)	14 100 (80.7, 100)	1 100 (5.0, 100)	53 100 (94.5, 100)
MRSE $\pm$ 0.50 D		1 100 (5.0, 100)	7 100 (65.2, 100)	13 92.9 (66.1, 99.8)	15 93.8 (69.8, 99.8)	13 92.9 (66.1, 99.8)	1 100 (5.0, 100)	50 94.3 (84.3, 98.8)
MRSE $\pm$ 1.00 D		1 100 (5.0, 100)	7 100 (65.2, 100)	14 100 (80.7, 100)	15 93.8 (69.8, 99.8)	14 100 (80.7, 100)	1 100 (5.0, 100)	52 98.1 (89.9, 100)
Sphere $\pm$ 0.50 D		1 100 (5.0, 100)	7 100 (65.2, 100)	13 92.9 (66.1, 99.8)	15 93.8 (69.8, 99.8)	14 100 (80.7, 100)	1 100 (5.0, 100)	51 96.2 (87.0, 99.5)
Sphere $\pm$ 1.00 D		1 100 (5.0, 100)	7 100 (65.2, 100)	14 100 (80.7, 100)	15 93.8 (69.8, 99.8)	14 100 (80.7, 100)	1 100 (5.0, 100)	52 98.1 (89.9, 100)
<b>Stability of MRSE</b>								
Change $\leq$ 1.00 D MRSE		1 100 (5.0, 100)	7 100 (65.2, 100)	14 100 (80.7, 100)	16 100 (82.9, 100)	13 100 (79.4, 100)	1 100 (5.0, 100)	52 100 (94.4, 100)

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Table 3-56 Summary of Key Safety Variables at 6 Months Stratified by Pre-Operative MRSE Non-Dominant Eyes with Myopic Astigmatism (N=53)

	<0 to -1 D (n=0)	<-1 to -2 D (n=1)	<-2 to -3 D (n=7)	<-3 to -4 D (n=14)	<-4 to -5 D (n=16)	<-5 to -6 D (n=14)	<-6 D (n=1)	Total (n=53)
Safety Variables	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
Loss of >2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
Loss of ≥2 lines BSCVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
BSCVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
BSCVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
Loss of >2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
Loss of ≥2 lines BCNVA	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
BCNVA worse than 20/25	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
BCNVA worse than 20/40	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)
Increase >2 D cylinder	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 17.1)	0 0.0 (0.0, 19.3)	0 0.0 (0.0, 95.0)	0 0.0 (0.0, 5.5)

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## 4.1 Surgical Planning and Procedures



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

### 4.1.1 Introduction

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

### 4.1.2 Pre-Operative (Examination of the Patient)

A complete examination, including but not limited to cycloplegic evaluation, must be performed. The patient's eye should be evaluated for dry eye syndromes. Ultrasonic pachymetry measurement is required. Pre-operative assessment of pupil size is also required. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey® 24-2 Fastpac or equivalent threshold test of the visual field should be performed.

To treat a patient using the WaveScan® data, the appropriate exams should be captured and reviewed by the surgeon in accord with the WaveScan WaveFront® System Operator's Instructions (Chapter 7).

The treatment is then generated at the WaveScan and the USB drive or floppy disk containing the treatment should be placed into the laser and the surgeon must verify that the patient loaded to be treated by the laser is the same as the patient lying under the laser.

Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients desiring wavefront-guided monovision LASIK surgery should be performed within 60 days of laser refractive surgery. Patients who wear soft contact lenses must discontinue their use for at least 2 weeks, and those who wear gas permeable or hard lenses must discontinue their use for at least 3 weeks. Failure to do so will adversely affect the end surgical result.

### **4.1.3 Peri-Operative (Anesthesia and Analgesia)**

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

### **4.1.4 Post-Operative**

#### **A. Medications**

Following completion of the excimer laser surgery, appropriate medications should be applied to the eye in a sterile manner. It is critical that the flap not be disturbed. Instruct patients not to touch their eyes. Patients will need to instill lubricating drops and wear eye shields to bed for at least a week.

#### **B. Follow-up Care**

A typical follow-up regimen consists of next-day check, followed by refractive examinations at 1 week, 1 month, and at 3 and 6 months.

## 5.1 STAR S4 IR™ Surgical Procedure



*Before proceeding, please refer to the laser preparation and shutdown procedures presented in the STAR S4 IR System Operator's Manual, Section 6.2, Turning System On and Off.*

*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. However, the fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms (including surgical instruments) is extremely low for 193 nm radiation.*

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

*The Professional Use Information Manual is to be used in conjunction with the STAR S4 IR System Operator's Manual.*

### 5.1.1 Step-by-Step Procedure

1. Power ON the system.
2. Complete all daily calibrations, as described in the STAR S4 IR System Operator's Manual, Chapter 8, Calibrating the System.



*Ablate a spherical lens after every third ocular treatment to verify the calibration of the STAR S4 IR System. Refer to the Operator's Manual, Chapter 8, Calibrating the System, for additional information on the calibration procedure.*

3. Ensure that all persons in the operating room obey all safety regulations. Caution all attendees in the operating room against touching the laser, patient, or patient chair during the procedure. Movement of personnel in the operating room should be minimized during the procedure. It is recommended that all attendees, including the doctor, wear surgical masks and protective eyewear.
4. Test the microkeratome for suction, movement, and correct function. Insert a new blade into the microkeratome, if applicable.
5. Transfer the saved CustomVue™ treatment file from the WaveScan WaveFront® System to the STAR S4 IR™ Excimer Laser using the VISX supplied USB drive. The instructions for transferring the file appear in Chapter 12, CustomVue Treatments, in the STAR S4 IR Operator's Manual.
6. Follow the system software prompts. A CustomVue Treatment Card is required to perform the treatment.
7. Check the surgical parameters entered into the computer against the surgical plan and confirm that all interlocks are cleared. The accuracy of the entered data is the responsibility of the doctor. Center the mechanical position of the chair using the guide

- marks found on the chair base.
8. The patient may be given a systemic medication (e.g., analgesic or sedative) at the physician's discretion before the procedure.
  9. Instruct the patient to remove earrings prior to using the vacuum pillow. Adjust the patient's head and vacuum pillow for comfort, angle, alignment, and stability. Connect the vacuum pillow suction tubing to the suction port located on the patient chair headrest. Make sure the patient's globe is in primary position and not in an upward or downward gaze. While keeping the patient properly aligned, conform the pillow shape to the patient's head, creating support under the occiput of the skull. This is more effective than creating lateral support for the head.
  10. Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.
  11. Position the patient so the lateral canthus aligns to the mark on the headrest.
  12. Place the vacuum pillow under the patient's head with the bottom portion of the "U" supporting the patient's neck. Assure that there is no head tilt or rotation present. This is accomplished by assuring that a line from the vertex of the chin through the nasion is parallel to the operating table. Holding the pillow support against the occiput, power ON the suction pump switch, which is between the two (2) tilt knobs on the headrest. After several seconds, the pillow will harden and conform to the patient's head. This creates a comfortable, stable platform for the patient. Disconnect the tubing after the pillow has hardened.
  13. If desired, apply topical ophthalmic antibiotic agent to the operative eye.
  14. Instill topical ophthalmic anesthetic to the operative eye.
  15. Perform a lid scrub with a topical surgical disinfectant.
  16. Cover the untreated eye with an opaque shield that protects the eye and occludes vision. A post-operative surgical shield covered with electrical tape is suitable for this purpose.
  17. Instruct the patient to keep both eyes opened during the surgical procedure.
  18. Allow the patient the opportunity to become familiar with the sounds of the laser during the calibration procedure.
  19. Monitor patient clearance while rotating the patient chair to the treatment position, then lock the patient chair in place by pressing the foot pedal in the locked position. The chair must be fully rotated and the foot pedal locked for the laser to operate. Correct positioning is confirmed by the green status bar on the computer screen, which allows the procedure to continue.



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

20. Place a lid speculum into position.
21. Continually encourage the patient to maintain fixation on the fixation light throughout the procedure.
22. Position the patient with the microscope set at low zoom magnification. When the cornea is visible in the microscope, focus the image of the cornea and increase the magnification. Refer to the Operator's Manual, Section 6.9, Focusing Instructions for the STAR S4 IR™ System Microscope. Instruct the patient to begin fixating on the fixation light.
23. Move the patient so the microscope reticle is centered over the patient's pupil. Chair movement is controlled by the doctor's keypad. Refer to the Operator's Manual, Section

6.4, Preparing Chair for Patient, for information regarding chair movement.



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

24. Verify that all color status bars are green in the procedure screen of the system software. If a yellow status bar is displayed, you may continue with the procedure; however, a condition exists that warrants attention as soon as possible after completion of treatment. A red status bar will prevent system operation. Therefore, any interlock must be cleared prior to a treatment.
25. After verification of green system status bars, warn all attendees to stand clear of the laser, patient, and patient chair. Accidental bumping of the laser, patient, or patient chair during the surgery can cause decentering of the treatment area. Movement in the operating room must be kept to a minimum during patient treatment.
26. Place the suction ring on the eye with a slight nasal displacement and apply suction. Perform tonometry to assure adequate suction. Place balanced saline solution (BSS) on the cornea and cut a flap with the microkeratome. Release the suction.
27. Using a forcep, displace the flap. Gently wipe the exposed corneal surface with an ophthalmic surgical sponge to ensure that the surgical area is free of epithelium and other debris. Remove fluid from the fornices with an ophthalmic surgical sponge.
28. Align the operative eye so that the reticle is centered on the entrance pupil while the patient views the fixation light. Again, verify that the patient's globe is in primary position and not in an upward or downward gaze. If the patient is unable to maintain fixation to the surgeon's satisfaction a fixation handpiece may be used to hold the eye.



***WARNING! Do not use a Chayet LASIK drain or similar device that obscures the limbus during the surgery.***

29. Adjust and maintain the focus on the anterior corneal surface.
30. Activate ActiveTrak (see section 5.1.3) and the Iris Registration system (see section 5.1.2).
31. After ensuring that the reticle is centered over the patient's pupil and the patient is viewing the fixation light, fully depress the foot pedal to perform the laser treatment. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration. If necessary, stop the laser every 20 seconds and dry the cornea.



Keep the patient relaxed by explaining the process as you go along. Use the oblique halogen illumination at its lowest intensity during laser ablation.



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



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

32. Instill antibiotics on the corneal bed and the flap, and replace the flap into position. Irrigate underneath the flap and on top with BSS. Using a wet ophthalmic surgical sponge, gently stroke the flap into its original position. If necessary, use a dry ophthalmic surgical sponge to remove any excess moisture from the incision. Use pressure at the limbus to assure that the flap is re-adhered.
33. Move the patient away from the laser and apply topical ophthalmic medications to the cornea.
34. Print the laser treatment information.
35. Record the flap thickness, flap diameter, hinge diameter, hinge location, and environmental conditions (temperature and humidity).
36. If planned, and the first eye is without surgical complication, repeat this procedure on the fellow eye. Make sure the first eye is well occluded to avoid cross-fixation.
37. When the LASIK surgery is complete, remove the speculum and allow the patient to close the eye which has just undergone the laser surgery. Power OFF the microscope light and relieve the vacuum in the patient pillow.
38. Lower the patient chair to its lowest position, then rotate the patient chair from under the laser while carefully monitoring patient clearance. Remove the eye shield from the untreated eye.
39. Place appropriate post-operative medications in the treated eye. Following application of medication, apply a firm pressure patch to the eye.
40. Raise the chair backrest to a sitting position. Assist the patient to a waiting area.
41. Ensure that the patient is given post-operative instructions. An analgesic may be given to the patient prior to leaving the facility.
42. Review post-operative instructions, confirm the first follow-up appointment, and discharge the patient when stable.
43. Clean the debris removal nozzle with isopropyl alcohol wipes and prepare the system for the next patient.



**WARNING!** Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol, except for wiping down the debris removal nozzle with isopropyl alcohol. Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.



**WARNING!** Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol, except for wiping down the debris removal nozzle with isopropyl alcohol. Warn the patient about the hazards of driving immediately after surgery. The combination of analgesic and eye patch can be very dangerous.

### 5.1.2 Using the Iris Registration System

The iris registration system is used to align the laser treatment as measured and calculated by the WaveScan® System to the axis of the patient's eye under the laser. It is used in conjunction with the ActiveTrak® eye tracking system. The ActiveTrak System must be on and tracking to perform the iris registration. In addition, the iris registration system verifies that the WaveScan image selected for treatment is correct.

The image of the patient's eye taken on the WaveScan System during the measurement process is transferred to the STAR S4 IR™ System along with the CustomVue™ treatment file via a USB flash drive. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the WaveScan image to the same features located on the image of the iris taken by the STAR ST IR camera. The treatment is rotated by algorithms in the STAR S4 IR System to align precisely with the current rotation of the patient's eye under the laser.



*The iris registration system is only available for CustomVue treatments.*



*LASIK flap hinge location must be entered on the Operating Parameters screen for each CustomVue treatment when using the iris registration system.*

To activate the iris registration system:

1. Transfer the WaveScan treatment file using a USB flash drive. The floppy drive cannot be used with the iris registration system. All files are saved automatically to the USB flash drive when saving a STAR treatment on the WaveScan System.
2. Prepare the patient for the surgery. Center the patient's eye under the laser and focus on the corneal surface.
3. If the ActiveTrak<sup>®</sup> System and the iris registration system are not already on, turn them on by pressing the Track button and the Rotation (Rot) button on the Doctor's Keypad. The ActiveTrak System must be on to perform iris registration. If the iris registration is turned on first, iris registration will automatically start once the ActiveTrak System is turned on and the pupil is found. The iris registration system can be left on allowing the user to enable or disable both systems using the Track button alone. Iris registration can be re-initiated at any time during the treatment by turning iris registration off and back on using the Rotation (Rot) button.
4. A dialog box will appear on the computer screen with the message "**Iris Registration started, please wait... Capturing STAR S4 IR™ Image... Verifying STAR S4 IR™ Image...Performing Iris Registration Calculations...**"
5. The captured eye image will appear with the markers showing the degree of cyclotorsion between the WaveScan measurement and the STAR S4 IR measurement. The dialog box message changes to "**WaveScan Image: VERIFIED.**" The degree of rotation, the pupil diameter measurement, and the adjustment to the position of the treatment center will be shown.
6. These measurements are used to rotate the angle of the CustomVue™ treatment to precisely align the treatment to the current position of the eye.
7. The dialog box will add the message "**Treatment Registered to WaveScan References.** Press footswitch to start treatment."
8. Fully depress the laser footswitch to begin the treatment. This will automatically restore live microscope camera image.



**WARNING!** It may not be possible to capture ALL irides for iris registration. Should iris registration fail to capture at first attempt, users are encouraged to alter the ambient illumination (ring, oblique, and/or room) to allow more iris features to be available for capture. Should all attempts fail at registration, users are encouraged to align the cornea using limbal landmarks noted at the slit lamp prior to the surgical procedure.

### 5.1.3 Using the ActiveTrak® System

The ActiveTrak System allows the laser beam to follow the patient's eye movements during the surgery and enables the surgeon to select the treatment center of the ablation. The ActiveTrak System tracks the movement of the eye during the ablation. In addition, it has the capability of stopping the laser much faster than the surgeon can. The ActiveTrak System uses two infrared cameras to follow x and y motion. The ActiveTrak System also checks the vertical height (z axis) of the cornea relative to the initial treatment position from which the ActiveTrak System begins tracking.

The surgeon-selected treatment center must be within 0.5 mm of the center of the patient's natural pupil as determined by the tracking system. Do not use the ActiveTrak System if you intend to center the laser treatment more than 0.5 mm from the center of the pupil.

It is important to remember that the use of an eye tracking system does not replace a conscientious surgeon. The ActiveTrak System does not in any way automate the surgery, but rather is a useful accessory to the surgical procedure. Surgeons are reminded that an informed patient who is well instructed in the importance of good fixation on the Patient Fixation LED provides excellent treatment centration without an eye tracking system.

Surgeons are reminded that they should instruct the patient to fixate on the Patient Fixation LED during surgery with or without the use of the ActiveTrak System.



***WARNING! Do not use pharmacological dilating or constricting agents immediately before surgery with the ActiveTrak System. It is not necessary to pharmacologically dilate or constrict the pupil. The tracking system's working range is from a minimum pupil diameter of 1.5 mm to a maximum pupil diameter of 6.0 mm.***

Treatment will stop or pause when the ActiveTrak® System detects the following conditions:

- The patient's eye moves more than 1.5 mm from the surgeon-selected treatment center (the initial position from which the ActiveTrak System begins tracking).
- The vertical position (z axis) of the corneal surface moves more than 2.0 mm from the initial treatment position.
- The pupil diameter is not circular to within 32% or becomes smaller than 1.5 mm or larger than 6.0 mm during treatment.
- Eye motion exceeds 0.2 mm between video frames.
- Dark objects or reflective objects are in the ActiveTrak System's field of view.
- Surgical instruments or the surgeon's hands cross the ActiveTrak System's field of view.

If the treatment stops or pauses for more than a few seconds, turn off the ActiveTrak<sup>®</sup> System and treat as you normally would without the ActiveTrak System, or re-engage the ActiveTrak System.

The surgeon can choose to set the treatment center manually or use the automatic centering mode in which the treatment center is set by the ActiveTrak System. Auto centering is the default mode. The surgeon may choose manual centering on the Ablation Status screen before each treatment.

To use the ActiveTrak System:

1. Using the joystick, position the patient so that the patient's head is properly aligned under the laser and the corneal surface is properly focused (see Section 6.9 in the STAR S4 IR<sup>™</sup> Operator's Manual).
2. Ensure that the patient's pupil is centered in the reticle as the patient is fixating on the Patient Fixation LED. Instruct the patient to fixate on the Patient Fixation LED during the surgery.



***If you see shadows on the iris or pupil, reposition the patient's head to eliminate these shadows. Make sure the patient's globe is in primary position and not in an upward or downward gaze. Ensure that the patient's head is centered and is not tilted to either side. If shadows are still present, tilt the patient's chin down towards his or her chest or gently depress the lid speculum.***

3. Turn on the ActiveTrak System by pressing the **Track** button on the Doctor's Keypad. When the ActiveTrak System is turned on, the outside ring and the center cross of the reticle will flash.
  - If you are using automatic centering, recenter the pupil and refocus so that the corneal surface and the reticle are in sharp focus. The ActiveTrak System will then locate the pupil and set the treatment center. Once the pupil is located, the outside ring on the reticle will stop flashing and the treatment center will automatically be set to the center of the pupil.
  - If you are setting the treatment center manually, recenter the pupil and refocus so that the corneal surface and the reticle are in sharp focus before pressing the laser footswitch to the first position to set the treatment center.
4. Once the treatment center is set, the center cross of the reticle stops flashing. (The ActiveTrak System will maintain this position throughout the treatment.)



***WARNING! The reticle must be centered to within 0.5 mm of the center of the pupil.***

***Do not place any dark objects or reflective objects that potentially could appear dark in the camera's field of view when turning on the ActiveTrak System. The introduction of any object will make the location of the pupil center unavailable.***

5. Fully depress the laser footswitch to begin the treatment.
6. The center cross of the reticle will flash slowly during the treatment when the ActiveTrak System is on and tracking the pupil.
7. If the ActiveTrak System loses track of the pupil or detects an artifact, the center cross of the reticle will flash quickly and the laser status bar displays **Pupil Tracking Lost**. Treatment will stop.



***Treatment will stop if objects such as surgical instruments or the surgeon's hands cross the camera's field of view.***

8. To continue the treatment, recenter the pupil and refocus so that the corneal surface and the reticle are in sharp focus before fully depressing the laser footswitch.



***When the ActiveTrak System is activated, you may use the joystick to correct for head (translational) motion during the treatment. Do NOT use the joystick to correct for eye rotation when the ActiveTrak System is activated.***

# **Facts You Need to Know About CustomVue™ Monovision Laser Assisted In-Situ Keratomileusis (LASIK) Laser Treatment**

## **Patient Information Booklet**

**For Monovision Treatment of Presbyopic Patients with Low to Moderate Nearsightedness (Myopia) with and without Astigmatism**

**Please read this entire booklet. Discuss what it says with your doctor. Make sure your doctor answers all your questions to your satisfaction. Ask all questions you may have before you agree to the surgery.**

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## 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. They may be a corticosteroid, or a non-steroidal 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 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.

**Corneal Haze:** a cloudiness of the cornea that occurs 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.

**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 blisters to appear on the face or other parts of the body.

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

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

**Intraocular Pressure (IOP):** fluid pressure inside the eye.

**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. A microkeratome (an automated cutting instrument) creates a flap. An excimer laser reshapes the cornea underneath the flap. The doctor replaces the flap on the corneal bed.

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

**Microkeratome:** an automated surgical tool that cuts a flap of tissue from the front surface of the cornea with a blade or laser.

**Monovision:** a clinical technique for visually correcting presbyopia by treating one eye for viewing close up and one eye for viewing far away.

**Myopia:** a refractive error in which the eye focus light rays from distant objects in front of the retina. This causes images of distant objects to appear blurry. Nearsightedness is another term for myopia.

**Nearsightedness:** another term for myopia.

**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.

**Presbyopia:** is the normal age-related loss of ability to focus on near objects.

**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. The eye does not bring light rays 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. It 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 reveal differences in the paths of light rays as the eye bends them.

**WavePrint<sup>®</sup>** : a color map that displays wavefront errors measured by the VISX WaveScan WaveFront<sup>®</sup> System.

**WaveScan<sup>®</sup>** : the VISX WaveScan WaveFront System is a diagnostic instrument that objectively measures the refractive errors of the eye.

# INTRODUCTION

CustomVue™ Monovision LASIK (laser assisted *in situ* keratomileusis) may help nearsighted patients with *presbyopia* see well close-up and far away. Presbyopia is the gradual loss of the eye's ability to focus close-up, such as for reading. Presbyopia gets worse with age. *Monovision* is a method of visual correction used in people with presbyopia. The goal of monovision is for you to use one eye (your dominant eye) for seeing far away and one eye (your non-dominant eye) for seeing close up. Most people are able to ignore the image from the eye that is not in clear focus when both eyes are working together.

Having nearsightedness in one eye may enable you to see up close. You may already have an ideal amount of nearsightedness to see close up. You may only need treatment in your other eye for seeing far away. If you have one or both eyes treated, the result is monovision if the dominant eye sees at distance and the non-dominant eye sees close up.

Your doctor and VISX, Incorporated provide the information in this booklet to help you decide if you should have a CustomVue™ Monovision LASIK treatment to reduce your need for glasses or contact lenses. There are other ways to correct both your distance and near vision. You can wear bifocal glasses or multi-focal contact lenses. You can wear contact lenses of different strengths in each eye to have monovision. There are other surgical options. Traditional CustomVue™ LASIK can correct both eyes for seeing far away and you can wear reading glasses when needed. RK (radial keratotomy) and ALK (automated lamellar keratectomy) are also available.

Since monovision corrects one eye for seeing far and the other eye for seeing close up, the two eyes may not work together as well as they did before. This might be noticed more in dim light or when

performing tasks requiring very sharp vision. You may still need to wear glasses or contact lenses to correct both eyes for distance when driving at night or operating dangerous equipment. You may still need to wear glasses or contact lenses to correct both eyes for near when reading small print.

Some patients cannot get used to having one eye blurred at all times. **If you are considering CustomVue™ Monovision LASIK, find out if you can tolerate monovision by wearing monovision contact lenses before having the surgery performed on your eyes.** Find out if you can pass your state's driver's license requirements with monovision.

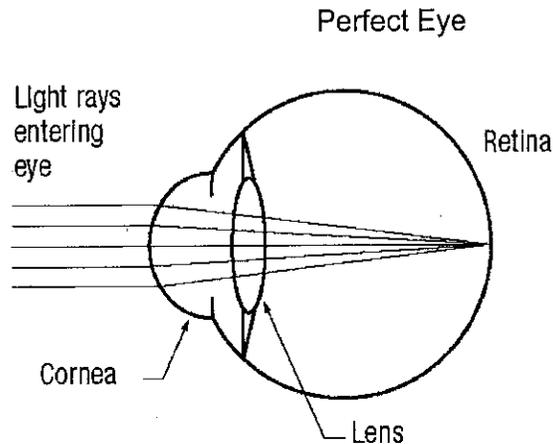
Consider how much your doctor expects your presbyopia to increase in the future. Ask your doctor when glasses may be required to see close up objects clearly.

Please read this booklet completely. Ask your doctor any questions before you decide if CustomVue™ Monovision LASIK is right for you. Only an eye care professional trained in laser vision correction can decide if you are a good candidate. Some people, such as pilots, have job-related vision requirements and cannot have Monovision LASIK.

If after Monovision LASIK you have problems getting used to your vision, you may wish to have your eyes treated again to remove the unequal vision. Discuss the risks of a second treatment with your doctor.

## How Refractive (Wavefront) Errors Affect Your Vision

The eye works like a camera that focuses images onto film. The cornea and lens of the eye bend light rays to focus on the retina at the back of the eye.



**Figure 1: A diagram showing how the eye focuses light rays to create a sharp image on the retina.**

Figure 1 shows a perfect eye with no focusing errors. All of the rays of light going through the eye focus to a single point on the retina.

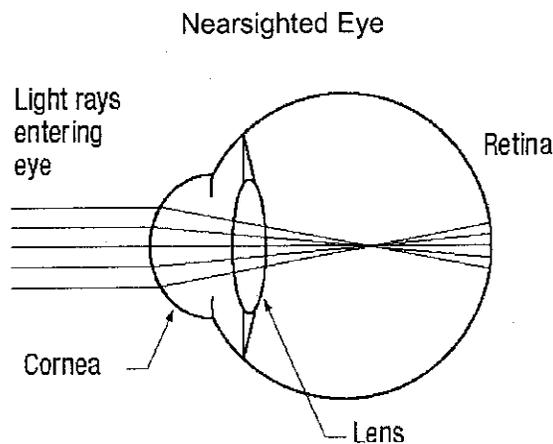
Actually, all eyes have some focusing imperfections. One way to measure them is to measure the *wavefront* of the eye. The VISX WaveScan WaveFront<sup>®</sup> System is a tool to measure the wavefront of an eye. The WaveScan<sup>®</sup> System measures the wavefront errors using a camera sensor.

The wavefront of a perfect eye is uniform because all of the light rays travel evenly through the eye. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others. Some rays strike different locations on the retina than others. Wavefront errors include both simple and

complex errors. Lenses can correct the simple wavefront errors, which are called *refractive errors*. Refractive errors include *myopia* and *astigmatism*.

Myopia (nearsightedness) usually starts in childhood and can get worse through your teens. It usually stops changing by your late teens. Sometimes it continues to get worse into your mid-twenties.

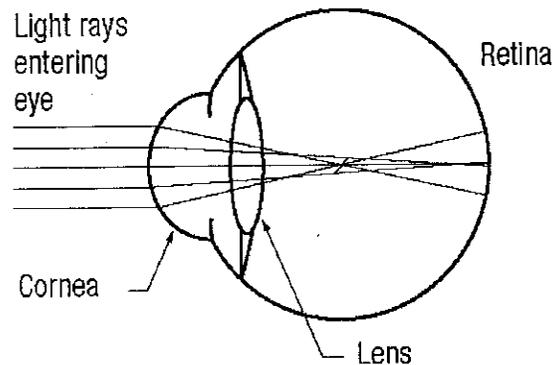
As shown in Figure 2, nearsighted eyes bend light too much, so that light rays focus to a single spot in front of the retina. Things that are far away look blurry because the rays spread apart instead of focus sharply when they strike the retina.



**Figure 2: A diagram of a nearsighted eye showing the light rays focusing in front of the retina.**

As shown in Figure 3, astigmatism causes the rays of light entering through different parts of the eye to focus unequally on the retina. Some rays may focus on the retina but other rays focus in front of it. Things look blurry because images never focus clearly on the retina.

### Nearsighted and Astigmatic Eye



**Figure 3: A diagram of an eye with astigmatism showing light rays that do not ever come to a focus at one point.**

The CustomVue™ treatment is “custom” because it includes information from the WaveScan® System that is more individualized than what a doctor uses to program a non-custom treatment. The doctor uses information from the WaveScan® System, as well as other measurements of how you see, to design your CustomVue™ Monovision LASIK treatment.

## How Presbyopia Affects Your Vision

Presbyopia is a part of the normal aging process. It causes you to have trouble focusing while reading up close. Presbyopia begins around age 40 and gets worse as you get older. This normal aging change happens to all people in different amounts. The CustomVue™ Monovision LASIK treatment does not cure presbyopia. It adjusts one eye to see well close up and the other eye to see well far away.

## **The VISX WaveScan WaveFront® System**

Before the doctor can program the laser for your CustomVue™ Monovision LASIK treatment, the WaveScan® System must measure your eyes. The WaveScan® System is a small device that measures your eyes with special cameras. You will sit in front of the WaveScan® System and look into it at a light while it scans your eye. Your doctor will use the best measurement for the CustomVue™ Monovision LASIK treatment. Your doctor will also take other measurements of your vision to help design your treatment.

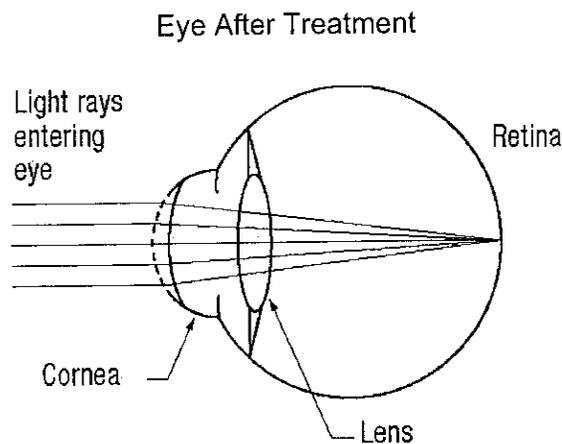
## **The VISX STAR S4 IR™ Excimer Laser**

The laser produces a beam of invisible light. The doctor enters your information into a computer program that controls the laser. The laser creates a series of rapid pulses that remove precise amounts of your cornea. Excimer laser light does not penetrate into the eye. It leaves other eye structures (iris, lens, and retina) untouched. Advanced camera systems on the laser properly align the treatment on the eye using iris features as a guide. An eye tracking system compensates for many of your eye movements during the treatment.

## **How the CustomVue™ Monovision LASIK Procedure Works**

LASIK is a type of laser surgery that corrects refractive errors of the eye. They include nearsightedness and astigmatism. Before starting the laser, the doctor makes a flap on your eye using a *microkeratome*. A microkeratome is a tool with a blade or a laser. It cuts a small flap from the surface of the eye. The doctor lifts the flap and folds it out of the way of the laser. After the laser finishes, the doctor puts the flap back in place.

As shown in Figure 4, the laser changes your vision by changing the shape of the cornea. To correct nearsightedness the laser removes more from the center of the cornea. When there is astigmatism, the laser sculpts the eye vertically or horizontally. The doctor creates a unique treatment plan from the WaveScan<sup>®</sup> System to guide the laser. The laser removes tissue from the eye according to the treatment plan.



**Figure 4: A diagram of an eye after treatment showing where tissue is removed.**

## **Important Things to Consider Regarding Monovision**

- Monovision may not be appropriate for individuals with unrealistic expectations. Patients who expect perfect results, perfect vision under all light conditions, or an instant improvement in vision may be poor candidates for CustomVue<sup>™</sup> Monovision LASIK. As with any refractive procedure, CustomVue<sup>™</sup> does not guarantee perfect results. Your vision may not be perfect and you may need to wear glasses or contact lenses after the procedure.

- You should be aware that as with any type of vision correction there are advantages and compromises associated with monovision correction. The benefit of the improved near vision provided by monovision may be accompanied by compromised visual acuity and depth perception for distance and near tasks. Symptoms such as mild blurred vision, dizziness, headaches and a feeling of slight imbalance may be experienced. The ability to adapt to these symptoms should be determined during a monovision contact lens trial period.
- You should successfully complete a monovision trial using glasses or contact lenses. It is important that you follow your doctor's suggestions for adaptation to monovision during this trial period. You should discuss any concerns that you may have during the adaptation period. It is in your best interest to assure that you are comfortable with the visual result of this monovision trial.
- The goal of the CustomVue™ Monovision LASIK procedure for monovision is to improve your ability to see objects up close. Because you will have improved near vision in one eye and distance vision in the other, it is important to avoid too large of differences between your eyes, since this can result in symptoms such as reduced depth perception, blurred distance vision, and difficulties with night vision. Your doctor will limit the amount of effect you obtain with regard to near vision, to avoid inducing a large difference in refraction between your two eyes, and the associated visual symptoms.
- Some monovision patients require supplemental glasses to provide the clearest vision for important tasks and activities:
  - **You may not be comfortable functioning under low levels of light, such as driving at night. You**

**may want to discuss with your doctor having corrective lenses prescribed so that both eyes are corrected for distance when sharp binocular distance vision (vision using both eyes for distance) is required.**

- If you require very sharp near vision (visual acuity and depth perception, or good binocular vision) during prolonged close work, you may want to have additional corrective lenses prescribed so that both eyes are corrected for near when sharp binocular near vision is required.
- Occupational and environmental visual demands should be considered. If you require very sharp near vision it must be determined during the monovision contact lens trial whether you can function adequately with the monovision created by CustomVue™ Monovision LASIK. Monovision may not be optimal for activities such as:
  - **Visually demanding situations such as operating potentially dangerous machinery (ie. fork-lift, crane) or performing other potentially hazardous activities (piloting aircraft).**
  - **Driving automobiles (e.g. driving at night). If you cannot pass your state driver's license requirements with monovision correction, you may require that additional over-correction (glasses) be prescribed.**
- Your vision may continue to change over time. Your ability to read is a combination of your eye's current focusing ability and the power (add) used in your reading glasses. As you get older, your focusing abilities diminish, requiring stronger reading glasses to compensate. Therefore after the

CustomVue™ treatment, as you continue to age and your focusing abilities diminish, your near vision may change over time with eventual need for glasses or contact lens correction.

- Your presbyopia will increase over time.
- If your results with CustomVue™ are not satisfactory and you desire a second procedure, it is unknown at this time whether retreatment procedures with CustomVue™ or other refractive procedures will be successful.
- Your vision may not be perfect and you may need to wear glasses or contact lenses for some activities even after having the CustomVue™ procedure.
- All patients do not function equally well with monovision correction. You may not perform as well for certain tasks with this correction as you may have with bifocal reading glasses. Monovision correction, as well as presbyopic contact lenses or other alternatives can create a vision compromise that may reduce visual acuity and depth perception for distance and near tasks.
- The goal of CustomVue™ for monovision is to improve your ability to see objects up close and it is likely to result in a significant reduction in distance vision in the eye treated for near.
- The decision to undergo CustomVue™ for monovision is most appropriately left to you in conjunction with your doctor after carefully considering your vision needs.

## BENEFITS

CustomVue™ Monovision LASIK treatment of presbyopic patients with low to moderate nearsightedness can correct up to -6 diopters (D) of nearsightedness. It can also correct up to -3 diopters of astigmatism. CustomVue™ Monovision LASIK treatment may help you to see clearly both far away and close up without glasses or contact lenses.

## RISKS

As with any surgery, CustomVue™ Monovision LASIK has risks. It is important to discuss the risks with your doctor before you decide to have surgery. If the results of the surgery are not satisfactory, you may need to have another laser treatment. Usually, your doctor will perform CustomVue™ Monovision LASIK on both eyes. Sometimes it is better to have this treatment on one eye. Ask your doctor if it would be better to treat one or both of your eyes.

The primary risks of LASIK are related to making the corneal flap. Corneal flap complications include but are not limited to:

- Cutting an incomplete, irregular flap or free flap.
- Misalignment of the flap.
- Perforation of the cornea.
- Inflammation of the cornea under the flap.
- Corneal surface cell growth under the flap.

Corneal flap complications range in severity. Some require the treatment to be postponed for several months. Others can create corneal irregularities causing permanently blurred vision.

Other risks of LASIK include:

- Eye movement during treatment. Even though the STAR S4 IR™ System has an eye tracker, you will be asked to look at a blinking light while the laser is running. It is important to stare at the light for the entire laser procedure. The treatment may not be positioned correctly on your eye if your eye moved too much during treatment. This may result in blurry vision after LASIK.
- Inaccurate WavePrint® measurement. If your contact lenses were worn too close to the exam time for the doctor to obtain a stable measurement, your WavePrint® measurement may be inaccurate. This may result in poor vision after LASIK.
- Some patients had the following adverse events and complications during clinical studies:
  - Dry eyes.
  - Blurry vision.
  - Fluctuation of vision.
  - Increase of pressure in the eye.
  - Ghost or double images.
  - Night vision difficulties.
  - Halos around lights.

**WARNING:**

**Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities, such as driving at night or reading small type, after monovision 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. These conditions may cause temporary and unpredictable changes in your cornea. LASIK treatment may improperly change the shape of your cornea.
- You have collagen vascular disease (e.g., rheumatoid arthritis). You have autoimmune disease (e.g., lupus). You have immunodeficiency diseases (e.g., AIDS). These conditions affect the body's ability to heal.
- You show signs of keratoconus (cone-shaped cornea) or another condition that causes a thinning of your cornea. These conditions can lead to serious corneal problems during and after LASIK surgery. They may result in need for additional surgery. They may result in poor vision after LASIK.
- You are taking medications with ocular side effects. Examples are Isotretinoin (Accutane<sup>®1</sup>) for acne treatment or Amiodarone

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<sup>1</sup> Accutane<sup>®</sup> is a registered trademark of Hoffmann-La Roche, Inc.

hydrochloride (Cordarone<sup>®2</sup>) for normalizing heart rhythm. 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.

- Corneas are thin. Your corneas may be too thin to allow your doctor to cut a proper flap in the LASIK procedure. You cannot have LASIK because it is necessary to have a flap.

## WARNINGS

If you have any of the following conditions, discuss the seriousness of your condition with your doctor.

- 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 ever had *Herpes simplex* or a *Herpes zoster* in your eyes, LASIK may be more risky for you because you may have problems healing.
- 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. Dryness may 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. You may have problems healing.

Additional warnings you need to consider:

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<sup>2</sup> Cordarone<sup>®</sup> is a registered trademark of Sanofi-Synthelabo, Inc.

- Eye movement during treatment. Even though the STAR S4 IR™ System has an eye tracker, you will be asked to look at a blinking light while the laser is running. It is important to stare at the light for the entire laser procedure. The treatment may not be positioned correctly on your eye if your eye moved too much during treatment. This may result in blurry vision after LASIK.
- Inaccurate WavePrint® measurement. If your contact lenses were worn too close to the exam time for the doctor to obtain a stable measurement, your WavePrint® measurement may be inaccurate. This may result in poor vision after LASIK.

## PRECAUTIONS

It is not known if LASIK is safe and effective for the following conditions. You should discuss these conditions with your doctor:

- No prior experience of monovision. You should first try out monovision with contact lenses to see if you like having unequal vision. In the clinical trial for CustomVue™ Monovision LASIK, about 20% of patients who tried monovision using contact lenses decided not to have monovision LASIK treatment.
- Unstable vision that has changed more than 0.5 diopters in nearsightedness or astigmatism in the last 12 months. Your nearsightedness 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.
- Corneal disease or abnormality. This includes scars and infections of the eye. If you have an abnormal cornea it may affect the accuracy of the LASIK treatment. It may affect the way your cornea heals after LASIK. This may result in poor vision after LASIK. If your eyes have an active disease, it is not known if LASIK is safe and effective for your condition.
- History of injury or surgery to the center of the cornea (for example, surgery to correct vision such as RK, PRK, LASIK). Other surgery on your eye. If your eyes are injured or you have had surgery, it is not known if LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- Large pupils. Before surgery, your doctor should measure your pupil size under dim lighting conditions. Your doctor can check if you are over-focusing in your WaveScan® System measurements by comparing pupil size.

- History of glaucoma or have had eye pressure greater than 21 mmHg. It is not known if LASIK is safe and effective for you.
- Take medicines that might make it harder for wounds to heal, such as Sumatriptan (Imitrex<sup>®3</sup>) used for migraine headaches. It is not known if LASIK is safe and effective for this condition.
- Any other medications you are taking. Tell your doctor if you taking any medicines including ones you bought without a prescription. Your doctor will know if the medicine may interfere with healing or may contribute to poor vision after surgery.
- Younger than 40 years of age or over 65 years of age. It is not known if Monovision LASIK is safe and effective for you.
- Nearsightedness is worse than 6 diopters or astigmatism is worse than 3 diopters. It is not known if LASIK is safe and effective for you.
- For retreatment with this laser for LASIK. It is not known if LASIK is safe and effective for repeating the LASIK procedure on the same eye.
- 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. Dry eyes may cause some fluctuation in your vision.
- You might have difficulty seeing in dim lighting, rain, snow, fog, or bright glare. It is hard to predict if you will have poor vision under these conditions because it has been studied so little.
- It is not known if LASIK is safe and effective for periods longer

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<sup>3</sup> Imitrex<sup>®</sup> is a registered trademark of GlaxoSmithKline.

than 1 year.

## **ARE YOU A GOOD CANDIDATE FOR CUSTOMVUE™ MONOVISION LASIK?**

If you are considering CustomVue™ Monovision LASIK, you must:

- Be at least 40 years of age (with presbyopia) and have nearsightedness with or without astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality such as scars and infections.
- Have evidence that your vision prescription did not change by more than 0.50 diopters during the year before your treatment.
- Be informed of LASIK risks and benefits as compared to other available treatments for nearsightedness with or without astigmatism.
- Be able to tolerate monovision. VISX recommends that you undergo a monovision trial period of wearing contact lenses to see if you can tolerate Monovision LASIK.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign the informed consent form provided by your doctor.
- Be able to fix your gaze on the blinking light for the entire laser procedure.

# WHAT TO EXPECT

## Before Surgery

If you are interested in having LASIK, you will need to have a pre-operative exam to determine if your eye is healthy and suitable for surgery. This will include a complete medical and eye history. It will include a careful exam of both eyes, including WavePrint® scans and automated mapping of your eyes.

Ask your doctor about undergoing a trial period wearing monovision contact lenses. You will find out if you can tolerate Monovision LASIK. Some patients cannot get used to having one eye blurred at all times.

### **WARNING:**

**If you wear contact lenses, it is very important to stop wearing them 2 to 4 weeks before your pre-surgical exam and treatment for the doctor to obtain a stable eye measurement. Failure to do this might result in poor vision after LASIK.**

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, ask your doctor about eating or drinking immediately before surgery. You should also plan a ride home from your doctor's office. You must not drive immediately after the surgery. You may start driving again when you receive permission from your doctor.

## The Day of Surgery

Before the surgery, the doctor places local anesthetic (numbing) drops into the eye to be treated and escorts you into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will hold your eyelids open during the surgery.

There will also be a temporary shield covering the eye not having surgery. Listen to the sounds that the laser makes to prepare you for 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 (a surgical tool) creates a thin flap of tissue. The doctor will lift this flap of tissue after the suction releases. Vision will return to the eye after the suction releases, but it may be blurry.

The doctor will then reposition your head in the chair and refocus the microscope. You will need 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. The VISX STAR S4 IR™ Excimer Laser system then quickly removes small amounts of your cornea.

### **PRECAUTION:**

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

Usually the laser will pulse for less than 1 minute and, overall, the surgery may last about 10 minutes. The doctor may place some eye drops on your eye when the laser pulses are finished. The surgery is painless because of the numbing drop. When the numbness wears 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 until your doctor tells you it is safe.

## **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.

## **The First Week Following Surgery**

- Moderate pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing may occur as the cornea heals.
- You may be sensitive to bright lights.

During the early stages, especially during the first week, your eyesight may not have fully adjusted to new changes, and may not be able to demonstrate the full effectiveness of monovision. It may take several weeks for your eyes to adjust.

You may want to avoid or decrease your participation in visually demanding situations such as driving, until you have adjusted to your monovision and the potential change in your depth perception.

## **The First Two to Six Months Following Surgery**

- Your vision may change during this period. You may also have some eye dryness. Your doctor may prescribe eye drops to help resolve your dry eyes. Use the drops as prescribed.

## **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? If so, for how long?
- What are the benefits of CustomVue™ Monovision LASIK for my amount of refractive error?
- What vision can I expect in the first few months after surgery?
- If CustomVue™ Monovision 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 will CustomVue™ Monovision LASIK affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having LASIK?
- What if I can't get used to monovision?
- When can I have surgery on my other eye?

Discuss the cost of surgery and follow-up care requirements with your doctor. Most health insurance policies do not cover CustomVue™ Monovision LASIK.

## 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.

Find answers to SELF-TEST on page 31.

1. CustomVue™ LASIK surgery is risk free.	TRUE / FALSE
2. It doesn't matter if I wear my contact lenses when my doctor told me not to.	TRUE / FALSE
3. The laser does all the work; I just have to lie on the chair.	TRUE / FALSE
4. After the surgery, there is a good chance that I will be less dependent on eyeglasses.	TRUE / FALSE
5. I may need glasses after laser surgery.	TRUE / FALSE
6. There is a risk that I may lose some vision after CustomVue™ LASIK surgery.	TRUE / FALSE
7. It doesn't matter if I am pregnant.	TRUE / FALSE
8. If I have an autoimmune disease, I am still a good candidate for laser vision correction.	TRUE / FALSE

## SUMMARY OF IMPORTANT INFORMATION

- CustomVue™ Monovision LASIK is a permanent operation to the cornea and may be irreversible.
- CustomVue™ Monovision LASIK may not eliminate the need for reading glasses.
- Your vision must be stable for at least one year before CustomVue™ Monovision LASIK. You will need written evidence that your nearsightedness with or without astigmatism has changed less than 0.50 diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- CustomVue™ Monovision 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™ Monovision LASIK include, but are not limited to, glasses, contact lenses, RK, and ALK.
- CustomVue™ Monovision LASIK cannot meet the job-related vision requirements for some people such as pilots.
- VISX recommends a trial period of wearing monovision contact lenses to see if you can tolerate Monovision LASIK.
- It may take several weeks for your eyes to adjust to monovision. You may want to avoid or decrease your participation in visually demanding situations such as driving until you have adjusted to your monovision.
- It is very important to stop wearing contact lenses before the pre-surgical eye exam.
- Before considering laser vision correction you should:
  - a. Have a complete eye exam.
  - 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 18)
2. False (see What to Expect Before Surgery on page 26)
3. False (see What to Expect The Day of Surgery on page 27)
4. True (see Benefits on page 18)
5. True (see Risks on page 18)
6. True (see Risks on page 18)
7. False (see Contraindications on page 20)
8. False (see Contraindications on page 20)

# CLINICAL STUDY TO EVALUATE BENEFITS

VISX conducted a clinical study to evaluate the benefits of CustomVue™ Monovision LASIK treatment. This study involved 320 eyes of 160 patients treated at seven U.S. centers. This study started in September 2004. The last patient in this study was treated in September 2005. The study results shown in this booklet include all the available reported outcomes on these patients through November 2006. Each table lists the numbers of eyes (N) for which data were available at the reported time point.

## Study Patient Demographics

The age of study patients ranged from 40 to 65 years. Table 1 lists the age, gender, race, eye dominance, and contact lens history of study patients.

**Table 1 — Demographics of 160 Study Patients**

<b>Gender</b>	Male	35%
	Female	65%
<b>Race</b>	Caucasian	82%
	African American	5%
	Native American/Alaskan Native	.1%
	Asian	4%
	Other (Hispanic)	8%
<b>Eye Dominance</b>	Right	71%
	Left	29%
<b>Age</b>	Average	50 years
	Range	40 – 65 years
<b>Contact Lens Wear</b>	None	22%
	Soft	72%
	Hard	6%

## Vision Without Glasses After Treatment

A letter chart tested the sharpness of vision at three different distances. The exam tested vision with both eyes open (binocular) and with each eye separately (monocular). The exam tested “near” vision 16 inches away. This is a typical distance for reading. The exam tested “intermediate” vision at a distance of two feet. This is a typical distance for viewing a computer screen. The exam tested “far” vision about 13 feet away. This is a common distance for viewing television in your home.

### Binocular Far and Near Vision

Binocular vision (both eyes open) was tested without glasses for either distance or near. Before treatment 3% of patients were able to see 20/40 or better for objects both close up and far away. Table 2 shows that 100% of patients were able to see 20/40 or better for both far and near. Eighty percent (80%) were able to see 20/20 or better at both distances six months after treatment.

**Table 2 — Binocular Far and Near Vision Without Glasses after Treatment**

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/20 or better	76%	80%	80%	86%	86%
20/25 or better	96%	94%	92%	95%	97%
20/32 or better	99%	98%	99%	99%	99%
20/40 or better	100%	99%	100%	99%	99%

## Binocular Far Vision

Table 3 shows that 100% of patients were able to see 20/40 or better far away. Approximately 87% were able to see 20/20 or better six months after treatment.

**Table 3 — Binocular Far Vision Without Glasses After Treatment**

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	12%	18%	18%	24%	20%
20/16 or better	64%	67%	71%	69%	69%
20/20 or better	86%	88%	87%	93%	93%
20/25 or better	98%	98%	96%	96%	97%
20/32 or better	100%	99%	99%	99%	99%
20/40 or better	100%	99%	100%	100%	99%

## Binocular Intermediate Vision

An eye exam tested binocular intermediate vision without any glasses after CustomVue™ Monovision LASIK treatment. Table 4 shows that 99% of patients were able to see 20/40 or better at intermediate distances. Eighty-five percent (85%) were able to see 20/20 or better six months after treatment.

**Table 4 — Binocular Intermediate Vision Without Glasses After Treatment**

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	11%	13%	8%	9%	12%
20/16 or better	41%	48%	50%	55%	52%
20/20 or better	77%	78%	85%	89%	89%
20/25 or better	93%	93%	96%	97%	97%
20/32 or better	98%	98%	99%	100%	100%
20/40 or better	98%	99%	99%	100%	100%
20/80 or better	100%	100%	100%	100%	100%
20/100 or better	100%	100%	100%	100%	100%
Worse than 20/100	0%	0%	0%	0%	0%

## Binocular Near Vision

The study tested binocular near vision without any glasses after CustomVue™ Monovision LASIK treatment. Table 5 shows that 100% of patients were able to see 20/40 or better close up. Eighty-eight percent (88%) were able to see 20/20 or better six months after treatment.

**Table 5 — Binocular Near Vision Without Glasses After Treatment**

Time After Treatment	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
20/12.5 or better	6%	8%	8%	11%	9%
20/16 or better	43%	50%	45%	49%	44%
20/20 or better	87%	89%	88%	90%	92%
20/25 or better	98%	96%	97%	97%	99%
20/32 or better	99%	99%	100%	99%	99%
20/40 or better	100%	100%	100%	100%	100%
20/80 or better	100%	100%	100%	100%	100%
20/100 or better	100%	100%	100%	100%	100%
Worse than 20/100	0%	0%	0%	0%	0%

## Far Vision in the Dominant Eye Without Glasses

The Monovision LASIK treatment targeted the dominant eye of patients to see well at far distances. Table 6 shows that 88% of dominant eyes could see 20/20 or better in the eye treated for seeing far away six months after treatment.

**Table 6 — Far Vision in the Dominant Eye Without Glasses After Treatment**

Time After Treatment	1 Month n=158	3 Months n=156	6 Months n=157	9 Months n=151	12 Months n=148
20/12.5 or better	12%	16%	15%	19%	20%
20/16 or better	55%	64%	66%	64%	66%
20/20 or better	85%	86%	88%	90%	89%
20/25 or better	98%	97%	96%	96%	97%
20/32 or better	99%	99%	98%	99%	99%
20/40 or better	100%	100%	99%	100%	100%
20/80 or better	100%	100%	100%	100%	100%

## Near Vision in the Non-Dominant Eye

The Monovision LASIK treatment targeted the non-dominant eye of patients to see well close up. Table 7 shows that 81% of non-dominant eyes could see 20/20 or better six months after treatment.

**Table 7 — Near Vision in the Non-Dominant Eye Without Glasses After Treatment**

Time After Treatment	1 Month n=136	3 Months n=134	6 Months n=135	9 Months n=133	12 Months n=133
20/12.5 or better	5%	5%	7%	7%	6%
20/16 or better	34%	46%	43%	44%	37%
20/20 or better	75%	84%	81%	87%	86%
20/25 or better	94%	95%	96%	97%	98%
20/32 or better	98%	97%	100%	100%	98%
20/40 or better	100%	99%	100%	100%	99%

## Vision Without Glasses After Treatment Compared to With Glasses Before Treatment

The study compared eye chart scores before treatment with glasses or contact lenses to the eye chart scores after treatment with no glasses or contact lenses. On average, the study patients scored within one line of their vision with glasses before treatment. The average score after treatment was 20/16 far away and 20/20 close up. Table 8 shows that six months after treatment, 51% of patients were able to see as well or better at near with no glasses as they could see using glasses or contact lenses before treatment.

**Table 8 — Near Vision Without Glasses After Treatment Compared to With Glasses Before Treatment**

	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
More than 2 lines better	0%	0%	0%	0%	0%
2 lines better	1%	1%	2%	2%	2%
1 line better	8%	11%	11%	13%	11%
Less than 1 line change	38%	42%	38%	40%	40%
1 line worse	39%	29%	31%	29%	31%
2 lines worse	10%	14%	16%	13%	15%
More than 2 lines worse	4%	3%	3%	3%	1%

Table 9 shows that six months after treatment, 64% of patients were able to see as well or better far away with no glasses as they could see using glasses or contact lenses before treatment.

**Table 9 — Distance Vision Without Glasses After Treatment Compared to With Glasses Before Treatment**

	1 Month n=159	3 Months n=157	6 Months n=158	9 Months n=152	12 Months n=149
More than 2 lines better	0%	0%	0%	0%	0%
2 lines better	0%	1%	1%	0%	1%
1 line better	12%	15%	17%	22%	18%
Less than 1 line change	45%	44%	47%	44%	43%
1 line worse	30%	29%	22%	24%	29%
2 lines worse	10%	8%	10%	5%	5%
More than 2 lines worse	3%	4%	4%	5%	3%

## Quality of Vision

Patients rated their quality of vision before treatment with glasses or contact lenses. They rated their quality of vision after CustomVue™ Monovision LASIK without glasses or contact lenses. Table 10 compares the patient satisfaction with quality of vision without glasses at 6 months after treatment for 157 patients with that of 155 patients with glasses before treatment.

**Table 10 — Overall Quality of Vision Before and After Treatment**

Satisfaction with Quality of Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Overall satisfaction	66%	94%	5%	3%	29%	4%
Intermediate vision	81%	94%	0%	1%	19%	5%
Depth perception	90%	98%	1%	0%	9%	2%
Peripheral vision	85%	97%	3%	1%	12%	3%

Table 11 compares the patient satisfaction with quality of near vision without glasses at 6 months after treatment for 157 patients with that of 155 patients with glasses before treatment.

**Table 11 — Quality of Near Vision Before and After Treatment**

Satisfaction with Quality of Near Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Sustained near vision	76%	93%	1%	2%	23%	5%
Brief near vision	76%	96%	2%	1%	23%	3%
Reading small print	53%	85%	8%	5%	39%	10%

Table 12 compares the patient responses for satisfaction with quality of far vision without glasses at 6 months after treatment for 157 patients with those of 155 patients with glasses before treatment.

**Table 12 — Quality of Far Vision Before and After Treatment**

Satisfaction with Quality of Far Vision	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Far vision at night	72%	84%	6%	6%	23%	10%
Far vision at night with glare	63%	82%	10%	6%	27%	13%
Far vision at dusk	78%	89%	9%	3%	13%	8%
Far vision under active conditions	74%	94%	3%	1%	23%	5%

Table 13 shows the overall satisfaction with the CustomVue™ Monovision LASIK treatment of 157 patients 6 months after treatment.

**Table 13 — Overall Satisfaction with CustomVue™ Monovision LASIK Treatment**

Would you choose to have CustomVue™ Monovision LASIK Treatment again?	6 Months (n=157)			12 Months (n=149)		
	Yes	No	Not Sure	Yes	No	Not Sure
	97%	0%	3%	98%	1%	1%

Table 14 shows the change in satisfaction with quality of vision without glasses at 6 months after treatment for 152 patients compared to the quality of vision with glasses before treatment.

**Table 14 — Change in Satisfaction with Quality of Vision Before and After Treatment**

6 Months (n = 152)	Improve	No Change	Worse
Intermediate vision	17%	78%	5%
Depth perception	9%	89%	2%
Peripheral vision	14%	85%	1%
Near vision (sustained)	22%	76%	3%
Near vision (brief )	23%	76%	1%
Near vision (small print)	39%	57%	4%
Far vision at night	17%	77%	6%
Far vision at night with glare	22%	70%	7%
Far vision at dusk	14%	80%	7%
Far vision under active conditions	25%	72%	3%
Overall satisfaction	30%	67%	3%

## Glasses or Contact Lens Use

The questionnaire asked patients how often they used glasses or contact lenses after treatment. Patients used a five level scale (never, rarely, sometimes, often, or always). Table 15 shows the change (at least two levels) in use of lenses from before treatment to after treatment.

**Table 15 — Change in Use of Glasses or Contact Lenses**

6 Months (n=152)			12 Months (n=145)		
Decrease in Use	No Change	Increase in Use	Decrease in Use	No Change	Increase in Use
96%	4%	0%	91%	8%	1%

# CLINICAL STUDY TO EVALUATE RISKS

## Vision with Glasses After Treatment

Table 16 shows that after treatment 87% of eyes in the study saw as well or better with glasses close up. Ninety percent (90%) saw as well or better with glasses far away.

**Table 16 — Change in Vision with Glasses Before and After Treatment**

<b>6 Months After Treatment (n = 292)</b>	<b>Change in Near Vision</b>	<b>Change in Far Vision</b>
Decrease >2 lines	0%	0%
Decrease >1 to 2 lines	0%	1%
Decrease > 0 to 1 line	13%	9%
No change	43%	41%
Increase >0 to 1 line	38%	46%
Increase >1 to 2 lines	5%	3%
Increase >2 lines	0%	0%

## Contrast Sensitivity

Normal vision tests measure your ability to see a black and white eye chart. Contrast sensitivity tests measure how well you see in low contrast conditions such as in rain or fog. Contrast sensitivity was measured with glasses before and after surgery. More patients improved than got worse in three different tests. In one test (far vision in dim light), more patients (10%) got worse than improved better (9%).

**Table 17 — Change in Contrast Sensitivity with Glasses 6 Months After Treatment**

Condition	6 Months (n=158)		
	% of Eyes with Loss	% of Eyes That Stay the Same	% of Eyes with Gain
Far vision in bright light	1%	94%	5%
Far vision in dim light	10%	81%	9%
Far vision in dim light with glare	10%	75%	15%
Near vision in bright light	5%	88%	7%

**Table 18 — Change in Contrast Sensitivity without Glasses 24 Months After Treatment**

Thirty (30) patients had their contrast sensitivity without glasses measured two years after surgery. Compared to their contrast sensitivity with glasses before surgery, more people decreased their contrast sensitivity than increased. Table 18 presents the percentage of subjects who experienced clinically significant changes in contrast sensitivity.

Condition	24 Months (n=30)		
	% of Eyes with Decrease	% of Eyes That Stay the Same	% of Eyes with Increase
Far vision in bright light	3%	93%	3%
Far vision in dim light	27%	57%	17%
Far vision in dim light with glare	30%	57%	13%
Near vision in bright light	13%	87%	0%

### Depth Perception

A special vision test (viewed close up) measured depth perception (the ability to see 3-D) in the study. A decrease in depth perception can make some tasks more difficult such as walking down stairs or pouring a cup of coffee. On average, the test showed that depth perception for near tasks decreased moderately after treatment.

## Adverse Events and Complications

Table 19 shows the overall percentages of eyes in the clinical study that had adverse events and complications after CustomVue™ Monovision LASIK treatment.

**Table 19 — Adverse Events and Complications**

Greater than or equal to 1% of eyes (n=296) had:	
Inflammation of the cornea under the flap	4.1%
Corneal surface cells under the flap	1.0%
Ghost or double images*	17.5%†
Less than 1% of eyes (n=296) had:	
Inflammation of the iris	0.3%
Infection of the cornea	0.3%
Increase of pressure in the eye	0.7%
Misaligned flap	0.3%
Peripheral defect of the cornea	0.3%
Feeling of something in the eye	0.7%

\* The percentage of ghost or double images is reported as a percentage of subjects (n=160) rather than eyes.

† 17.5% of subjects (28/160) were reported with the Complication of ghost images or diplopia for at least one visit. These Complications at six months or later are limited to 17 subjects (10.6%). Of these, 13 cases spontaneously resolved with no intervention, one case resolved with a retreatment to improve near vision, and 5 subjects continued to experience these Complications at their last visit. For these 5 subjects with persisting Complications, no subjects reported diplopia as occurring "often" or "always" while 4 subjects reported ghost (or shadow) images as occurring "often" or "always."

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Infection of the cornea	0.3%
Increase of pressure in the eye	0.7%
Misaligned flap	0.3%
Peripheral defect of the cornea	0.3%
Feeling of something in the eye	0.7%

\* The percentage of ghost or double images is reported as a percentage of subjects (n=160) rather than eyes.

\*\*17.5% of subjects (28/160) were reported with the Complication of ghost images or diplopia for at least one visit. These Complications at six months or later are limited to 17 subjects (10.6%). Of these, 13 cases spontaneously resolved with no intervention, one case resolved with a retreatment to improve near vision, and 5 subjects continued to experience these Complications at their last visit. For these 5 subjects with persisting Complications, no subjects reported diplopia as occurring "often" or "always" while 4 subjects reported ghost (or shadow) images as occurring "often" or "always."

## • Patient Symptoms

The questionnaire asked patients to rank the frequency of their symptoms both before and after treatment. Table 20 lists the patient symptoms reported as “often” or “always” before treatment on 155 patients and at 6 months after treatment on 157 patients.

**Table 20 — Comparison of Symptoms Before and After Treatment**

Often or Always		
Symptoms	Before Treatment	6 Months After Treatment
Dryness	6%	11%
Blurry vision	3%	3%
Fluctuation of vision	3%	2%
Glare	3%	4%
Halos around lights	8%	10%
Difficulty at night	13%	10%
Ghosting or shadowing of images	2%	4%
Double images	1%	1%
Things appear distorted	1%	0%
My vision makes me dizzy	0%	0%
My vision gives me headaches	1%	0%

The study compared vision without glasses after treatment to vision with glasses before treatment for 152 patients. The questionnaire asked patients to rate their symptoms after treatment. They used a 5-level scale. An improvement or worsening reflects a change of 2 or more levels. Table 21 presents the results of this comparison.

**Table 21 — Change in Patient Symptoms for Vision *Without* Glasses After Treatment Compared to Vision *With* Glasses Before Treatment**

Symptoms	Improve	No Change	Worsen
Dryness	9%	77%	14%
Blurry vision	6%	90%	5%
Fluctuation of vision	12%	84%	5%
Glare	9%	83%	8%
Halos around lights	12%	77%	11%
Difficulty at night	14%	76%	11%
Ghosting or shadowing of images	6%	88%	6%
Double images	1%	97%	2%
Things appear distorted	3%	94%	3%
My vision makes me dizzy	3%	97%	0%
My vision gives me headaches	5%	95%	1%

# 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