Professional Use Information

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

CustomVue™ Treatments

For the reduction or elimination of myopia and myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D

For the reduction or elimination of hyperopia and hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 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 Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the STAR S4 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™ 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™ Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with "Gas Safety" (Section 4.5) and "Gas Maintenance" (Section 14.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

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

SKIN AND EYE EXPOSURE: The STAR S4 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 thyratron emits an electromagnetic pulse which is shielded by the metal coverings of the STAR S4™ 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™ Excimer Laser System

The STAR S4 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 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 System include:

Excimer Laser
An argon-fluoride excimer laser module, with an output wavelength of 193 nm.

Gas Management System
A gas cabinet containing a working gas cylinder for laser operation; a gas cleaning system; a gas leak audio alarm with a sensor to detect fluorine (one part-per-million); a gas discharge system, using an activated charcoal filter to absorb fluorine; an emergency safety system using a positive-action solenoid safety valve, which automatically seals the premix cylinder in the event of a power failure; and a second charcoal scrubber to neutralize fluorine in case of a leak.

Laser Beam Delivery System
Beam shaping and homogenizing optics designed to produce a uniform, coaxial beam profile; a spatial integrator and beam rotator for temporal integration; and an iris diaphragm and rotating slit blades used to shape the beam.

Patient Management System
The ActiveTrak® System, which enables the laser beam to track the patient's eye movements during the treatment, an operating microscope with reticle, used to observe a patient procedure and to facilitate accurate focus and laser beam alignment; a debris-removal system designed to evacuate the debris plume that occurs during ablation; a patient operating chair used to align the patient for treatment; a video camera and monitor used to record and monitor patient treatment; an illumination device used to illuminate the patient's eye for observation and treatment, and a fixation LED used by the patient to maintain proper alignment during treatment.

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

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

1.1.2 WaveScan WaveFront® System

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

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

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

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

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

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* Windows® is a registered trademark of Microsoft Corporation.

Features and components of the WaveScan WaveFront® System include:

Computer Control
The WaveScan WaveFront® System includes software to calculate the desired laser vision correction treatment (CustomVue™ treatment) from the WavePrint® measurement. The software generates two sets of laser instructions, one for PreVue® plastic and the other for the patient procedure. Both sets of instructions are loaded on to the STAR S4™ 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™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of myopia and myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D;
- in patients 21 years of age or older; and
- in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

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

- for the reduction or elimination of hyperopia and hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D;
- in patients 21 years of age or older; and
- in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

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

2.1.2 Contraindications

Laser refractive surgery is contraindicated:

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

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.

Lower uncorrected visual acuity may be anticipated in the treatment of higher degrees of myopia with and without astigmatism (>-5.0 D MRSE).

2.1.4 Precautions

A. General

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

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

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

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

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

- who are taking the medication Sumatriptan (Imitrex®*).

The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes or decentered pupils.

Pupil size should be evaluated under mesopic illumination conditions.

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

Pre-operative ultrasonic pachymetry measurement must be performed.

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

There may be significant differences between the wavefront defocus term and the MRSE in post-operative hyperopic patients, which should be considered in the surgical planning of retreatments.

The safety and effectiveness of wavefront-guided LASIK surgery has **ONLY** been established with an optical zone of 6 mm and an ablation zone of 8 mm for myopic astigmatism and an ablation zone of 9 mm for hyperopic astigmatism.

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

No higher order aberrations can be measured or treated outside the wavefront measurement region. If the surgeon tries to extend the nominal optical zone beyond the measured wavefront diameter, the nonuniform wavefront transition zone will overlie the attempted spherocylindrical treatment. The safety and effectiveness of setting the nominal optical zone larger than the wavefront measurement area are unknown.

It is important to maintain a carefully controlled surgical environment. Treatments performed at greater than or equal to 75° F were associated with less accurate outcomes. 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™ System have **NOT** been established for wavefront-guided LASIK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone.
- under 21 years of age.

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* Imitrex® is a registered trademark of GlaxoSmithKline.

- over the long term (more than 1 year after surgery).
- with prior intraocular or corneal surgery of any kind.
- For eyes with myopic astigmatism:
  - whose difference between WaveScan® and manifest sphere or cylinder powers (WaveScan power – manifest power) is more minus than 0.50 diopters or more plus than 0.75 diopters, or whose difference between WaveScan and manifest cylinder axis is greater than 15 degrees (if manifest cylinder power is greater than 0.50 diopters).
  - whose PreVue®-corrected acuity is worse than 20/20+3.
  - whose peak-to-valley higher order aberrations are greater than 8 µm of wavefront error.
  - whose BSCVA is worse than 20/20.
  - whose WaveScan-measured pupil size is < 6 mm.
  - for treatments greater than -6 diopters of MRSE or greater than 3 diopters of astigmatism.
  - for retreatment with CustomVue™ LASIK.
- For eyes with hyperopic astigmatism:
  - whose difference between WaveScan and manifest sphere or cylinder powers is not within ± 0.75 D of each other.
  - whose difference between manifest and cycloplegic sphere or cylinder powers is not within ± 0.75 D of each other.
  - whose difference between WaveScan and cycloplegic sphere or cylinder powers is not within ± 0.75 D of each other.
  - whose manifest cylinder axis is > 15 degrees from WaveScan cylinder axis (for eyes with manifest cylinder > 0.50 D.
  - whose anticipated post-op keratometry reading is > 50.0 D in any meridian.
  - whose BSCVA is worse than 20/25.
  - whose WaveScan-measured pupil size is < 5 mm.
  - for treatments > 3 diopters of MRSE or > 2 diopters of astigmatism.
  - for retreatment with CustomVue™ LASIK.

B. Patient Selection

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

- All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK).
- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.
- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for hard lenses. Prior to treatment and after at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard (PMMA) lenses must have 3 central keratometry readings and manifest refractions taken at 1 week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.
- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo laser refractive surgery.
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- Baseline evaluation of patients requesting CustomVue™ treatments should be performed within 30 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the WaveScan® refraction and the limits for peak to valley higher order aberrations, BSCVA, and pupil size, as outlined in the previous section of these Precautions.
- The minimum pupil size of the wavefront measurement must be ≥5 mm to calculate a CustomVue treatment.

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

C. Procedure

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

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

D. Post-Procedure

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

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

2.1.5 Adverse Events for Myopic Astigmatism Study

Three hundred and fifty-one (351) eyes were used for safety analyses. Three hundred and eighteen (318) eyes were followed for 3 months and two hundred and seventy-seven (277) eyes were followed for 6 months.

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

Table 2-1 — Summary of Adverse Events for Myopic Astigmatism Study: All Eyes, N=351

	1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	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	2	0.6	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
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
Miscreated Flap	1	0.3	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
Uncontrolled IOP >10 mm Hg Any reading > 25 mm Hg	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
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Other: Prior to the 1 month visit, five eyes of four subjects developed diffuse lamellar keratitis (DLK) on post-operative day 1 and day 7. Each case resolved within 8 days of onset with no loss of vision. Additionally, one eye experienced a corneal erosion at 18 months post-operatively. This case resolved within 7 days of onset with no loss of vision.

Table 2-2 — Summary of Complications for Myopic Astigmatism Study: All Eyes, N=351

	< 1 Month (n=351)		1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%	n	%
Misaligned flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema between 1 week and 1 month	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal abrasion	5	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral corneal epithelial defect at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface	1	0.3	1	0.3	2	0.6	1	0.4	0	0.0	0	0.0
Foreign body sensation at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pain at 1 month or later			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Diplopia (ghost images)	5	1.4	2	0.6	2	0.6	2	0.7	0	0.0	0	0.0

2.1.6 Adverse Events for Hyperopic Astigmatism Study

One hundred and forty-four (144) eyes were used for safety analyses. One hundred and thirty-seven (137) eyes were followed for 6 months. One hundred and twenty-four (124) eyes were followed for 9 months.

Adverse events for 1 month and later are provided in Table 2-3. Complications are presented in Table 2-4.

Table 2-3 — Summary of Adverse Events for Hyperopic Astigmatism Study: All Eyes, N=144

	<1 Month (n=144)		1 Month (n=142)		3 Months (n=142)		6 Months (n=137)		9 Months (n=124)		12 Months (n=27)	
	n	%	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal epithelial defect involving the keratectomy at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	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
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	2*	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Melting of the flap (LASIK only)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Uncontrolled IOP >10 mm Hg or Any reading > 25 mm Hg	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* Because no laser treatment was applied, the data from these 2 eyes were removed from all analyses.

Other: One eye of one subject developed diffuse lamellar keratitis (DLK) prior to the one-month visit, which resolved within six days of onset with no loss of vision.

Table 2-4 — Summary of Complications for Hyperopic Astigmatism Study: All Eyes, N=144

	<1 Month (n=144)		1 Month (n=142)		3 Months (n=142)		6 Months (n=137)		9 Months (n=124)		12 Months (n=27)	
	n	%	n	%	n	%	n	%				
Misaligned flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema between 1 week and 1 month after procedure	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral corneal epithelial defect at 1 month or later	3	2.1	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface	3	2.1	2	1.4	1	0.7	1	0.7	1	0.8	0	0.0
Foreign body sensation at 1 month or later	0	0.0	0	0.0	2	1.4	0	0.0	0	0.0	0	0.0
Pain at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Diplopia (ghost images) in the operative eye	0	0.0	16	11.3	10	7.1	11	8.0	8	6.5	0	0.0

3.1 Clinical Results

3.1.1 Myopia With or Without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have myopia from -0.5 D to -6.0 D with or without astigmatism up to -3.0 D, with a maximum manifest spherical equivalent of -6.0 D. To qualify for the study, patients also had to demonstrate agreement between the manifest and WaveScan® refraction, achieve a PreVue®-corrected acuity of 20/20+3 or better, have peak-to-valley higher order aberrations within 8 µm, a BSCVA of 20/20 or better, and a pupil size ≥6 mm. Less than 2% of eyes did not qualify for treatment using these PreVue lens admission criteria. All study treatments were conducted using a 6 mm optical zone and an 8 mm ablation zone with intention of full correction to emmetropia. Three hundred and fifty-one (351) eyes comprised the cohort used for both safety and effectiveness evaluations. 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, and stability. Safety analyses included change in best spectacle-corrected visual acuity (BSCVA), intraocular pressure, adverse events, and complications. The post-operative spectacle/contact lens wear frequency was not assessed.

B. Patient Accountability

Three hundred and fifty-one (351) eyes of 189 subjects treated at six centers in the United States were evaluated for safety and effectiveness. Table 3-1 presents the demographic characteristics of the patient population. Table 3-2 presents the percent accountability for all eyes treated in the study. Over 95% accountability was achieved at the 1, 3, 6, 9, and 12-month visits.

Table 3-1 — Demographics: All Eyes, N=351

Age (in years)	**Average ± Standard Deviation Minimum to Maximum**	**35.9 ±8.3 21 to 62**	
		Number	**% of Eyes**
Gender	Male	209	59.5
	Female	142	40.5
Race	Caucasian	309	88.0
	Asian/Pacific Islander	4	1.1
	African American	3	0.9
	Other*	35	10.0
Eyes	Right	184	52.4
	Left	167	47.6
Contact Lens History	None	138	50.9
	Soft	124	45.8
	RGP/PMMA	9	3.3

* "Other" classifications of race include: Hispanic, "White-Asian," Black-White", Arabic, and Thai.

Table 3-2 — Patient Accountability: All Eyes, N=351

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Available for Analysis	331	94.3	318	90.6	277	78.9	102	29.1	86	24.5
Discontinued*	0	0.0	0	0.0	12	3.4	13	3.7	13	3.7
Missed Visit	2	0.6	4	1.1	9	2.6	5	1.4	4	1.1
Not yet Eligible	18	5.1	29	8.3	53	15.1	231	65.8	248	70.7
Lost to Follow-Up	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
% Accountability†	**99.4%**		**98.8%**		**96.9%**		**95.3%**		**95.6%**	

* Twelve (12) of 13 eyes were discontinued due to retreatment in the study. One (1) eye was withdrawn from the study and retreated commercially.

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

C. Data Analysis and Results

1) Pre-Operative Characteristics

The mean age of the 189 subjects participating in this trial was 35.9 ± 8.3 years. There were 77 women and 112 men. Table 3-3 presents pre-operative refractive error stratified by manifest sphere and cylinder expressed in *plus* cylinder notation.

Table 3-3 — Pre-Operative Refractive Error Stratified by Sphere and Cylinder: All Eyes, N=351

	Cylinder											
	0 D		0.25 to 0.5 D		0.75 to 1.0 D		>1 to ≤ 2 D		>2 to ≤ 3 D		Total	
Sphere	n	%	n	%	n	%	n	%	n	%	n	%
<0 to ≥ -1 D	4	1.1	2	0.6	0	0.0	0	0.0	0	0.0	6	1.7
<-1 to ≥ -2 D	13	3.7	35	10.0	5	1.4	2	0.6	0	0.0	55	15.7
<-2 to ≥ -3 D	22	6.3	31	8.8	14	4.0	12	3.4	3	0.9	82	23.4
<-3 to ≥ -4 D	12	3.4	29	8.3	10	2.8	12	3.4	12	3.4	75	21.4
<-4 to ≥ -5 D	17	4.8	21	6.0	18	5.1	16	4.6	5	1.4	77	21.9
<-5 to ≥ -6 D	12	3.4	12	3.4	18*	5.1	10*	2.8	4*	1.1	56	16.0
Total	80	22.8	130	37.0	65	18.5	52	14.8	24	6.8	351	100

* Includes six eyes with a pre-operative sphere (in plus cylinder) of -6.25 D (n = 2), -6.5 D (n = 2), -6.75 D (n = 1), and -7.0 D (n = 1).

2) Uncorrected Visual Acuity (UCVA)

All eyes were targeted for emmetropia. Pre-operatively, 0% of eyes had an uncorrected visual acuity (UCVA) of 20/20 or better; at the 6 month visit, 94% (260/277) of these eyes had UCVA of 20/20 or better. Tables 3-4–3-6 present UCVA over time. Table 3-7 presents post-operative uncorrected visual acuity compared to pre-operative best spectacle-corrected visual acuity.

Table 3-4 — UCVA Over Time: All Eyes, N=351

	Pre-Op (n=351)		1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	67	20.2	75	23.6	74	26.7	27	26.5	20	23.3
20/16 or better	0	0.0	229	69.2	223	70.1	204	73.6	80	78.4	60	69.8
20/20 or better	0	0.0	304	91.8	281	88.4	260	93.9	101	99.0	84	97.7
20/25 or better	1	0.3	314	94.9	297	93.4	271	97.8	101	99.0	84	97.7
20/32 or better	4	1.1	323	97.6	304	95.6	273	98.6	102	100	85	98.8
20/40 or better	7	2.0	324	97.9	306	96.2	276	99.6	102	100	86	100
20/80 or better	50	14.2	330	99.7	316	99.4	277	100	102	100	86	100
20/200 or better	227	64.7	331	100	318	100	277	100	102	100	86	100
Worse than 20/200	124	35.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-5 — UCVA Over Time: Spherical Myopia, N=80

	Pre-Op (n=80)		1 Month (n=80)		3 Months (n=79)		6 Months (n=71)		9 Months (n=29)		12 Months (n=23)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	26	32.5	28	35.4	27	38.0	11	37.9	6	26.1
20/16 or better	0	0.0	57	71.3	51	64.6	52	73.2	20	69.0	15	65.2
20/20 or better	0	0.0	73	91.3	72	91.1	68	95.8	29	100	23	100
20/25 or better	1	1.3	75	93.8	75	94.9	71	100	29	100	23	100
20/32 or better	1	1.3	78	97.5	75	94.9	71	100	29	100	23	100
20/40 or better	2	2.5	79	98.8	76	96.2	71	100	29	100	23	100
20/80 or better	10	12.5	80	100	79	100	71	100	29	100	23	100
20/200 or better	51	63.8	80	100	79	100	71	100	29	100	23	100
Worse than 20/200	29	36.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-6 — UCVA Over Time: Astigmatic Myopia, N=271

	Pre-Op (n=271)		1 Month (n=251)		3 Months (n=239)		6 Months (n=206)		9 Months (n=73)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	41	16.3	47	19.7	47	22.8	16	21.9	14	22.2
20/16 or better	0	0.0	172	68.5	172	72.0	152	73.8	60	82.2	45	71.4
20/20 or better	0	0.0	231	92.0	209	87.4	192	93.2	72	98.6	61	96.8
20/25 or better	0	0.0	239	95.2	222	92.9	200	97.1	72	98.6	61	96.8
20/32 or better	3	1.1	245	97.6	229	95.8	202	98.1	73	100	62	98.4
20/40 or better	5	1.8	245	97.6	230	96.2	205	99.5	73	100	63	100
20/80 or better	40	14.8	250	99.6	237	99.2	206	100	73	100	63	100
20/200 or better	176	64.9	251	100	239	100	206	100	73	100	63	100
Worse than 20/200	95	35.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

At six months, more than 79% of eyes were able to achieve a post-operative uncorrected vision that was either the same or better than their pre-operative best-corrected vision.

Table 3-7 — Post-Operative Uncorrected Visual Acuity Compared to Pre-Operative Best Spectacle-Corrected Visual Acuity, N=351

	1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%
>2 lines better	0	0.0	0	0.0	1	0.4	0	0.0	0	0.0
2 lines better	6	1.8	6	1.9	9	3.2	2	2.0	2	2.3
1 line better	74	22.4	83	26.1	75	27.1	30	29.4	22	25.6
Equal	167	50.5	151	47.5	134	48.4	55	53.9	45	52.3
1 line worse	58	17.5	45	14.2	41	14.8	13	12.7	13	15.1
2 lines worse	9	2.7	12	3.8	12	4.3	1	1.0	2	2.3
>2 lines worse	17	5.1	21	6.6	5	1.8	1	1.0	2	2.3

3) Accuracy of MRSE Over Time

At 6 months post-operatively, 90% (250/277) of eyes were within 0.50 D and 99% (275/277) were within 1 D of attempted correction. At the 1, 3, 6, 9, and 12-month visits, no eye was overcorrected by more than one diopter or undercorrected by more than two diopters. Tables 3-8–3-10 present the accuracy of MRSE over time.

Table 3-8 — Accuracy of Manifest Refraction Attempted vs. Achieved: All Eyes, N=351

	Pre-Op (n=351)		1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	307	92.7	277	87.1	250	90.3	98	96.1	80	93.0
± 1.00 D	10	2.8	326	98.5	309	97.2	275	99.3	102	100	86	100
± 2.00 D	81	23.1	331	100	318	100	277	100	102	100	86	100
Overcorrected						(Hyperopic)						
> +1.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
> +2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected						(Myopic)						
< -1.00 D			5	1.5	9	2.8	2	0.7	0	0.0	0	0.0
< -2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-9 — Accuracy of Manifest Refraction Attempted vs. Achieved: Eyes with Spherical Myopia (by Manifest), N=80

	Pre-Op (n=80)		1 Month (n=80)		3 Months (n=79)		6 Months (n=71)		9 Months (n=29)		12 Months (n=23)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	74	92.5	68	86.1	65	91.5	28	96.6	20	87.0
± 1.00 D	4	5.0	79	98.8	79	100	70	98.6	29	100	23	100
± 2.00 D	17	21.3	80	100	79	100	71	100	29	100	23	100
Not Reported	0		0		0		0		0		0	
Overcorrected					(Hyperopic)							
> +1.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
> +2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected					(Myopic)							
< -1.00 D			1	1.3	0	0.0	1	1.4	0	0.0	0	0.0
< -2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-10 — Accuracy of Manifest Refraction Attempted vs. Achieved: Eyes with Astigmatic Myopia (by Manifest), N=271

	Pre-Op (n=271)		1 Month (n=251)		3 Months (n=239)		6 Months (n=206)		9 Months (n=73)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	233	92.8	209	87.4	185	89.8	70	95.9	60	95.2
± 1.00 D	6	2.2	247	98.4	230	96.2	205	99.5	73	100	63	100
± 2.00 D	64	23.6	251	100	239	100	206	100	73	100	63	100
Overcorrected					(Hyperopic)							
> +1.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
> +2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected					(Myopic)							
< -1.00 D			4	1.6	9	3.8	1	0.5	0	0.0	0	0.0
< -2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

4) Stability of Outcome

Stability of outcome is evaluated both by the cohort of eyes with a refraction at each visit (n = 275), as well as the cohort of eyes who were available for two consecutive visits, but not for all visits. Refractive stability is reached at 3 months and confirmed at the 6-month visit. Tables 3-11 and 3-12 present refractive stability over time.

Table 3-11 — Refractive Stability: Eyes That Underwent the 1, 3, and 6 Month Visits, N=275

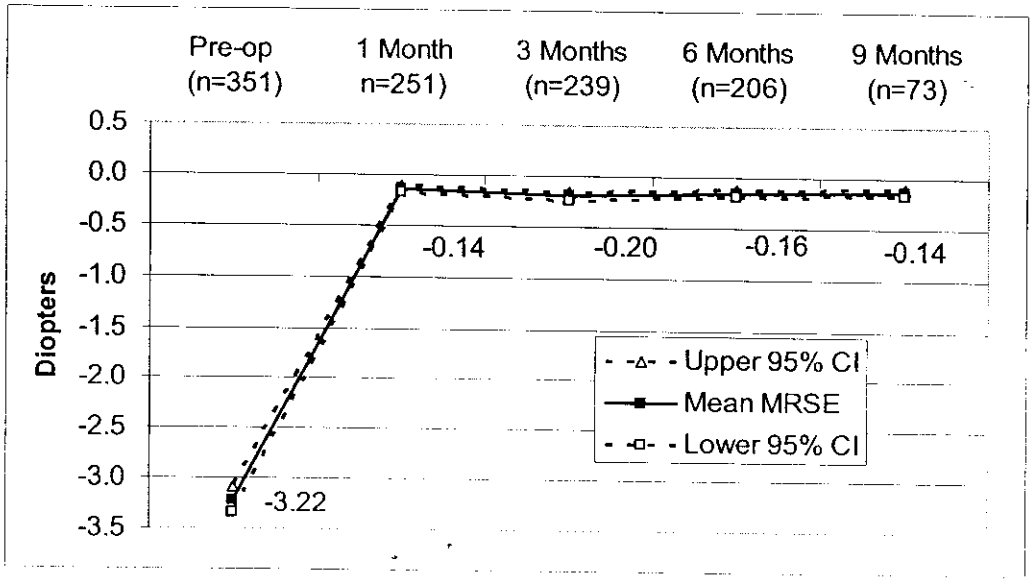
	Between 1 and 3 Months			Between 3 and 6 Months		
	All Eyes (n=275)	Spherical Myopia (n=71)	Astigmatic Myopia (n=204)	All Eyes (n=275)	Spherical Myopia (n=71)	Astigmatic Myopia (n=204)
Change in MRSE by ≤ 0.5 D	265	69	196	266	69	197
%	96.4	97.2	96.1	96.7	97.2	96.6
Change in MRSE by ≤ 1.0 D	274	71	203	273	71	202
%	99.6	100	99.5	99.3	100	99.0
Mean Change in MRSE	-0.04	-0.04	-0.04	0.00	0.00	0.00
SD	0.24	0.24	0.24	0.26	0.24	0.26
95% CI for Mean	(-0.07, -0.01)	(-0.10, 0.01)	(-0.07, -0.01)	(-0.03, 0.03)	(-0.05, 0.06)	(-0.04, 0.04)

Table 3-12 — Refractive Stability: Eyes With Two Consecutive Exams

	Between 1 and 3 Months			Between 3 and 6 Months			Between 6 and 9 Months			Between 9 and 12 Months		
	All Eyes (n=316)	Spherical Myopia (n=79)	Astigmatic Myopia (n=237)	All Eyes (n=277)	Spherical Myopia (n=71)	Astigmatic Myopia (n=206)	All Eyes (n=102)	Spherical Myopia (n=29)	Astigmatic Myopia (n=73)	All Eyes (n=83)	Spherical Myopia (n=22)	Astigmatic Myopia (n=61)
Change in MRSE by ≤0.5 D	305	77	228	268	69	199	99	28	71	83	22	61
%	96.5	97.5	96.2	96.8	97.2	96.6	97.1	96.6	97.3	100	100	100
Change in MRSE by ≤1.0 D	315	79	236	275	71	204	102	29	73	83	22	61
%	99.7	100	99.6	99.3	100	99.0	100	100	100	100	100	100
Mean Change in MRSE	-0.05	-0.05	-0.05	0.00	0.00	0.00	0.03	0.03	0.03	-0.03	-0.03	-0.03
SD	±0.25	±0.25	±0.25	±0.26	±0.24	±0.26	±0.23	±0.26	±0.22	±0.24	±0.31	0.21
95% CI for Mean	(-0.08, -0.02)	(-0.11, 0.00)	(-0.08, -0.02)	(-0.03, 0.03)	(-0.05, 0.06)	(-0.04, 0.03)	(-0.01, 0.08)	(-0.06, 0.12)	(-0.02, 0.08)	(-0.08, 0.02)	(-0.16, 0.10)	(-0.08, 0.02)

When plotted over time, the mean manifest spherical equivalents illustrate that stability is achieved by the 3-month visit. This trend is further supported by almost no change between the 3 and 6-month visits.

Figure 3-1 — Stability of MRSE Over Time (All Eyes, N=351)



5) Efficacy of Correction of Astigmatism

Efficacy of correction of astigmatism was evaluated at the point of stability (3 months) for eyes with myopic astigmatism. Table 3-13 displays the mean % reduction of cylinder for eyes stratified by pre-op cylinder.

Table 3-13 — Reduction of Absolute (Non-Vector) Cylinder

Pre-Operative Cylinder	Mean % Reduction
ALL (n=239)	67.6
>0 to ≤0.50 D (n=127)	55.1
>0.50 to ≤1.0 D (n=61)	81.7
>1.0 to ≤2.0 D (n=35)	78.5
>2.0 to ≤3.0 D (n=16)	89.2

Table 3-14 displays the ratio of achieved versus intended vector magnitude. The correction ratio is defined as the absolute Surgically Induced Refractive Cylinder (SIRC) divided by the absolute Intended Refractive Change (IRC).

Table 3-14 — Vector Analysis at Stability (3 Months)

Pre-Operative Cylinder	Correction Ratio (SIRC/IRC) Mean ± SD
ALL (n=239)	1.04 ± 0.50
>0 to ≤0.50 D (n=127)	1.13 ± 0.63
>0.50 to ≤1.0 D (n=61)	0.95 ± 0.29
>1.0 to ≤2.0 D (n=35)	0.91 ± 0.26
>2.0 to ≤3.0 D (n=16)	0.93 ± 0.14

6) Higher Order Aberrations

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

7) WaveScan® Spherical Equivalent

The difference between MRSE and WaveScan-measured spherical equivalent at 3 months post-op was -0.15 ± 0.49 D, compared to -0.42 ± 0.31 D preoperatively. The mean WaveScan-measured spherical equivalent at 3 months was -0.44 D.

8) Best Spectacle-Corrected Visual Acuity (BSCVA)

At the 3-month visit, 1 eye (0.3%) lost 2 lines of BSCVA. No eye lost more than 2 lines of BSCVA and no eye lost more than 1 line of vision after 3 months. Table 3-15 presents the change in lines of BSCVA over time.

Table 3-15 — Change in BSCVA Over Time: All Eyes, N=351

	1 Month (n=331)		3 Months (n=318)		6 Months (n=277)		9 Months (n=102)		12 Months (n=86)	
	n	%	n	%	n	%	n	%	n	%
Decrease > 2 Lines	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease > 1 to ≤ 2 Lines*	4	1.2	2	0.6	0	0.0	0	0.0	0	0.0
Decrease > 0 to ≤ 1 Line	28	8.5	34	10.7	24	8.7	5	4.9	5	5.8
No Change	135	40.8	114	35.8	75	27.1	24	23.5	24	27.9
Increase >0 to ≤ 1 Line	148	44.7	149	46.9	149	53.8	65	63.7	50	58.1
Increase > 1 to ≤ 2 Lines	16	4.8	18	5.7	27	9.7	8	7.8	7	8.1
Increase > 2 Lines	0	0.0	1	0.3	2	0.7	0	0.0	0	0.0

* Eyes that lost 2 lines of BSCVA: 1 month, 0 (0.0%); 3 months, 1 (0.3%).

9) Contrast Sensitivity Analysis

Table 3-16 presents the results of the contrast sensitivity analysis. When analyzed using the paired-t for the means, the difference of the means from pre-operative to 1, 3, and 6 months consistently demonstrated a statistically significant improvement in all three test conditions: dim with and without glare and bright without glare.

Table 3-16 — Contrast Sensitivity: All Eyes, N=351

	Pre-Op				Change from Pre-Op to 1 Month				Change from Pre-Op to 3 Months				Change from Pre-Op to 6 Months				Change from Pre-Op to 12 Months			
CPD	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**
Dim w/ Glare	**n=351**				**n=329***				**n=318**				**n=277**				**n=86**			
Mean	1.54	1.56	1.04	0.61	0.04	0.10	0.14	0.15	0.05	0.10	0.12	0.14	0.07	0.12	0.17	0.17	0.02	0.04	0.11	0.13
(SE)	0.012	0.017	0.021	0.021	0.013	0.019	0.024	0.025	0.013	0.019	0.024	0.024	0.016	0.020	0.025	0.026	0.024	0.036	0.036	0.041
P Value ≤†					0.002	0.000	0.000	0.000	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.419	0.236	0.004	0.002
Dim w/o Glare	**n=351**				**n=329***				**n=318**				**n=277**				**n=86**			
Mean	1.60	1.69	1.20	0.74	0.04	0.05	0.10	0.11	0.05	0.04	0.08	0.07	0.06	0.06	0.16	0.13	0.04	0.01	0.01	0.04
(SE)	0.011	0.013	0.020	0.021	0.012	0.014	0.022	0.024	0.013	0.016	0.024	0.024	0.013	0.016	0.024	0.025	0.024	0.029	0.036	0.040
P Value ≤†					0.003	0.000	0.000	0.000	0.000	0.010	0.000	0.003	0.000	0.000	0.000	0.000	0.101	0.787	0.762	0.274
Bright w/o Glare	**n=351**				**n=329***				**n=318**				**n=277**				**n=86**			
Mean	1.76	1.97	1.65	1.22	0.02	0.02	0.04	0.03	0.04	0.04	0.04	0.03	0.05	0.05	0.06	0.04	0.02	0.02	0.02	0.02
(SE)	0.009	0.010	0.011	0.013	0.010	0.011	0.013	0.014	0.010	0.013	0.014	0.015	0.011	0.013	0.014	0.017	0.020	0.022	0.024	0.033
P Value ≤†					0.012	0.025	0.003	0.043	0.000	0.002	0.004	0.023	0.000	0.000	0.000	0.013	0.321	0.328	0.373	0.637

* Two eyes of 1 subject did not undergo contrast sensitivity testing at the 1-month visit.

† Two-tailed paired t test for the means.

10) Retreatments

Twelve eyes of 10 subjects (12/351 or 3.4%) underwent wavefront-guided retreatment. Twelve retreatments are insufficient to yield clinically useful information; however, caution should be taken and was taken to assure refractive stability before performing additional procedures.

11) Patient Symptoms

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

Table 3-17 — Summary of Patient Symptoms: All Eyes, N=332*

	Pre-Op (N=332)					3 Months (N=297)					6 Months (N=258)				
	Never	Rarely	Some-times	Often	Always	Never	Rarely	Some-times	Often	Always	Never	Rarely	Some-times	Often	Always
Dryness	27.1%	42.2%	24.4%	5.7%	0.6%	15.2%	29.0%	44.4%	9.4%	2.0%	17.1%	43.0%	30.6%	5.8%	3.5%
Blurry Vision	37.3%	41.0%	19.6%	0.6%	1.5%	32.3%	35.0%	26.9%	4.0%	1.7%	32.2%	46.1%	20.2%	0.8%	0.8%
Fluctuation of vision	44.9%	40.1%	12.7%	2.4%	0.0%	34.0%	42.1%	19.5%	3.0%	1.3%	39.1%	38.0%	19.8%	2.3%	0.8%
Glare	30.7%	40.7%	26.2%	2.4%	0.0%	41.4%	39.1%	15.5%	2.7%	1.3%	38.0%	44.6%	13.2%	3.9%	0.4%
Halos Around Lights	41.3%	33.1%	20.2%	2.7%	2.7%	40.7%	30.3%	21.9%	5.1%	2.0%	41.1%	34.5%	17.4%	4.3%	2.7%
Difficulty at Night W/Glare	23.5%	35.2%	28.0%	9.3%	3.9%	34.3%	35.4%	21.9%	5.7%	2.7%	35.7%	35.3%	22.9%	5.4%	0.8%
Ghost or Double Images	78.3%	18.7%	2.4%	0.0%	0.6%	76.8%	17.8%	2.4%	2.4%	0.7%	77.5%	14.0%	7.4%	0.4%	0.8%

* Questionnaires were not completed for 19 eyes.

Table 3-18 — Summary of Patient Satisfaction: All Eyes, N=332*

	Pre-Op (N=332)					3 Months (N=297)					6 Months (N=258)				
	Very Satisfied	Satisfied	Not Sure	Somewhat Dissatisfied	Very Dissatisfied	Very Satisfied	Satisfied	Not Sure	Somewhat Dissatisfied	Very Dissatisfied	Very Satisfied	Satisfied	Not Sure	Somewhat Dissatisfied	Very Dissatisfied
Sharpness and Clarity	26.2%	61.7%	3.0%	8.7%	0.3%	59.6%	26.9%	4.7%	7.4%	1.3%	66.3%	26.4%	2.3%	4.3%	0.8%
Overall Visual Comfort	31.6%	47.3%	4.5%	14.5%	2.1%	69.0%	26.3%	3.0%	1.3%	0.3%	69.0%	26.4%	2.3%	1.6%	0.8%
Consistency of Vision	27.1%	57.2%	4.2%	11.4%	0.0%	52.5%	35.7%	7.7%	3.4%	0.7%	57.0%	34.9%	5.0%	3.1%	0.0%
Daylight Vision	32.5%	61.7%	1.8%	3.9%	0.0%	66.3%	27.6%	0.7%	4.4%	1.0%	73.3%	22.9%	1.9%	1.9%	0.0%
Night Vision	11.7%	53.0%	9.9%	24.1%	1.2%	41.1%	39.4%	6.1%	11.4%	2.0%	44.2%	40.7%	6.2%	7.4%	1.6%
Night Vision with Glare	7.5%	52.4%	11.1%	24.4%	4.5%	33.0%	45.1%	9.8%	10.1%	2.0%	35.3%	45.7%	11.2%	6.2%	1.6%

* Questionnaires were not completed for 19 eyes.

12) Summary of Key Safety and Effectiveness Variables

The key safety and effectiveness variables for all eyes are presented in Tables 3-19–3-21. The key safety and effectiveness variables stratified by pre-operative manifest refraction spherical equivalent are presented in Tables 3-22–3-24.

Table 3-19 — Summary of Key Safety and Effectiveness Variables: All Eyes, N=351

Criteria	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)	FDA Targets
EFFECTIVENESS VARIABLES						
N=351	n=331	n=318	n=277	n=102	n=86	
UCVA 20/20 or better	304 91.8 (88.4, 94.6)	281 88.4 (84.3, 91.7)	260 93.9 (90.4, 96.4)	101 99.0 (94.7, 100)	84 97.7 (91.9, 99.7)	
UCVA 20/40 or better	324 97.9 (95.7, 99.1)	306 96.2 (93.5, 98.0)	276 99.6 (98.0, 100)	102 100 (97.1, 100)	86 100 (96.6, 100)	≥85%
MRSE ± 0.50 D	307 92.7 (89.4, 95.3)	277 87.1 (82.9, 90.6)	250 90.3 (86.1, 93.5)	98 96.1 (90.3, 98.9)	80 93.0 (85.4, 97.4)	≥50%
MRSE ± 1.00 D	326 98.5 (96.5, 99.5)	309 97.2 (94.7, 98.7)	275 99.3 (97.4, 99.9)	102 100 (97.1, 100)	86 100 (96.6, 100)	≥75%
MRSE ± 2.00 D	331 100 (99.1, 100)	318 100 (99.1, 100)	277 100 (98.9, 100)	102 100 (97.1, 100)	86 100 (96.6, 100)	
Stability*						
N=351		n=316	n=277	n=102	n=83	
Change ≤ 1.00 D		315 99.7 (98.2, 100)	275 99.3 (97.4, 99.9)	102 100 (97.1, 100)	83 100 (96.5, 100)	≥95%
Mean Change in MRSE		-0.05 ± 0.25 (-0.08, -0.02)	0.00 ± 0.26 (-0.03, 0.03)	0.03 ± 0.23 (-0.01, 0.08)	-0.03 ± 0.24 (-0.08, 0.02)	
SAFETY VARIABLES						
N=351	n=331	n=318	n=277	n=102	n=86	
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 0.9)	1 0.3 (0.0, 1.7)	0 0.0 (0.0, 1.1)	0 0.0 (0.0, 2.9)	0 0.0 (0.0, 3.4)	
Loss of > 2 lines BSCVA	0 0 (0.0, 0.9)	0 0.0 (0.0, 0.9)	0 0.0 (0.0, 1.1)	0 0.0 (0.0, 2.9)	0 0.0 (0.0, 3.4)	<5%
BSCVA worse than 20/25	0 0.0 (0.0, 0.9)	1 0.3 (0.0, 1.7)	0 0.0 (0.0, 1.1)	0 0.0 (0.0, 2.9)	0 0.0 (0.0, 3.4)	
BSCVA worse than 20/40	0 0.0 (0.0, 0.9)	0 0.0 (0.0, 0.9)	0 0.0 (0.0, 1.1)	0 0.0 (0.0, 2.9)	0 0.0 (0.0, 3.4)	
N=80†	n=80	n=79	n=71	n=29	n=23	
Increase > 2 D cylinder	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	<5%

* Includes eyes with two consecutive exams, but not all exams.

† For eyes treated with spherical myopia.

Table 3-20 — Summary of Key Safety and Effectiveness Variables: Eyes with Spherical Myopia (by Manifest), N=80

Criteria	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)	FDA Targets
EFFECTIVENESS VARIABLES						
N=80	n=80	n=79	n=71	n=29	n=23	
UCVA 20/20 or better	73 91.3 (82.8, 96.4)	72 91.1 (82.6, 96.4)	68 95.8 (88.1, 99.1)	29 100 (90.2, 100)	23 100 (87.8, 100)	
UCVA 20/40 or better	79 98.8 (93.2, 100)	76 96.2 (89.3, 99.2)	71 100 (95.9, 100)	29 100 (90.2, 100)	23 100 (87.8, 100)	≥85%
MRSE ± 0.50 D	74 92.5 (84.4, 97.2)	68 86.1 (76.5, 92.8)	65 91.5 (82.5, 96.8)	28 96.6 (82.2, 99.9)	20 87.0 (66.4, 97.2)	≥50%
MRSE ± 1.00 D	79 98.8 (93.2, 100)	79 100 (96.3, 100)	70 98.6 (92.4, 100)	29 100 (90.2, 100)	23 100 (87.8, 100)	≥75%
MRSE ± 2.00 D	80 100 (96.3, 100)	79 100 (96.3, 100)	71 100 (95.9, 100)	29 100 (90.2, 100)	23 100 (87.8, 100)	
Stability*						
N=80		n=79	n=71	n=29	n=22	
Change ≤ 1.00 D		79 100 (96.3, 100)	71 100 (95.9, 100)	29 100 (90.2, 100)	22 100 (87.3, 100)	≥95%
Mean Change in MRSE		-0.05 ± 0.25 (-0.11, 0.00)	0.00 ± 0.24 (-0.05, 0.06)	0.03 ± 0.26 (-0.06, 0.12)	-0.03 ± 0.31 (-0.16, 0.10)	
SAFETY VARIABLES						
N=80	n=80	n=79	n=71	n=29	n=23	
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	
Loss of > 2 lines BSCVA	0 0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	<5%
BSCVA worse than 20/25	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	
BSCVA worse than 20/40	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	
N=80†	n=80	n=79	n=71	n=29	n=23	
Increase > 2 D cylinder	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 12.2)	<5%

* Includes eyes with two consecutive exams, but not all exams.

† For eyes treated with spherical myopia.

Table 3-21 — Summary of Key Safety and Effectiveness Variables: Eyes with Astigmatic Myopia (by Manifest), N=271

Criteria	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)	FDA Targets
EFFECTIVENESS VARIABLES						
N=271	n=251	n=239	n=206	n=73	n=63	
UCVA 20/20 or better	231 92.0 (88.0, 95.1)	209 87.4 (82.6, 91.4)	192 93.2 (88.9, 96.2)	72 98.6 (92.6, 100)	61 96.8 (89.0, 99.6)	
UCVA 20/40 or better	245 97.6 (94.9, 99.1)	230 96.2 (93.0, 98.3)	205 99.5 (97.3, 100)	73 100 (96.0, 100)	63 100 (95.4, 100)	≥85%
MRSE ± 0.50 D	233 92.8 (88.9, 95.7)	209 87.4 (82.6, 91.4)	185 89.8 (84.8, 93.6)	70 95.9 (88.5, 99.1)	60 95.2 (86.7, 99.0)	≥50%
MRSE ± 1.00 D	247 98.4 (96.0, 99.6)	230 96.2 (93.0, 98.3)	205 99.5 (97.3, 100)	73 100 (96.0, 100)	63 100 (95.4, 100)	≥75%
MRSE ± 2.00 D	251 100 (98.8, 100)	239 100 (98.8, 100)	206 100 (98.6, 100)	73 100 (96.0, 100)	63 100 (95.4, 100)	
Stability*						
N=271		n=237	n=206	n=73	n=61	
Change ≤ 1.00 D		236 99.6 (97.7, 100)	204 99.0 (96.5, 99.9)	73 100 (96.0, 100)	61 100 (95.2, 100)	≥95%
Mean Change in MRSE		-0.05 ± 0.25 (-0.08, -0.02)	0.00 ± 0.26 (-0.04, 0.03)	0.03 ± 0.22 (-0.02, 0.08)	-0.03 ± 0.21 (-0.08, 0.02)	
SAFETY VARIABLES						
N=271	n=251	n=239	n=206	n=73	n=63	
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 1.2)	1 0.4 (0.0, 2.3)	0 0.0 (0.0, 1.4)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.6)	
Loss of > 2 lines BSCVA	0 0 (0.0, 1.2)	0 0.0 (0.0, 1.2)	0 0.0 (0.0, 1.4)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.6)	<5%
BSCVA worse than 20/25	0 0.0 (0.0, 1.2)	1 0.4 (0.0, 2.3)	0 0.0 (0.0, 1.4)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.6)	
BSCVA worse than 20/40	0 0.0 (0.0, 1.2)	0 0.0 (0.0, 1.2)	0 0.0 (0.0, 1.4)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.6)	

* Includes eyes with two consecutive exams, but not all exams.

Table 3-22 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 3 Months

Criteria	Stratified by Pre-Operative MRSE, All Eyes, N=318						Cum Total n/N, % (%CI)
	0.0 to -1.0 n/N, % (%CI)	<-1.0 to -2.0 n/N, % (%CI)	<-2.0 to -3.0 n/N, % (%CI)	<-3.0 to -4.0 n/N, % (%CI)	<-4.0 to -5.0 n/N, % (%CI)	<-5.0 to -6.0 n/N, % (%CI)	
EFFECTIVENESS VARIABLES							
N=318	n=10	n=67	n=80	n=71	n=58	n=32	N=318
UCVA 20/20 or better	9 90.0 (55.5, 99.7)	65 97.0 (89.6, 99.6)	72 90.0 (81.2, 95.6)	65 91.5 (82.5, 96.8)	47 81.0 (68.6, 90.1)	23 71.9 (53.3, 86.3)	281 88.4 (84.3, 91.7)
UCVA 20/40 or better	10 100 (74.1, 100)	67 100 (95.6, 100)	78 97.5 (91.3, 99.7)	69 97.2 (90.2, 99.7)	54 93.1 (83.3, 98.1)	28 87.5 (71.0, 96.5)	306 96.2 (93.5, 98.0)
MRSE ± 0.50 D	10 100 (74.1, 100)	64 95.5 (87.5, 99.1)	76 95.0 (87.7, 98.6)	60 84.5 (74.0, 92.0)	47 81.0 (68.6, 90.1)	20 62.5 (43.7, 78.9)	277 87.1 (82.9, 90.6)
MRSE ± 1.00 D	10 100 (74.1, 100)	67 100 (95.6, 100)	79 98.8 (93.2, 100)	70 98.6 (92.4, 100)	55 94.8 (85.6, 98.9)	28 87.5 (71.0, 96.5)	309 97.2 (94.7, 98.7)
MRSE ± 2.00 D	10 100 (74.1, 100)	67 100 (95.6, 100)	80 100 (96.3, 100)	71 100 (95.9, 100)	58 100 (95.0, 100)	32 100 (91.1, 100)	318 100 (99.1, 100)
SAFETY VARIABLES							
N=318	n=10	n=67	n=80	n=71	n=58	n=32	n=318
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 4.4)	1 1.3 (0.0, 6.8)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 8.9)	1 0.3 (0.0, 1.7)
Loss of > 2 lines BSCVA	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 4.4)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 8.9)	0 0.0 (0.0, 0.9)
BSCVA worse than 20/25	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 4.4)	1 1.3 (0.0, 6.8)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 8.9)	1 0.3 (0.0, 1.7)
BSCVA worse than 20/40	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 4.4)	0 0.0 (0.0, 3.7)	0 0.0 (0.0, 4.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 8.9)	0 0.0 (0.0, 0.9)
N=79*	n=4	n=13	n=21	n=12	n=17	n=12	n=79
Increase > 2 D cylinder	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)

* For eyes treated with spherical myopia.

Table 3-23 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 3 Months (Stratified by Pre-Operative MRSE): Eyes with Spherical Myopia (by Manifest), N=79

Criteria	0.0 to -1.0 n/N, % (%CI)	<-1.0 to -2.0 n/N, % (%CI)	<-2.0 to -3.0 n/N, % (%CI)	<-3.0 to -4.0 n/N, % (%CI)	<-4.0 to -5.0 n/N, % (%CI)	<-5.0 to -6.0 n/N, % (%CI)	Cum Total n/N, % (%CI)
EFFECTIVENESS VARIABLES							
N=79	n=4	n=13	n=21	n=12	n=17	n=12	N=79
UCVA 20/20 or better	4 100 (47.3, 100)	12 92.3 (64.0, 99.8)	19 90.5 (69.6, 98.8)	12 100 (77.9, 100)	16 94.1 (71.3, 99.9)	9 75.0 (42.8, 94.5)	72 91.1 (82.6, 96.4)
UCVA 20/40 or better	4 100 (47.3, 100)	13 100 (79.4, 100)	20 95.2 (76.2, 99.9)	12 100 (77.9, 100)	16 94.1 (71.3, 99.9)	11 91.7 (61.5, 99.8)	76 96.2 (89.3, 99.2)
MRSE ± 0.50 D	4 100 (47.3, 100)	12 92.3 (64.0, 99.8)	19 90.5 (69.6, 98.8)	9 75.0 (42.8, 94.5)	16 94.1 (71.3, 99.9)	8 66.7 (34.9, 90.1)	68 86.1 (76.5, 92.8)
MRSE ± 1.00 D	4 100 (47.3, 100)	13 100 (79.4, 100)	21 100 (86.7, 100)	12 100 (77.9, 100)	17 100 (83.8, 100)	12 100 (77.9, 100)	79 100 (96.3, 100)
MRSE ± 2.00 D	4 100 (47.3, 100)	13 100 (79.4, 100)	21 100 (86.7, 100)	12 100 (77.9, 100)	17 100 (83.8, 100)	12 100 (77.9, 100)	79 100 (96.3, 100)
SAFETY VARIABLES							
N=79	n=4	n=13	n=21	n=12	n=17	n=12	n=79
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)
Loss of > 2 lines BSCVA	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)
BSCVA worse than 20/25	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)
BSCVA worse than 20/40	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)
N=79	n=4	n=13	n=21	n=12	n=17	n=12	n=79
Increase > 2 D cylinder	0 0.0 (0.0, 52.7)	0 0.0 (0.0, 20.6)	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 3.7)

Table 3-24 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 3 Months (Stratified by Pre-Operative MRSE): Eyes with Astigmatic Myopia (by Manifest), N=239

Criteria	0.0 to -1.0 n/N, % (%CI)	<-1.0 to -2.0 n/N, % (%CI)	<-2.0 to -3.0 n/N, % (%CI)	<-3.0 to -4.0 n/N, % (%CI)	<-4.0 to -5.0 n/N, % (%CI)	<-5.0 to -6.0 n/N, % (%CI)	Cum Total n/N, % (%CI)
EFFECTIVENESS VARIABLES							
N=239	n=6	n=54	n=59	n=59	n=41	n=20	N=239
UCVA 20/20 or better	5 83.3 (35.9, 99.6)	53 98.1 (90.1, 100)	53 89.8 (79.2, 96.2)	53 89.8 (79.2, 96.2)	31 75.6 (59.7, 87.6)	14 70.0 (45.7, 88.1)	209 87.4 (82.6, 91.4)
UCVA 20/40 or better	6 100 (60.7, 100)	54 100 (94.6, 100)	58 98.3 (90.9, 100)	57 96.6 (88.3, 99.6)	38 92.7 (80.1, 98.5)	17 85.0 (62.1, 96.8)	230 96.2 (93.0, 98.3)
MRSE ± 0.50 D	6 100 (60.7, 100)	52 96.3 (87.3, 99.5)	57 96.6 (88.3, 99.6)	51 86.4 (75.0, 94.0)	31 75.6 (59.7, 87.6)	12 60.0 (36.1, 80.9)	209 87.4 (82.6, 91.4)
MRSE ± 1.00 D	6 100 (60.7, 100)	54 100 (94.6, 100)	58 98.3 (90.9, 100)	58 98.3 (90.9, 100)	38 92.7 (80.1, 98.5)	16 80.0 (56.3, 94.3)	230 96.2 (93.0, 98.3)
MRSE ± 2.00 D	6 100 (60.7, 100)	54 100 (94.6, 100)	59 100 (95.0, 100)	59 100 (95.0, 100)	41 100 (93.0, 100)	20 100 (86.1, 100)	239 100 (98.8, 100)
SAFETY VARIABLES							
N=239	n=6	n=54	n=59	n=59	n=41	n=20	N=239
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 5.4)	1 1.7 (0.0, 9.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 7.0)	0 0.0 (0.0, 13.9)	1 0.4 (0.0, 2.3)
Loss of > 2 lines BSCVA	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 7.0)	0 0.0 (0.0, 13.9)	0 0.0 (0.0, 1.2)
BSCVA worse than 20/25	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 5.4)	1 1.7 (0.0, 9.1)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 7.0)	0 0.0 (0.0, 13.9)	1 0.4 (0.0, 2.3)
BSCVA worse than 20/40	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 5.4)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 7.0)	0 0.0 (0.0, 13.9)	0 0.0 (0.0, 1.2)

3.1.2 Hyperopia With or Without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted at six U.S. centers. The refractive inclusion criteria specified that the patient have hyperopia ≤ 6.0 D sphere with refractive astigmatism ≤ 5.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of 6.0 D. To qualify for the study, patients also had to demonstrate agreement between the manifest, WaveScan®, and cycloplegic refraction, a BSCVA of 20/25 or better, and a wavefront-measured pupil size ≥5 mm. All study treatments were conducted using a 6 mm optical zone and a 9 mm ablation zone with intention of full correction to emmetropia. One hundred and forty-four (144) eyes were evaluated for safety and 136 eyes were evaluated for effectiveness. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopy.

A. About the Study

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

B. Patient Accountability

One hundred and forty-four (144) eyes of 74 subjects were evaluated for safety and 136 eyes were evaluated for effectiveness. Table 3-17 presents the demographic characteristics of the patient population. Table 3-18 presents the percent accountability for all eyes treated in the study. Over 95% accountability was achieved at the 1, 3, and 6-month visits.

Table 3-17 — Demographics: All Eyes, N=144

Age (in years)	**Average ± Standard Deviation Minimum to Maximum**	**51.7 ± 8.4 21 to 65**	
		Number	**% of Eyes**
Gender	Male	60	41.7
	Female	84	58.3
Race	Caucasian	124	86.1
	Asian/Pacific Islander	0	0.0
	African American	2	1.4
	American Indian/Aleut Eskimo	0	0.0
	Hispanic	18	12.5
Eyes	Right	74	51.4
	Left	70	48.6
Contact Lens History	None	122	84.7
	Soft	22	15.3
	RGP/PMMA	0	0.0

Table 3-18 — Patient Accountability: Safety Cohort: All Eyes, N=144

	1 Month		3 Months		6 Months		9 Months		12 Months	
	n	%	n	%	n	%	n	%	n	%
Available for Analysis	142	98.6	142	98.6	137	95.1	124	86.1	27	18.8
Discontinued	0	0.0	0	0.0	1	0.7	6	4.2	6	4.2
Missed Visit	2	1.4	2	1.4	4	2.8	10	6.9	0	0.0
Not yet Eligible	0	0.0	0	0.0	0	0.0	0	0.0	107	74.3
Lost to Follow-Up	0	0.0	0	0.0	2	1.4	4	2.8	4	2.8
% Accountability*	98.6%		98.6%		95.8%		89.9%		87.1%	

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

C. Data Analysis and Results

1) Pre-Operative Characteristics

The mean age of the 74 subjects participating in this trial was 51.7 ± 8.4 years. There were 43 women and 31 men. Table 3-19 presents the pre-operative refractive error stratified by manifest sphere and cylinder expressed in plus cylinder notation for the safety cohort. Table 3-20 presents the pre-operative refractive error stratified by manifest spherical equivalent and cylinder expressed in plus cylinder notation for the effectiveness cohort.

Table 3-19 — Pre-Operative Refractive Error Stratified by Manifest Sphere and Cylinder: Safety Cohort, N=144

	Cylinder													
	0 to 0.5D		>0.5 to 1D		>1 to 2 D		>2 to 3 D		>3 to 4 D		>4 to 5 D		Total	
Sphere	n	%	n	%	n	%	n	%	n	%	n	%	n	%
>0 to 1 D*	13	9.0	9	6.3	8*	5.6	2*	1.4	0	0.0	0	0.0	32	22.2
>1 to 2 D	40	27.8	20	13.9	5	3.5	1	0.7	0	0.0	0	0.0	66	45.8
>2 to 3 D	13	9.0	8	5.6	5	3.5	0	0.0	2	1.4	0	0.0	28	19.4
>3 to 4 D	5	3.5	3	2.1	1	0.7	1	0.7	2	1.4	0	0.0	12	8.3
>4 to 5 D	4	2.8	1	0.7	1	0.7	0	0.0	0	0.0	0	0.0	6	4.2
Total	75	52.1	41	28.5	20	13.9	4	2.8	4	2.8	0	0.0	144	100

* Refractions were performed at 8 feet. When adjusted for optical infinity, 4 eyes (2 with pre-operative cylinder >1 to 2 D and 2 eyes with pre-operative cylinder >2 to 3 D) have myopic spherical power (-0.16 D).

Table 3-20 — Pre-Operative Refractive Error Stratified by Manifest Spherical Equivalent and Cylinder: Effectiveness Cohort, N=136

	Cylinder							
	0 to 0.5D		>0.5 to 1D		>1 to 2 D		Total	
MRSE	n	%	n	%	n	%	n	%
>0 to 1 D	12	8.8	3	2.2	4	2.9	19	14.0
>1 to 2 D	41	30.1	18	13.2	8	5.9	67	49.3
>2 to 3 D	13	9.6	16	11.8	2	1.5	31	22.8
>3 to 4 D	3	2.2	1	0.7	5	3.7	9	6.6
>4 to 5 D	6	4.4	3	2.2	1	0.7	10	7.4
Total	75	55.1	41	30.1	20	14.7	136	100

2) Uncorrected Visual Acuity (UCVA)

All eyes in this study were targeted for emmetropia. Pre-operatively 0% of eyes had an uncorrected visual acuity (UCVA) of 20/20 or better; at the 6-month visit, 62% (81/131) of these eyes had UCVA of 20/20 or better. Tables 3-21–3-23 present the uncorrected distance acuity results for those eyes treated in the effectiveness cohort.

Table 3-21 — UCVA Over Time: All Eyes, N=136

	Pre-Op (n=136)		1 Month (n=134)		3 Months (n=134)		6 Months (n=131)		9 Months (n=118)		12 Months (n=27)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/16 or better	0	0.0	19	14.2	27	20.1	26	19.8	28	23.7	8	29.6
20/20 or better	0	0.0	78	58.2	80	59.7	81	61.8	85	72.0	21	77.8
20/25 or better	0	0.0	107	79.9	112	83.6	104	79.4	103	87.3	24	88.9
20/32 or better	0	0.0	119	88.8	124	92.5	118	90.1	111	94.1	25	92.6
20/40 or better	9	6.6	129	96.3	130	97.0	125	95.4	112	94.9	25	92.6
20/80 or better	68	50.0	134	100	134	100	131	100	118	100	27	100
20/200 or better	126	92.6	134	100	134	100	131	100	118	100	27	100
Worse than 20/200	10	7.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-22 — UCVA Over Time: Spherical Hyperopia, N=75

	Pre-Op (n=75)		1 Month (n=75)		3 Months (n=75)		6 Months (n=74)		9 Months (n=65)		12 Months (n=18)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/16 or better	0	0.0	13	17.3	16	21.3	15	20.3	16	24.6	5	27.8
20/20 or better	0	0.0	50	66.7	47	62.7	49	66.2	49	75.4	15	83.3
20/25 or better	0	0.0	62	82.7	65	86.7	61	82.4	59	90.8	17	94.4
20/32 or better	0	0.0	68	90.7	72	96.0	67	90.5	62	95.4	18	100
20/40 or better	3	4.0	73	97.3	74	98.7	72	97.3	62	95.4	18	100
20/80 or better	40	53.3	75	100	75	100	74	100	65	100	18	100
20/200 or better	70	93.3	75	100	75	100	74	100	65	100	18	100
Worse than 20/200	5	6.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-23 — UCVA Over Time: Astigmatic Hyperopia, N=61

	Pre-Op (n=61)		1 Month (n=59)		3 Months (n=59)		6 Months (n=57)		9 Months (n=53)		12 Months (n=9)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/16 or better	0	0.0	6	10.2	11	18.6	11	19.3	12	22.6	3	33.3
20/20 or better	0	0.0	28	47.5	33	55.9	32	56.1	36	67.9	6	66.7
20/25 or better	0	0.0	45	76.3	47	79.7	43	75.4	44	83.0	7	77.8
20/32 or better	0	0.0	51	86.4	52	88.1	51	89.5	49	92.5	7	77.8
20/40 or better	6	9.8	56	94.9	56	94.9	53	93.0	50	94.3	7	77.8
20/80 or better	28	45.9	59	100	59	100	57	100	53	100	9	100
20/200 or better	56	91.8	59	100	59	100	57	100	53	100	9	100
Worse than 20/200	5	8.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

At six months, more than 41% of eyes were able to achieve a post-operative uncorrected vision that was either the same or better than their pre-operative best-corrected vision.

Table 3-24 — Post-Operative Uncorrected Visual Acuity Compared to Pre-Operative Best Spectacle-Corrected Visual Acuity, N=136

	1 Month (n=134)		3 Months (n=134)		6 Months (n=131)		9 Months (n=118)	
	n	%	n	%	n	%	n	%
>2 lines better	0	0.0	0	0.0	1	0.8	0	0.0
2 lines better	1	0.7	1	0.7	0	0.0	2	1.7
1 line better	8	6.0	10	7.5	14	10.7	9	7.6
Equal	38	28.4	41	30.6	39	29.8	47	39.8
1 line worse	45	33.6	47	35.1	40	30.5	37	31.4
2 lines worse	24	17.9	21	15.7	14	10.7	10	8.5
>2 lines worse	18	13.4	14	10.4	23	17.6	13	11.0

3) Accuracy of MRSE Over Time

At 6 months post-operatively, 65% (85/131) of eyes were within ± 0.5 D, and 91% (119/131) were within ± 1 D of attempted correction. At the 1, 3, and 6 month visits, 1 eye was overcorrected by more than 2 diopters. No eyes were undercorrected by more than 2 diopters at the 1, 3, 6, or 9 month visits. Tables 3-25–3-27 present accuracy of MRSE over time.

Table 3-25 — Accuracy of Manifest Refraction Attempted vs. Achieved: All Eyes, N=136

	Pre-Op (n=136)		1 Month (n=134)		3 Months (n=134)		6 Months (n=131)		9 Months (n=118)		12 Months (n=27)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	1	0.7	73	54.5	80	59.7	85	64.9	91	77.1	22	81.5
± 1.00 D	19	14.0	120	89.6	125	93.3	119	90.8	108	91.5	25	92.6
± 2.00 D	86	63.2	133	99.3	133	99.3	130	99.2	118	100	27	100
Overcorrected						(Myopic)						
< -1.00 D			10	7.5	6	4.5	6	4.6	4	3.4	2	7.4
< -2.00 D			1	0.7	1	0.7	1	0.8	0	0.0	0	0.0
Undercorrected						(Hyperopic)						
>+1.00			4	3.0	3	2.2	6	4.6	6	5.1	0	0.0
>+2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-26 — Accuracy of Manifest Refraction Attempted vs. Achieved: Spherical Hyperopia, N=75

	Pre-Op (n=75)		1 Month (n=75)		3 Months (n=75)		6 Months (n=74)		9 Months (n=65)		12 Months (n=18)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	46	61.3	50	66.7	52	70.3	56	86.2	16	88.9
± 1.00 D	12	16.0	71	94.7	71	94.7	70	94.6	62	95.4	18	100
± 2.00 D	53	70.7	75	100	75	100	74	100	65	100	18	100
Overcorrected						(Myopic)						
< -1.00 D			2	2.7	1	1.3	0	0.0	0	0.0	0	0.0
< -2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected						(Hyperopic)						
>+1.00			2	2.7	3	4.0	4	5.4	3	4.6	0	0.0
>+2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-27 — Accuracy of Manifest Refraction Attempted vs. Achieved: Astigmatic Hyperopia, N=61

	Pre-Op (n=61)		1 Month (n=59)		3 Months (n=59)		6 Months (n=57)		9 Months (n=53)		12 Months (n=9)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	1	1.6	27	45.8	30	50.8	33	57.9	35	66.0	6	66.7
± 1.00 D	7	11.5	49	83.1	54	91.5	49	86.0	46	86.8	7	77.8
± 2.00 D	33	54.1	58	98.3	58	98.3	56	98.2	53	100	9	100
Overcorrected						(Myopic)						
< -1.00 D			8	13.6	5	8.5	6	10.5	4	7.5	2	22.2
< -2.00 D			1	1.7	1	1.7	1	1.8	0	0.0	0	0.0
Undercorrected						(Hyperopic)						
>+1.00			2	3.4	0	0.0	2	3.5	3	5.7	0	0.0
>+2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

4) Stability of MRSE

Between the 3, 6, and 9-month visits, more than 98% (116/118) of eyes experienced a change in MRSE ≤ 1.0 D. Refractive stability is reached at 6 months and confirmed at 9 months post-operatively.

Table 3-28 — Refractive Stability: Eyes That Underwent the 1, 3, 6, and 9 Month Visits: Effectiveness Cohort: All Eyes, N=118

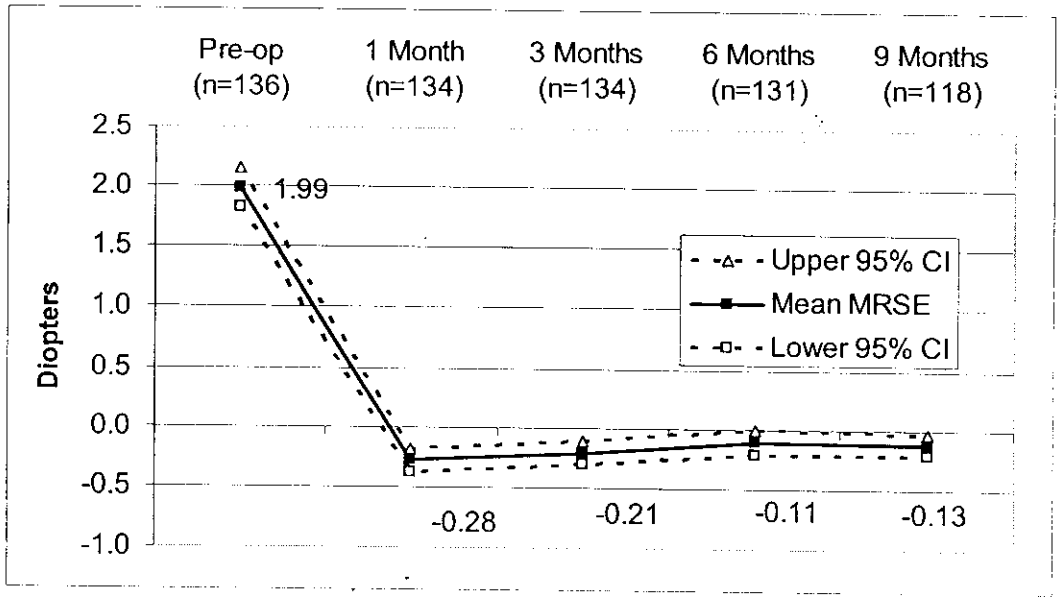
	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months
Change in MRSE by ≤ 1.0 D	114	116	116
%	96.6	98.3	98.3
95% CI	(91.5, 99.1)	(94.0, 99.8)	(94.0, 99.8)
Mean Change in MRSE	0.06	0.12	0.01
SD	0.38	0.36	0.31
95% CI	(-0.010, 0.129)	(0.056, 0.184)	(-0.046, 0.067)

Table 3-29 — Refractive Stability: Eyes That Underwent Two Consecutive Visits: Effectiveness Cohort: All Eyes

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
	n = 134	n = 131	n = 118	n = 25
Change in MRSE by ≤ 1.0 D	130	129	116	25
%	97.0	98.5	98.3	100
95% CI	(92.5, 99.2)	(94.6, 99.8)	(94.0, 99.8)	(88.7, 100)
Mean Change in MRSE	0.07	0.11	0.01	0.05
SD	0.37	0.35	0.31	0.22
95% CI	(0.008, 0.132)	(0.045, 0.166)	(-0.046, 0.067)	(-0.035, 0.135)

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

Figure 3-2 — Stability of MRSE Over Time (All Eyes, N=136)



5) Efficacy of Correction of Astigmatism

Efficacy of correction of astigmatism was evaluated at the point of stability (6 months) for eyes with hyperopic astigmatism. At 6 months post-operatively, 68% of eyes were within ± 0.5 D of intended cylinder correction, and 95% were within ± 1 D. Table 3-31 displays the mean percent reduction of cylinder for each eye for eyes stratified by pre-op cylinder.

Table 3-30 — Accuracy of Sphere to Target and Cylinder to Zero Component: Astigmatic Hyperopia, N=61

	Pre-Op (n=61)		6 Months (n=57)	
	n	%	n	%
Cylinder				
± 0.50 D	0	0.0	39	68.4
± 1.00 D	41	67.2	54	94.7

Table 3-31 — Cylinder Correction Efficacy Stratified by Pre-Operative Manifest Cylinder: Effectiveness Cohort: Astigmatic Hyperopia, N=57

Pre-Operative Cylinder	6 Months
	Mean % Reduction of Absolute Cylinder (Not a Vector)
ALL (n=57)	58.4
>0.50 to ≤1.0 D (n=37)	56.8
>1.0 to ≤2.0 D (n=20)	61.4

Table 3-32 displays the ratio of the achieved versus intended vector magnitude. The correction ratio is defined as the absolute Surgically Induced Refractive Cylinder (SIRC) divided by the absolute Intended Refractive Change (IRC) at the point of stability (6 months).

Table 3-32 — Vector Analysis Summary at 6 Months: Effectiveness Cohort: Astigmatic Hyperopia, N=57

Pre-Operative Cylinder	Correction Ratio Mean ± SD
ALL (n=57)	1.04 ± 0.38
>0.50 to ≤1.0 D (n=37)	1.03 ± 0.44
>1.0 to ≤2.0 D (n=20)	1.06 ± 0.26

6) Higher Order Aberrations

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

7) WaveScan® Spherical Equivalent

The correlation between MRSE and WaveScan-measured spherical equivalent was stronger preoperatively than postoperatively for hyperopic-treated eyes. Six months postoperatively, the mean difference between WaveScan-measured spherical equivalent and MRSE was -0.90 ± 0.35 D, compared to -0.58 ± 0.24 D preoperatively. At six months, the mean WaveScan-measured spherical equivalent was 0.79 D.

8) Best Spectacle-Corrected Visual Acuity (BSCVA)

No eye lost more than 2 lines of BSCVA at the 3, 6, 9, or 12-month visits. Table 3-33 presents the change in lines of BSCVA over time.

Table 3-33 — Change in BSCVA Over Time: All Eyes, N=144

	1 Month (n=142)		3 Months (n=142)		6 Months (n=137)		9 Months (n=124)		12 Months (n=27)	
	n	%	n	%	n	%	n	%	n	%
Decrease > 2 Lines	1	0.7	0	0.0	0	0.0	0	0.0	0	0.0
Decrease > 1 to ≤ 2 Lines*	5	3.5	5	3.5	1	0.7	1	0.8	0	0.0
Decrease > 0 to ≤ 1 Line	54	38.0	49	34.5	48	35.0	42	33.9	5	18.5
No Change	53	37.3	55	38.7	45	32.8	46	37.1	13	48.1
Increase >0 to ≤ 1 Line	27	19.0	29	20.4	38	27.7	31	25.0	8	29.6
Increase > 1 to ≤ 2 Lines	2	1.4	4	2.8	4	2.9	4	3.2	1	3.7
Increase > 2 Lines	0	0.0	0	0.0	1	0.7	0	0.0	0	0.0

* Eyes that lost 2 lines of BSCVA: 1 month, 2 (1.4%); 3 months, 1 (0.7%), 6, 9, and 12 months; 0 (0.0%).

9) Contrast Sensitivity Analysis

Table 3-34 presents the results of the contrast sensitivity analysis pre-operatively and at 1, 3, and 6 months post-operatively. The data are sorted to allow for a two-tailed paired-t analysis for the means. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease. Table 3-35 presents the change in contrast sensitivity from a baseline of more than 2 log units (>0.30) at 2 or more spatial frequencies for all eyes treated in the study.

Table 3-34 — Contrast Sensitivity: Safety Cohort: All Eyes, N=144

	Pre-Op				Change from Pre-Op to 1 Month				Change from Pre-Op to 3 Months				Change from Pre-Op to 6 Months			
CPD	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**	**3**	**6**	**12**	**18**
Dim w/ Glare	**n = 144**				**n = 139***				**n = 142**				**n = 133***			
Mean	1.52	1.51	1.01	0.57	-0.04	-0.12	-0.16	-0.11	-0.05	-0.12	-0.11	-0.10	-0.03	-0.04	-0.12	-0.06
(SE)	0.02	0.03	0.03	0.03	0.03	0.03	0.04	0.04	0.02	0.03	0.04	0.04	0.02	0.03	0.04	0.04
P Value ≤†					0.09	0.00	0.00	0.00	0.04	0.00	0.00	0.01	0.20	0.21	0.00	0.11
Dim w/o Glare	**n = 144**				**n = 139***				**n = 142**				**n = 133***			
Mean	1.56	1.63	1.19	0.70	0.00	-0.05	-0.15	-0.10	-0.03	-0.05	-0.14	-0.08	-0.02	-0.03	-0.13	-0.06
(SE)	0.02	0.02	0.03	0.03	0.03	0.03	0.04	0.04	0.02	0.03	0.04	0.04	0.02	0.03	0.04	0.03
P Value ≤†					0.99	0.05	0.00	0.01	0.27	0.08	0.00	0.03	0.44	0.21	0.00	0.04
Bright w/o Glare	**n = 144**				**n = 139***				**n = 142**				**n = 133***			
Mean	1.73	1.94	1.60	1.13	-0.02	-0.06	-0.10	-0.09	-0.01	-0.01	-0.03	-0.04	0.00	-0.02	-0.03	-0.03
(SE)	0.02	0.02	0.02	0.02	0.02	0.02	0.03	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
P Value ≤†					0.20	0.00	0.00	0.00	0.32	0.59	0.15	0.07	0.78	0.26	0.12	0.25

* Three eyes at the 1-month visit and 4 eyes at the 6-month visit did not undergo contrast sensitivity testing.

† Two-tailed paired t test for the means.

Table 3-35 — Change in Contrast Sensitivity: Safety Cohort: All Eyes, N=144

	3 Months, N=142			6 Months, N=133*		
	Decrease	No Change	Increase	Decrease	No Change	Increase
Bright without Glare	12	125	5	6	123	4
%	8.5	88.0	3.5	4.5	92.5	3.0
Dim without Glare	39	87	16	29	90	14
%	27.5	61.3	11.3	21.8	67.7	10.5
Dim with Glare	48	79	15	36	79	18
%	33.8	55.6	10.6	27.1	59.4	13.5

* Four (4) eyes did not undergo contrast sensitivity testing at the 6-month visit.

10) Retreatments

Five (5) eyes have undergone retreatment in the study (5/144, 3.5%) for undercorrections.

11) Patient Symptoms

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

Table 3-36 — Summary of Patient Symptoms: Effectiveness Cohort, N=136

	Never			Rarely			Sometimes			Often			Always			Not Reported		
	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M
	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
Dryness	44 32.4	16 11.9	18 14.1	48 35.3	40 29.9	30 23.4	36 26.5	62 46.3	58 45.3	7 5.1	12 9.0	17 13.3	1 0.7	4 3.0	5 3.9	0 0.0	0 0.0	0 0.0
Blurry Vision	42 30.9	16 11.9	19 14.8	33 24.3	40 29.9	44 34.4	52 38.2	68 50.7	52 40.6	7 5.1	8 6.0	6 4.7	2 1.5	2 1.5	7 5.5	0 0.0	0 0.0	0 0.0
Fluctuation of Vision	46 33.8	15 11.2	24 18.8	41 30.1	55 41.0	45 35.2	41 30.1	50 37.3	41 32.0	7 5.1	12 9.0	13 10.2	1 0.7	2 1.5	5 3.9	0 0.0	0 0.0	0 0.0
Glare	25 18.4	35 26.1	27 21.1	49 36.0	52 38.8	58 45.3	49 36.0	27 20.1	32 25.0	13 9.6	20 14.9	11 8.6	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Halos Around Lights	67 49.3	56 41.8	65 50.8	33 24.3	39 29.1	26 20.3	29 21.3	19 14.2	24 18.8	7 5.1	14 10.4	9 7.0	0 0.0	6 4.5	4 3.1	0 0.0	0 0.0	0 0.0
Difficulty at Night W/Glare	29 21.3	41 30.6	41 32.0	29 21.3	41 30.6	39 30.5	57 41.9	35 26.1	34 26.6	20 14.7	17 12.7	10 7.8	1 0.7	0 0.0	4 3.1	0 0.0	0 0.0	0 0.0
Ghost or Double Images	94 69.1	82 61.7	78 60.9	32 23.5	24 18.0	26 20.3	6 4.4	20 15.0	15 11.7	2 1.5	6 4.5	7 5.5	2 1.5	1 0.8	2 1.6	0 0.0	1 0.7	0 0.0

Table 3-37 — Summary of Patient Symptoms: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision: Effectiveness Cohort: All Eyes, N=136

	3 Months, N=134							6 Months, N=128						
	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR
	n	%	n	%	n	%	n	n	%	n	%	n	%	n
Dryness	4	3.0	108	80.6	22	16.4	0	5	3.9	92	71.9	31	24.2	0
Blurry Vision	13	9.7	101	75.4	20	14.9	0	14	10.9	94	73.4	20	15.6	0
Fluctuation of Vision	9	6.7	104	77.6	21	15.7	0	7	5.5	99	77.3	22	17.2	0
Glare	17	12.7	108	80.6	9	6.7	0	14	10.9	106	82.8	8	6.3	0
Halos Around Lights	16	11.9	94	70.1	24	17.9	0	16	12.5	91	71.1	21	16.4	0
Difficulty at Night With Glare	32	23.9	91	67.9	11	8.2	0	30	23.4	88	68.8	10	7.8	0
Ghost or Double Images	4	3.0	112	84.2	17	12.8	1	4	3.1	107	83.6	17	13.3	0

Table 3-38 — Summary of Patient Satisfaction: Effectiveness Cohort, N=136

	Very Satisfied			Satisfied			Not Sure			Somewhat Dissatisfied			Very Dissatisfied			Not Reported		
	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M	Pre	3M	6M
	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
Sharpness and Clarity	26 19.1	51 38.1	55 43.3	64 47.1	58 43.3	44 34.4	6 4.4	6 4.5	11 8.6	29 21.3	14 10.4	10 7.8	11 8.1	5 3.7	8 6.3	0 0.0	0 0.0	0 0.0
Consistency of Vision	27 19.9	39 29.1	44 34.4	67 49.3	62 46.3	51 39.8	14 10.3	14 10.4	8 6.3	16 11.8	16 11.9	23 18.0	12 8.8	3 2.2	2 1.6	0 0.0	0 0.0	0 0.0
Daylight Vision	32 23.5	59 44.0	59 46.1	75 55.1	62 46.3	55 43.0	8 5.9	5 3.7	5 3.9	15 11.0	5 3.7	5 3.9	6 4.4	3 2.2	4 3.1	0 0.0	0 0.0	0 0.0
Night Vision	10 7.4	34 25.4	43 33.6	57 41.9	75 56.0	51 39.8	14 10.3	10 7.5	14 10.9	40 29.4	12 9.0	15 11.7	15 11.0	3 2.2	5 3.9	0 0.0	0 0.0	0 0.0
Night Vision with Glare	6 4.4	28 20.9	29 22.7	40 29.6	64 47.8	55 43.0	28 20.7	17 12.7	19 14.8	46 34.1	22 16.4	22 17.2	15 11.1	3 2.2	3 2.3	1 0.7	0 0.0	0 0.0

Table 3-39 — Summary of Patient Satisfaction: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision: Effectiveness Cohort: All Eyes, N=136

	3 Months, N=134							6 Months, N=128						
	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR	Improve (+ ≥ 2)		No Change (0 ± 1)		Worsen (- ≥ 2)		NR
	n	%	n	%	n	%	n	n	%	n	%	n	%	n
Sharpness and Clarity	32	23.9	93	69.4	9	6.7	0	31	24.2	86	67.2	11	8.6	0
Consistency of Vision	24	17.9	94	70.1	16	11.9	0	23	18.0	89	69.5	16	12.5	0
Daylight Driving	20	14.9	111	82.8	3	2.2	0	20	15.6	100	78.1	8	6.3	0
Night Driving	47	35.1	81	60.4	6	4.5	0	47	36.7	70	54.7	11	8.6	0
Night Vision with Glare	48	36.1	74	55.6	11	8.3	1	51	39.8	63	49.2	14	10.9	0

12) Summary of Key Safety and Effectiveness Variables

The key safety and effectiveness variables are presented in Tables 3-40–3-42. The key safety and effectiveness variables stratified by pre-operative manifest refraction spherical equivalent at the point of stability (6 months) are presented in Tables 3-43–3-45.

Table 3-40 — Summary of Key Safety and Effectiveness Variables: All Eyes, N=144

Criteria	Pre-Op n % (95% CI)	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)
EFFECTIVENESS COHORT						
N=136	n=136	n=134	n=134	n=131	n=118	n=27
UCVA 20/20 or better	0 0.0 (0.0, 2.2)	78 58.2 (49.4, 66.7)	80 59.7 (50.9, 68.1)	81 61.8 (52.9, 70.2)	85 72.0 (63.0, 79.9)	21 77.8 (57.7, 91.4)
UCVA 20/40 or better	9 6.6 (3.1, 12.2)	129 96.3 (91.5, 98.8)	130 97.0 (92.5, 99.2)	125 95.4 (90.3, 98.3)	112 94.9 (89.3, 98.1)	25 92.6 (75.7, 99.1)
MRSE ± 0.50 D	1 0.7 (0.0, 4.0)	73 54.5 (45.7, 63.1)	80 59.7 (50.9, 68.1)	85 64.9 (56.1, 73.0)	91 77.1 (68.5, 84.3)	22 81.5 (61.9, 93.7)
MRSE ± 1.00 D	19 14.0 (8.6, 21.0)	120 89.6 (83.1, 94.2)	125 93.3 (87.6, 96.9)	119 90.8 (84.5, 95.2)	108 91.5 (85.0, 95.9)	25 92.6 (75.7, 99.1)
MRSE ± 2.00 D	86 63.2 (54.5, 71.3)	133 99.3 (95.9, 100)	133 99.3 (95.9, 100)	130 99.2 (95.8, 100)	118 100 (97.5, 100)	27 100 (89.5, 100)
STABILITY*			n=134	n=131	n=118	n=25
Change ≤ 1.00 D MRSE			130 97.0 (92.5, 99.2)	129 98.5 (94.6, 99.8)	116 98.3 (94.0, 99.8)	25 100 (88.7, 100)
Mean Change in MRSE ± SD			0.07 ± 0.37	0.11 ± 0.35	0.01 ± 0.31	0.05 ± 0.22
SAFETY COHORT						
N=144		n=142	n=142	n=137	n=124	n=27
Loss of > 2 lines BSCVA		1 0.7 (0.0, 3.9)	0 0.0 (0.0, 2.1)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.4)	0 0.0 (0.0, 10.5)
Loss of ≥ 2 lines BSCVA		3 2.1 (0.4, 6.0)	1 0.7 (0.0, 3.9)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.4)	0 0.0 (0.0, 10.5)
BSCVA worse than 20/25		2 1.4 (0.2, 5.0)	2 1.4 (0.2, 5.0)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.4)	0 0.0 (0.0, 10.5)
BSCVA worse than 20/40		0 0.0 (0.0, 2.1)	0 0.0 (0.0, 2.1)	0 0.0 (0.0, 2.2)	0 0.0 (0.0, 2.4)	0 0.0 (0.0, 10.5)
N=75†		n=75	n=75	n=74	n=65	n=18
Increase > 2 D cylinder		0 0.0 (0.0, 3.9)	0 0.0 (0.0, 3.9)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)

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

† For eyes treated with spherical hyperopia defined as having ≤ 0.5 D pre-operative manifest cylinder.

Table 3-41 — Summary of Key Safety and Effectiveness Variables: Spherical Hyperopia, N=75

Criteria	Pre-Op n % (95% CI)	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)
EFFECTIVENESS COHORT						
N=75	n=75	n=75	n=75	n=74	n=65	n=18
UCVA 20/20 or better	0 0.0 (0.0, 3.9)	50 66.7 (54.8, 77.1)	47 62.7 (50.7, 73.6)	49 66.2 (54.3, 76.8)	49 75.4 (63.1, 85.2)	15 83.3 (58.6, 96.4)
UCVA 20/40 or better	3 4.0 (0.8, 11.2)	73 97.3 (90.7, 99.7)	74 98.7 (92.8, 100)	72 97.3 (90.6, 99.7)	62 95.4 (87.1, 99.0)	18 100 (84.7, 100)
MRSE ± 0.50 D	0 0.0 (0.0, 3.9)	46 61.3 (49.4, 72.4)	50 66.7 (54.8, 77.1)	52 70.3 (58.5, 80.3)	56 86.2 (75.3, 93.5)	16 88.9 (65.3, 98.6)
MRSE ± 1.00 D	12 16.0 (8.6, 26.3)	71 94.7 (86.9, 98.5)	71 94.7 (86.9, 98.5)	70 94.6 (86.7, 98.5)	62 95.4 (87.1, 99.0)	18 100 (84.7, 100)
MRSE ± 2.00 D	53 70.7 (59.0, 80.6)	75 100 (96.1 100)	75 100 (96.1, 100)	74 100 (96.0, 100)	65 100 (95.5, 100)	18 100 (84.7, 100)
STABILITY*			n=75	n=74	n=65	n=16
Change ≤ 1.00 D MRSE			74 98.7 (92.8, 100)	74 100 (96.0, 100)	64 98.5 (91.7, 100)	16 100 (82.9, 100)
Mean Change in MRSE ± SD			0.08 ± 0.29	0.08 ± 0.33	0.03 ± 0.30	0.06 ± 0.24
SAFETY COHORT						
N=75		n=75	n=75	n=74	n=65	n=18
Loss of > 2 lines BSCVA		0 0.0 (0.0, 3.9)	0 0.0 (0.0, 3.9)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)
Loss of ≥ 2 lines BSCVA		2 2.7 (0.3, 9.3)	1 1.3 (0.0, 7.2)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)
BSCVA worse than 20/25		1 1.3 (0.0, 7.2)	1 1.3 (0.0, 7.2)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)
BSCVA worse than 20/40		0 0.0 (0.0, 3.9)	0 0.0 (0.0, 3.9)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)
N=75†		n=75	n=75	n=74	n=65	n=18
Increase > 2 D cylinder		0 0.0 (0.0, 3.9)	0 0.0 (0.0, 3.9)	0 0.0 (0.0, 4.0)	0 0.0 (0.0, 4.5)	0 0.0 (0.0, 15.3)

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

† For eyes treated with spherical hyperopia defined as having ≤ 0.5 D pre-operative manifest cylinder.

Table 3-42 — Summary of Key Safety and Effectiveness Variables: Astigmatic Hyperopia, N=69

Criteria	Pre-Op n % (95% CI)	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)
EFFECTIVENESS COHORT						
N=59	n=61	n=59	n=59	n=57	n=53	n=9
UCVA 20/20 or better	0 0.0 (0.0, 4.8)	28 47.5 (34.3, 60.9)	33 55.9 (42.4, 68.8)	32 56.1 (42.4, 69.3)	36 67.9 (53.7, 80.1)	6 66.7 (29.9, 92.5)
UCVA 20/40 or better	6 9.8 (3.7, 20.2)	56 94.9 (85.9, 98.9)	56 94.9 (85.9, 98.9)	53 93.0 (83.0, 98.1)	50 94.3 (84.3, 98.8)	7 77.8 (40.0, 97.2)
MRSE ± 0.50 D	1 1.6 (0.0, 8.8)	27 45.8 (32.7, 59.2)	30 50.8 (37.5, 64.1)	33 57.9 (44.1, 70.9)	35 66.0 (51.7, 78.5)	6 66.7 (29.9, 92.5)
MRSE ± 1.00 D	7 11.5 (4.7, 22.2)	49 83.1 (71.0, 91.6)	54 91.5 (81.3, 97.2)	49 86.0 (74.2, 93.7)	46 86.8 (74.7,94.5)	7 77.8 (40.0, 97.2)
MRSE ± 2.00 D	33 54.1 (40.8, 66.9)	58 98.3 (90.9, 100)	58 98.3 (90.9, 100)	56 98.2 (90.6, 100)	53 100 (94.5, 100)	9 100 (71.7, 100)
STABILITY*			n=59	n=57	n=53	n=9
Change ≤ 1.00 D MRSE			56 94.9 (85.9, 98.9)	55 96.5 (87.9, 99.6)	52 98.1 (89.9, 100)	9 100 (71.7, 100)
Mean Change in MRSE ± SD			0.06 ± 0.46	0.13 ± 0.39	0.00 ± 0.33	0.04 ± 0.14
SAFETY COHORT						
N=69		n=67	n=67	n=63	n=59	n=9
Loss of > 2 lines BSCVA		1 1.5 (0.0, 8.0)	0 0.0 (0.0, 4.4)	0 0.0 (0.0, 4.6)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 28.3)
Loss of ≥ 2 lines BSCVA		1 1.5 (0.0, 8.0)	0 0.0 (0.0, 4.4)	0 0.0 (0.0, 4.6)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 28.3)
BSCVA worse than 20/25		1 1.5 (0.0, 8.0)	1 1.5 (0.0, 8.0)	0 0.0 (0.0, 4.6)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 28.3)
BSCVA worse than 20/40		0 0.0 (0.0, 4.4)	0 0.0 (0.0, 4.4)	0 0.0 (0.0, 4.6)	0 0.0 (0.0, 5.0)	0 0.0 (0.0, 28.3)

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

Table 3-43 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months

Criteria	Stratified by Pre-Operative MRSE, All Eyes, N=137										Cum Total n/N, %	
	0.0 to 1.0 n/N, %		>1.0 to 2.0 n/N, %		>2.0 to 3.0 n/N, %		>3.0 to 4.0 n/N, %		>4.0 to 5.0 n/N, %			
EFFECTIVENESS VARIABLES												
N=131	n=19		n=63		n=30		n=9		n=10		N=131	
UCVA 20/20 or better	15	78.9	41	65.1	16	53.3	6	66.7	3	30.0	81	61.8
UCVA 20/40 or better	19	100	60	95.2	28	93.3	9	100	9	90.0	125	95.4
MRSE ± 0.50 D	14	73.7	44	69.8	17	56.7	5	55.6	5	50.0	85	64.9
MRSE ± 1.00 D	18	94.7	58	92.1	28	93.3	8	88.9	7	70.0	119	90.8
MRSE ± 2.00 D	19	100	63	100	29	96.7	9	100	10	100	130	99.2
SAFETY VARIABLES												
N=137	n=19		n=65		n=31		n=10		n=12		N=137	
Loss of ≥ 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/25	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
N=74*	n=12		n=40		n=13		n=3		n=6		N=74	
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

* For eyes treated with spherical hyperopia defined as having ≤ 0.5 D pre-operative manifest cylinder.

Table 3-44 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months

Criteria	Stratified by Pre-Operative MRSE, Spherical Hyperopia, N=74										Cum Total n/N, %
	0.0 to 1.0 n/N, %		>1.0 to 2.0 n/N, %		>2.0 to 3.0 n/N, %		>3.0 to 4.0 n/N, %		>4.0 to 5.0 n/N, %		
EFFECTIVENESS VARIABLES											
N=74	n=12		n=40		n=13		n=3		n=6		N=74
UCVA 20/20 or better	10	83.3	26	65.0	8	61.5	3	100	2	33.3	49 66.2
UCVA 20/40 or better	12	100	39	97.5	13	100	3	100	5	83.3	72 97.3
MRSE ± 0.50 D	10	83.3	28	70.0	7	53.8	2	66.7	5	83.3	52 70.3
MRSE ± 1.00 D	12	100	37	92.5	13	100	3	100	5	83.3	70 94.6
MRSE ± 2.00 D	12	100	40	100	13	100	3	100	6	100	74 100
SAFETY VARIABLES											
N=74	n=12		n=40		n=13		n=3		n=6		N=74
Loss of ≥ 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
BSCVA worse than 20/25	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
N=74*	n=12		n=40		n= 13		n=3		n=6		N=74
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0

* For eyes treated with spherical hyperopia defined as having ≤ 0.5 D pre-operative manifest cylinder.

Table 3-45 — Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months

Criteria	Stratified by Pre-Operative MRSE, Astigmatic Hyperopia, N=63										Cum Total n/N, %
	>0.0 to 1.0 n/N, %		>1.0 to 2.0 n/N, %		>2.0 to 3.0 n/N, %		>3.0 to 4.0 n/N, %		>4.0 to 5.0 n/N, %		
EFFECTIVENESS VARIABLES											
N=57	n=7		n=23		n=17		n=6		n=4		N=57
UCVA 20/20 or better	5	71.4	15	65.2	8	47.1	3	50.0	1	25.0	32 56.1
UCVA 20/40 or better	7	100	21	91.3	15	88.2	6	100	4	100	53 93.0
MRSE ± 0.50 D	4	57.1	16	69.6	10	58.8	3	50.0	0	0.0	33 57.9
MRSE ± 1.00 D	6	85.7	21	91.3	15	88.2	5	83.3	2	50.0	49 86.0
MRSE ± 2.00 D	7	100	23	100	16	94.1	6	100	4	100	56 98.2
SAFETY VARIABLES											
N=63	n=7		n=25		n=18		n=7		n=6		N=63
Loss of ≥ 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
BSCVA worse than 20/25	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0 0.0