Professional Use Information

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

CustomVue™ Treatments

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

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

This document provides information concerning the intended clinical use of the STAR S4 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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Revision	**Description**	**Date**	**ECN #**
A	CustomVue™ Treatments (not printed)	5/21/03	8696
B	CustomVue Treatments	5/28/03	8756
C	Contrast Sensitivity Data Added	4/21/04	9043

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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.

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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 ® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of 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.

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 based on a CustomVue™ treatment is contraindicated:

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

* Accutane® is a registered trademark of Hoffmann-La Roche Inc.
† Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc.

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

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

Pupil size should be evaluated under mesopic illumination conditions.

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

Pre-operative ultrasonic pachymetry measurement must be performed.

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* Imitrex® is a registered trademark of GlaxoSmithKline.

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

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

The WaveScan® sensor measures the higher order aberrations only over the diameter of the patient's pupil, to a maximum of 6.0 mm. No optical zone diameters other than 6 mm were studied in the U.S. clinical trial.

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.

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.
- over the long term (more than 1 year after surgery).
- with prior intraocular or corneal surgery of any kind.
- 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.

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) or Photorefractive Keratectomy (PRK) surgery.

- 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 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 this evaluation, 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 with and without 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

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: 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: 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

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.

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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.

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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 3-4a –3-4c present UCVA over time. Table 3-5 presents post-operative uncorrected visual acuity compared to pre-operative best spectacle-corrected visual acuity.

Table 3-4a — 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

At six months, over 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.

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Table 3-4b — 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 3-4c — 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

Table 3-5 — 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

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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 3-6a –3-6c present the accuracy of MRSE over time.

Table 3-6a — 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 3-6b — 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 3-6c — 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 3-7 and 3-8 present refractive stability over time.

Table 3-7 — 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)

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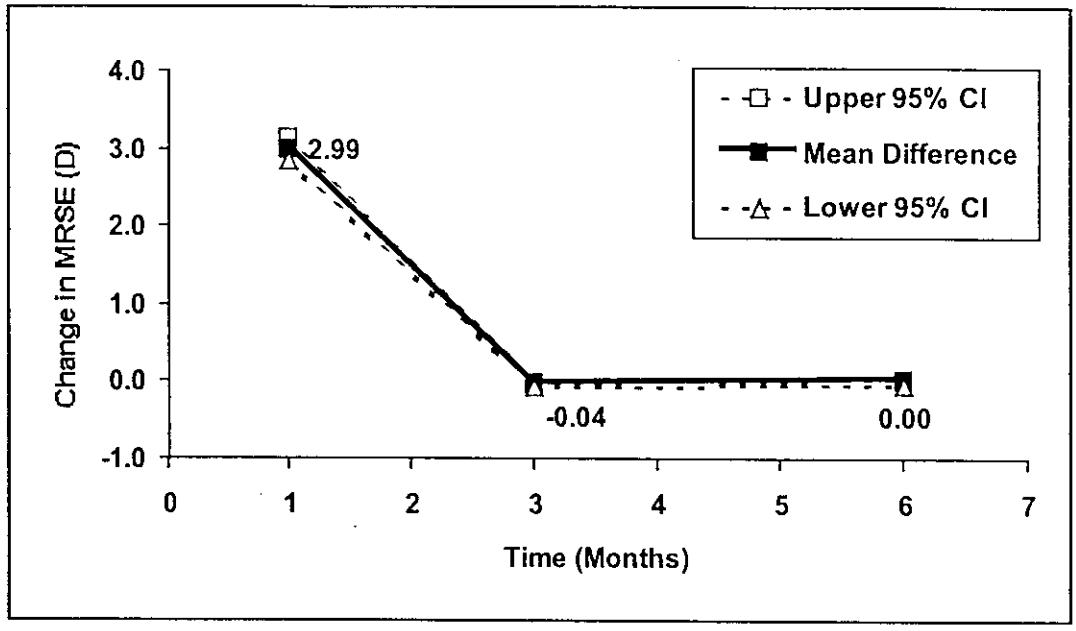
Table 3-8 — Refractive Stability: Eyes With Two Consecutive Exams

	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 of the differences in manifest spherical equivalent 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 Plot: Change in MRSE Over Time (Eyes with Visits at 1, 3, and 6 Months, N=275)



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 3-9 displays the mean % reduction of cylinder for eyes stratified by pre-op cylinder.

Table 3-9 — 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 3-10 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 3-10 — 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) 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 3-11 presents the change in lines of BSCVA over time.

Table 3-11 — 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%).

8) Contrast Sensitivity Analysis

Table 3-12 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 3-12 — 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.

9) 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.

10) Patient Symptoms

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

Table 3-13 — 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 3-14 — 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.

11) Summary of Key Safety and Effectiveness Variables

The key safety and effectiveness variables for all eyes are presented in Tables 3-15a –3-15c. The key safety and effectiveness variables stratified by pre-operative manifest refraction spherical equivalent are presented in Tables 3-16a–16c.

Table 3-15a — 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 3-15b — 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.

Table 3-15c — 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 3-16a — 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 3-16b — 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 3-16c — 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)

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4.1 Surgical Planning and Procedures

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

4.1.1 Introduction

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

4.1.2 Pre-Operative (Examination of the Patient)

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

To treat a patient using the WaveScan® data, the appropriate exams should be captured and reviewed by the surgeon in accord with the WaveScan WaveFront® System Operator's Instructions (Chapter 7). The treatment is then generated at the WaveScan and the floppy disk containing the treatment should be placed into the laser and the surgeon must verify that the patient loaded to be treated by the laser is the same as the patient lying under the laser.

Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients with myopia with and without astigmatism desiring refractive surgery should be performed within 30 days of laser refractive surgery. Patients who wear soft contact lenses must discontinue their use for at least 2 weeks, and those who wear gas permeable or hard lenses must discontinue their use for at least 3 weeks. Failure to do so will adversely affect the end surgical result.

4.1.3 Peri-Operative (Anesthesia and Analgesia)

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

4.1.4 Post-Operative

A. Medications

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

B. Follow-up Care

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

5.1 STAR S4™ Surgical Procedure

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

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

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

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

5.1.1 Step-by-Step Procedure

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

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

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

14. Instruct the patient to remove earrings prior to using the vacuum pillow. Adjust the patient's head and vacuum pillow for comfort, angle, alignment, and stability. Connect the vacuum pillow suction tubing to the suction port located on the patient chair headrest. Make sure the patient's globe is in primary position and not in an upward or downward gaze. While keeping the patient properly aligned, conform the pillow shape to the patient's head, creating support under the occiput of the skull. This is more effective than creating lateral support for the head. Holding the pillow support against the occiput, power ON the suction pump switch, which is between the two (2) tilt knobs on the headrest. After several seconds, the pillow will harden and conform to the patient's head. This creates a comfortable, stable platform for the patient. Disconnect the tubing after the pillow has hardened.

15. Position the patient with the microscope set at low zoom magnification. When the cornea is visible in the microscope, focus the image of the cornea and increase the magnification. Refer to the Operator's Manual, Section 6.9, Focusing Instructions for the STAR S4™ System Microscope. Instruct the patient to begin fixating on the fixation light.

16. Move the patient so the microscope reticle is centered over the patient's pupil. Chair movement is controlled by the doctor's keypad. Refer to the Operator's Manual, Section 6.4, Preparing Chair for Patient, for information regarding chair movement.

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

17. Continually encourage the patient to maintain fixation on the fixation light throughout the procedure.

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

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

20. The patient may be given a systemic medication (e.g., analgesic or sedative) at the physician's discretion before the procedure.

21. Perform a lid scrub with a topical surgical disinfectant.

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5. Transfer the floppy disk with the saved CustomVue™ treatment file from the WaveScan WaveFront® System to the STAR S4™ Excimer Laser. The instructions for transferring the file appear in Chapter 12, CustomVue Treatments, in the STAR S4 Operator's Manual.
6. Follow the system software prompts. A CustomVue Treatment Card is required to perform the treatment.
7. Center the mechanical position of the chair using the guide marks found on the chair base.
8. Seat the patient and lower the patient chair backrest to a full reclining position while monitoring patient clearance. Ensure that the patient is comfortable.
9. Position the patient so the lateral canthus aligns to the mark on the headrest.
10. Place the vacuum pillow under the patient's head with the bottom portion of the "U" supporting the patient's neck. Assure that there is no head tilt or rotation present. This is accomplished by assuring that a line from the vertex of the chin through the nasion is parallel to the operating table.
11. Cover the untreated eye with an opaque shield that protects the eye and occludes vision. A post-operative surgical shield covered with electrical tape is suitable for this purpose. Instruct the patient to keep both eyes opened during the surgical procedure.
12. Monitor patient clearance while rotating the patient chair to the treatment position, then lock the patient chair in place by pressing the foot pedal in the locked position. The chair must be fully rotated and the foot pedal locked for the laser to operate. Correct positioning is confirmed by the green status bar on the computer screen, which allows the procedure to continue.

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

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

22. If desired, apply topical ophthalmic antibiotic agent to the operative eye.
23. Insert a new blade into the microkeratome. Test the microkeratome for suction, movement, and correct function.
24. Instill topical ophthalmic anesthetic to the operative eye.
25. Place a lid speculum into position.
26. Place the suction ring on the eye with a slight nasal displacement and apply suction. Perform tonometry to assure adequate suction. Place balanced saline solution (BSS) on the cornea and cut a flap with the microkeratome. Release the suction.
27. Using a forcep, displace the flap. Gently wipe the exposed corneal surface with an ophthalmic surgical sponge to ensure that the surgical area is free of epithelium and other debris. Remove fluid from the fornices with an ophthalmic surgical sponge.
28. Align the operative eye so that the reticle is centered on the entrance pupil while the patient views the fixation light. Again, verify that the patient's globe is in primary position and not in an upward or downward gaze. If the patient is unable to maintain fixation to the surgeon's satisfaction a fixation handpiece may be used to hold the eye.
29. Adjust and maintain the focus on the anterior corneal surface.
30. After ensuring that the reticle is centered over the patient's pupil and the patient is viewing the fixation light, fully depress the foot pedal to perform the laser treatment. If necessary, stop the laser every 20 seconds and dry the cornea.

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

31. The footswitch has two (2) positions. The first position powers ON the aspirator and pumps within the laser. The footswitch is only partially depressed in the first position. The second position allows the laser to fire and initiates the laser surgery. The footswitch is fully depressed in the second position. It is the doctor's responsibility to continually monitor the position of the patient's eye during the surgery to assure proper ablation centration.

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

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

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

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol, except for wiping down the debris removal nozzle with isopropyl alcohol.

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

5.1.2 Using the ActiveTrak® System

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

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

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

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

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

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

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

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

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

To use the ActiveTrak System:

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

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

3. Turn on the ActiveTrak System by pressing the **Track** button on the Doctor's Keypad. When the ActiveTrak System is turned on, the outside ring and the center cross of the reticle will flash.

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- If you are using automatic centering, recenter the pupil and refocus so that the corneal surface and the reticle are in sharp focus. The ActiveTrak® System will then locate the pupil and set the treatment center. Once the pupil is located, the outside ring on the reticle will stop flashing and the treatment center will automatically be set to the center of the pupil.
- If you are setting the treatment center manually, recenter the pupil and refocus so that the corneal surface and the reticle are in sharp focus before pressing the laser footswitch to the first position to set the treatment center.

4. Once the treatment center is set, the center cross of the reticle stops flashing. (The ActiveTrak System will maintain this position throughout the treatment.)

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

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

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

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

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

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