SUMMARY OF SAFETY AND EFFECTIVENESS DATA
FOR A SUPPLEMENTAL PREMARKET APPROVAL APPLICATION

I. GENERAL INFORMATION

Device Generic Name:	Ophthalmic Excimer Laser System
Device Trade Name:	VISX STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and WaveScan WaveFront® System
Applicant's Name and Address:	VISX, Incorporated 3400 Central Expressway Santa Clara, CA 95051-0703
Date of Panel Recommendation:	None
Premarket Approval (PMA) Application Number:	P930016/S025
Date of Notice of Approval to Applicant:	July 11, 2007

The STAR Excimer Laser was originally approved on March 27, 1996, under PMA P930016, for the limited indication for myopic photorefractive keratectomy (PRK) using a 6.0 mm ablation zone in patients 18 years of age or older with 1.0 to 6.0 diopters (D) of myopia with astigmatism of ≤ 1.0 D whose refractive change for one year prior to treatment is within ± 0.5 D.

This clinical indication was expanded in supplements 3 (approved on April 24, 1997), 5 (approved on January 29, 1998), 7 (approved November 2, 1998), and 10 (approved October 18, 2000) to include PRK in patients 21 years of age or older in PRK treatments for the reduction or elimination of myopia (nearsightedness) of between 0 and -12.0 D spherical myopia at the spectacle plane and up to -4.0 D of astigmatism, hyperopia (sphere only) of between +1.0 and +6.0 D spherical equivalent with no more than 1.0 D of refractive astigmatism, and hyperopia between +0.5 and +5.0 D sphere at the spectacle plane with refractive astigmatism from +0.5 to +4.0 D with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D. On November 19, 1999 (P990010), the clinical indication was further expanded to include laser in situ keratomileusis (LASIK) treatments in patients 18 years of age or older for the reduction or elimination of myopia (nearsightedness) from 0 to -14.0 D with or without -0.50 to -5.0 D of astigmatism. Supplement 12 (approved April 27, 2001) expanded the indication to include patients 21 years of age or older in treatments for the reduction or elimination of naturally occurring hyperopia between +0.5 D and +5.0 D sphere at the spectacle plane with or without refractive astigmatism up to +3.0 D with a maximum manifest refraction spherical equivalent (MRSE) of +6.0 D. Supplement 14 (approved November 16, 2001) expanded the indication for the reduction or elimination of naturally occurring mixed astigmatism where the magnitude of cylinder (≤ 6.0 D at the spectacle plane) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs. Supplement 15 (approved August 7, 2002) added an auto-centering function to the ActiveTrak™ eye tracking system and changed the trade name to the STAR S4. Supplement 16 (approved May 23, 2003) expanded the clinical indication for

wavefront-guided LASIK for the reduction or elimination of myopic astigmatism up to - 6.00 D MRSE, with cylinder between 0.00 and -3.00 D. Supplement 18 (approved June 7, 2004) introduced the Fourier Transform Analysis of Hartmann-Shack data in WaveScan Version 3.50. Supplement 17 (approved December 14, 2004) expanded the clinical indication for wavefront-guided LASIK for the reduction or elimination of hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D. Supplement 19 (approved February 18, 2005) added an iris registration system, an ozone compensation system, and changed the trade name to the STAR S4 IR™ Excimer Laser System. Supplement 20 (approved March 17, 2005) expanded the clinical indication for wavefront-guided LASIK for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs. Supplement 22 (approved May 2, 2005) included refinements to the iris registration system. Supplement 21 (approved August 3, 2005) expanded the clinical indication for wavefront-guided LASIK to include the reduction or elimination of high myopic astigmatism up to -11.00 D MRSE with cylinder up to -3.00 D. Supplement 23 (approved September 28, 2005) implemented an algorithm adjustment for wavefront-guided LASIK treatments of high myopic astigmatism. Supplement 24 (approved May 3, 2006) introduced WaveScan software user interface changes.

The sponsor submitted this supplement to further expand the wavefront-guided LASIK clinical indications to include the visual correction of presbyopic patients with monovision, achieved by the targeted retention of -1.25 D to -2.0 D of myopia in the non-dominant eye of presbyopic myopes with low to moderate myopic astigmatism (up to -6.00 D MRSE with cylinder up to -3.00 D). The updated clinical data to support the expanded indication is provided in this summary. For more information on the data which supported the approved indications, the summaries of safety and effectiveness data (SSED) for P930016 and P990010 should be referenced. Written requests for copies of the SSED can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857 under Docket # 97M-0084 (P930016 and S3), Docket # 99M-0293 (S5), Docket # 00M-1391 (S7), Docket # 01M-0015 (S10), Docket # 01M-0305 (S12), Docket # 01M-0522 (S14), Docket # 03M-0333 (S16), Docket # 05M-0055 (S17), Docket # 05M-0151 (S20), Docket # 05M-0382 (S21), and Docket # 00M-1447 (P990010) or you may download the files from the internet sites http://www.fda.gov/cdrh/pdf/p930016.pdf and http://www.fda.gov/cdrh/pdf/p990010.pdf.

II. INDICATIONS FOR USE

The STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK) to achieve monovision by the targeted retention of myopia (-1.25 to -2.00 D) in the non-dominant eye of presbyopic myopes:

- 40 years or older who may benefit from increased spectacle independence across a range of distances with useful near vision,
- with myopic astigmatism up to -6.00 D MRSE, with cylinder up to -3.00 D, and minimum pre-operative myopia in their non-dominant eye at least as great as their targeted myopia,
- with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination; and
- with a successful preoperative trial of monovision or history of monovision experience.

III. 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®) or amiodarone hydrochloride (Cordarone®).

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the device labeling.

V. DEVICE DESCRIPTION

A. WaveScan WaveFront® System

The WaveScan WaveFront System is an integral part of this approval. It is a class III accessory device and has a separate user manual. It 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® system 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 is 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 Fourier Transform analysis. 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.

1. Data Collection

   The eye of the patient is centered in the instruments field of view and the image of the eye is brought in focus. As the patient fixates on the target, the fogging system is engaged to optically adjust the position of the target beyond the far point of the patient. This forces the patient to relax their accommodative system, so that the refraction of the eye is measured accurately. There is no pharmaceutical eye dilation required for the patient.

2. Wavefront Measurement

   During the data capture, four images are captured from the Hartmann-Shack camera within a short interval of time. The pupil camera of the instrument captures the image of the eye during the same time interval. The spot pattern images are processed to reconstruct the wavefront and if two or more of them pass the acceptance criteria, the valid measurements are averaged to yield the final measurement for the examination.

3. Registration

   Internal instrument calibration establishes the coordinate transformation between the pupil imaging camera and the Hartmann-Shack camera, so that the wavefront map can be correctly centered at the center of the pupil during the measurement.

4. Treatment Design

   The target treatment shape is automatically calculated by the WaveScan instrument from the wavefront data. Once the target shape is established, VSS™ software module generates the commands for the laser to create the target shape on the cornea. Corneal geometry, represented by the keratometry values, is taken into account in computing the laser instructions. CustomVue™ ablations to achieve monovision by the targeted retention of between approximately -1.25 to -2.00 D myopia in the non-dominant eye of presbyopic patients with low to moderate myopia and myopic astigmatism are approved for an optical zone of 6.0 mm, and an ablation zone of 8.0 mm. No treatments with optical zones greater than 6.0 mm were attempted in the U.S. Clinical Trial. All treatments utilized a variable repetition rate to a maximum of 20 Hz.

5. New Software Features

   The final commercial release versions for CustomVue™ Monovision LASIK are WaveScan software version 3.8 together with STAR software version 5.21. The WaveScan software is capable of calculating treatments with an optical zone up to 9.0 mm with total ablation zone up to 9.5 mm. WaveScan® System Software 3.8 is designed to allow the targeted retention of up to -2.00 (D) diopters of myopia in the non-dominant

eye of presbyopic patients with myopia. The upper limit of the Physician Adjustment of Sphere is increased to +2.75 (D) diopters. WaveScan® System Software 3.8 also contains a Chromatic Aberration Adjustment which compensates for differences in measured refractive values between the WaveScan® System and manifest refractions due to chromatic aberration that consists of a -0.50 D spherical offset. The effect of this adjustment will ensure that WaveScan® System-derived refractions will more closely match the measured manifest refractions, when compared at optical infinity. This adjustment affects the displayed refraction and intended ablation target derived from all WaveScan® System measurements. An additional feature of WaveScan® System Software 3.8 is a treatment algorithm adjustment to ensure that the chromatic aberration adjustment does not compromise the accuracy of intended outcomes after CustomVue™ treatments. Compensatory algorithm adjustments have been made in WaveScan® System upgrade to Software 3.8. The algorithm adjustment for high myopia introduced in WaveScan® System Software 3.65 has been removed, and a new algorithm adjustment consisting of a 0.25 D spherical offset and 8% boost in ablation efficiency is applied consistently to all treatments. After the WaveScan® System upgrade to Software 3.8, exams measured with previous versions of software will not be eligible for treatment planning.

6. Data Transfer

   The treatment files produced by the WaveScan® instrument contain information about the patient, such as name, ID and refractive data and the set of instructions for the VISX STAR laser system. They are copied onto a USB flash drive or floppy disk for transfer to the laser. The files are encrypted to prevent data tampering or data corruption.

7. Features and components of the WaveScan WaveFront® System include:
   - Computer Control
   - PC and Monitor
   - Isolation Transformer
   - Power Supply
   - LED
   - Optical Head
   - Printer
   - Motorized table

B. Microkeratome

The LASIK procedure required the use of a commercially available keratome that has been cleared for marketing via premarket notification. Three different keratomes were used in this study. Two devices consisted of a sterilization/storage tray which includes the shaper head, a left/right eye adapter, suction ring, suction handle, blade handling pin, and corneal reference marker. The instrument motor, tonometer, cleaning brush, disposable blades, power/suction supply unit with vacuum and motor footswitches and power cords are provided as separate components in an accessory stand and equipment suitcase which complete the system. The third device was a femtosecond ophthalmic surgical laser that creates a LASIK flap through precise

individual microphotodisruptions of tissue, created by tightly focused ultrashort pulses which are delivered through a disposable applanation lens while fixating the eye under very low vacuum.

C. STAR S4 IR™ Excimer Laser System

The STAR S4 IR laser system is a 193 nm excimer laser system that delivers spatially scanning ultraviolet pulses of variable diameters and slits on to the cornea. The range of diameters and slits available during treatments are 0.65 mm to 6 mm. An auto-centering dual camera infrared eye tracking system (ActiveTrak™), together with the delivery system, aligns the treatment to the eye, and compensates for eye movements during laser correction to maximize the corneal reshaping accuracy. An operating microscope is used to observe the patient procedures and to facilitate accurate focus and laser beam alignment. A debris-removal system is designed to evacuate the debris plume that occurs during ablation. The operating chair and fixation LED align the patient, while a video camera and monitor records the patient treatment.

The variable spot scanning (VSS™) feature of the laser, used for CustomVue™ treatments delivers variable diameter ultraviolet pulses to precise locations by the scanning delivery system. The VSS algorithm optimizes the ablation pattern by choosing the best combination of beam diameters and locations to achieve a target shape. VSS expands the laser capability to achieve a broader spectrum of ablation shapes than conventional treatments because the conventional algorithm optimizes only the diameter for myopic treatments and slits for hyperopic treatments.

Conventional STAR treatments utilize sphere, cylinder and axis components which are entered manually into the laser by the operator to generate the ablation treatment. CustomVue™ treatment information is generated on the WaveScan® system and transferred to the STAR S4 IR™ Excimer Laser System. The transferred information includes patient information, eye and refraction information, image of the eye, eye alignment information, and ablation instructions to the laser for beam diameters and the exact locations of the beam on the cornea. The VISX® Treatment card defines the number and the types of treatments available.

Wavefront-guided treatments using the STAR S4 IR™ and WaveScan Systems utilize an automated iris registration (IR™) system. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the WaveScan image to the same features located in the image of the iris taken using the STAR S4 IR™ camera. The treatment is rotated to align precisely with the rotation of the patient's eye under the laser. In supplement 19, VISX received approval allowing the iris registration (IR) modification to be used with all existing approved indications. Minor software improvements to the IR subsystem were also approved in supplement 22.

The STAR S4 IR laser software also contains a refinement to the method of STAR laser beam energy control by inclusion of an ozone compensation system.

Features and components of the STAR S4 IR System include:

- Excimer Laser
- Gas Management System
- Laser Beam Delivery System
- Patient Management System
- Computer Control
- VISX Treatment Card

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are currently several other alternatives for visual correction in presbyopic patients with myopic astigmatism:

- Bifocal, trifocal or progressive lens spectacles.
- Contact lenses, either monofocal, multifocal, or monovision.
- Other laser refractive surgery (wavefront-guided LASIK, conventional LASIK, or PRK) to correct distance vision, with reading glasses used for near vision.
- Other non-laser refractive surgery such as Radial Keratotomy (RK) or Automated lamellar keratoplasty (ALK) to correct distance vision, with reading glasses used for near vision.

Each alternative has its own advantages and disadvantages. A prospective patient should fully discuss with his/her care provider these alternatives in order to select the correction method that best meets his/her expectation and lifestyle.

VII. MARKETING HISTORY

The WaveScan WaveFront® System has been distributed in approximately 48 countries (Argentina, Aruba, Australia, Austria, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Cyprus, Czech Republic, Dominican Republic, Egypt, Finland, France, Germany, Greece, Guatemala, Hong Kong, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Korea, Kuwait, Malaysia, Mexico, The Netherlands, Philippines, Russia, Saudi Arabia, Singapore, Spain, Sweden, Taiwan, Thailand, Trinidad & Tobago, Turkey, UAE, United Kingdom, the United States, Uruguay and Vietnam). The WaveScan WaveFront System has not been withdrawn from any country or market for reasons of safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse reactions associated with LASIK include: loss of best spectacle corrected visual acuity (BSCVA), worsening of patient complaints such as double vision, sensitivity to bright lights, increased difficulty with night vision, fluctuations in vision, increase in intraocular pressure, corneal haze, secondary surgical intervention, corneal infiltrate or ulcer, corneal epithelial defect, corneal edema, problems associated with the flap including a lost, misplaced or misaligned flap, retinal detachment, and retinal vascular accidents.

Please refer to the complete listing of adverse events and complications observed during the clinical study which are presented in tables 31 and 32 of the Summary of Clinical Studies section.

IX. SUMMARY OF PRECLINICAL STUDIES

A. STAR Excimer Laser System

For a summary of non-clinical studies (excluding hazard analysis and software testing) for the STAR Excimer Laser System, refer to the SSED of the original PMA #P930016.

B. WaveScan Wavefront® System

1. Hazard Analysis

   Hazard Analysis and Software Testing was conducted for the combined use of the WaveScan WaveFront System and the STAR Excimer Laser System.

2. Testing for Measurement of Refractive Errors of the Eye with WaveScan Wavefront System

   A bench top study for the measurement of total refractive errors of the eye, including myopia, astigmatism, coma, spherical aberrations, trefoil and other higher order aberrations through sixth order, and Software Testing was conducted for the WaveScan WaveFront® System. The test was designed to measure conventional aberrations in a VISX model eye and in 8 phase plates with different combinations of Zernike aberrations. The data from this study indicated the VISX WaveScan WaveFront System provides an adequate and reliable measurement of total refractive errors of the eye, including myopia, astigmatism, coma, spherical aberration, trefoil and other higher order aberration through sixth order.

3. Profilometry of Ablation

   As a part of this PMA, VISX validated the accuracy of spherical adjustment of the WaveScan-derived ablation target by performing test ablations on plastic surfaces, with and without a spherical adjustment. Ablations were scanned with a surface profilometer and showed very good agreement to theoretical targets.

X. SUMMARY OF CLINICAL STUDIES

A clinical study of LASIK treatment, with the VISX STAR S4 IR® Excimer Laser System with Variable Spot Scanning and WaveScan® System-derived ablation targets to achieve monovision for the correction of presbyopic patients with low to moderate myopia with or without astigmatism, was conducted under IDE G040024. The data from this study are presented as a basis for consideration and approval. Specifically, safety and effectiveness outcomes at 6 months postoperatively were assessed, as stability was reached by that time. The IDE study is described in detail as follows:

A. Study Objective

The objective of this clinical investigation was to demonstrate that monovision LASIK treatment with the VISX STAR Excimer Laser System with Variable Spot Scanning and WaveScan derived ablation targets is safe and effective for the visual correction of presbyopic patients with myopia with and without astigmatism.

B. Study Design

This was a prospective, multi-center, open-label, non-randomized study where the primary control was the preoperative state of the treated eye (i.e., comparison of pretreatment and post-treatment visual parameters in the same eye).

C. Inclusion and Exclusion Criteria

Enrollment in the study on the effect of LASIK treatment with the VISX STAR Excimer Laser System using Variable Spot Scanning technology with WaveScan® System-derived ablation targets was limited to those subjects who met the following inclusion criteria in their operative eye(s):

- Male or female, of any race, and at least 40 years old at the time of the pre-operative examination.
- Dominant eye with manifest refraction spherical equivalent up to -6.0 D, with astigmatism up to -3.0 D at the spectacle plane.
- Non-dominant eye with MRSE up to -6.0 D, with astigmatism up to -3.0 D at the spectacle plane, and minimum pre-operative myopia at least as great as the targeted post-operative myopia, with a planned laser treatment (based on the WaveScan measurement) of at least 0.75 diopter sphere or spherical equivalent, or no required treatment to achieve the intended outcome.
- Best spectacle corrected visual acuity (BSCVA) of 20/20 or better.
- Wavefront measurement diameter $\geq$ 5.0 mm.
- Manifest refraction within $\pm$ 0.50 D of WaveScan refraction (sphere and cylinder) and no more than 15 degrees of difference between axes for eyes with cylinder greater than 0.50 D.
- Manifest refraction within $\pm$ 0.50 D of Cycloplegic refraction (sphere).
- WaveScan refraction within $\pm$ 0.50 D of Cycloplegic refraction (sphere and cylinder) and no more than 15 degrees of difference between axes for eyes with cylinder greater than 0.50 D.
- Pachymetric measurement minus the maximal depth ablated (as described by the VISX software) added to the flap thickness is greater than or equal to 250 microns (i.e., Pachymetry $-$ [Depth of ablation + Flap thickness] $\geq$ 250 microns).
- Eyes that demonstrated refractive stability confirmed by a change of less than or equal to 0.50 diopter (sphere and cylinder) at an exam at least 12 months prior to the baseline examination. The astigmatic axis must also be within 15 degrees for eyes with cylinder greater than 0.50 D.
- Contact lens wearers who removed soft lenses at least 1 week prior and rigid (Gas permeable and PMMA) lenses at least 2 weeks prior to baseline measurements. At that baseline examination, cycloplegic and manifest refractions as well as corneal topography were obtained. If the investigator determined that the topography was

within normal limits, surgery was scheduled at least one week after the initial exam, with no contact lens wear permitted prior to the surgery. If on the day of scheduled surgery, for the operative eye, repeat central keratometry readings and manifest refraction spherical equivalents did not differ significantly from the initial exam measurements (by more than 0.50 diopter), surgery proceeded. If the refractive change exceeded this criterion, the surgery was rescheduled after refractive stability was achieved.

- Planned treatment such that the anticipated post-operative keratometry value in any meridian will be > 33 D. Anticipated post-operative keratometry values will be calculated by multiplying the MRSE by 0.8, and subtracting that value from the mean pre-operative keratometry value. In other words, [((Flat K + Steep K) x 0.5) - (MRSE x 0.8)] > 33 D.
- Subjects willing and capable of returning for follow-up examinations for the duration of the study.

Subjects were not permitted to enroll in the study if they met any of the following exclusion criteria:

- Female subjects who were pregnant, breast-feeding or intended to become pregnant over the course of the study.
- Subjects whose fellow eye did not meet all inclusion criteria or fall within approved indications for treatment using the VISX STAR Excimer Laser.
- Subjects who used concurrent topical or systemic medications which might have impaired healing, including but not limited to: antimetabolites, isotretinoin (Accutane®) within 6 months of treatment, and amiodarone hydrochloride (Cordarone®) within 12 months of treatment.

  NOTE: The use of topical or systemic corticosteroids, whether chronic or acute, was deemed to adversely affect healing and subjects using such medication were specifically excluded from eligibility.
- Subjects who had a history of any of the following medical conditions, or any other condition that could have affected wound healing: collagen vascular disease, autoimmune disease, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to unstable thyroid disorders and diabetes), lupus, and rheumatoid arthritis.

  NOTE: The presence of diabetes (either type 1 or 2), regardless of disease duration, severity or control, specifically excluded subjects from eligibility.
- Subjects who had a history of prior intraocular or corneal surgery (including cataract extraction), active ophthalmic disease or abnormality (including, but not limited to, blepharitis, recurrent corneal erosion, dry eye syndrome, neovascularization > 1mm from limbus), clinically significant lens opacity, clinical evidence of trauma (including scarring), at risk for developing strabismus, evidence of glaucoma, or propensity for narrow angle glaucoma in the operative eye(s).

  NOTE: This included any subject with open angle glaucoma, regardless of medication regimen or control. Additionally, any subject with an intraocular pressure (IOP) greater than 21 mm Hg at baseline was specifically excluded from eligibility.
- Subjects who had evidence of keratoconus, corneal irregularity, or abnormal videokeratography in the operative eye(s).

- Subjects who had known sensitivity or inappropriate responsiveness to any of the medications used in the post-operative course.
- Subjects who were participating in any other clinical trial.

D. Study Plan, Subject Assessments, and Efficacy Criteria

All subjects were expected to return for follow-up examinations at 1 and 7 days, and 1, 3, 6, 9, 12 and 24 months postoperatively.

Subjects were permitted to have second eyes (fellow eyes) treated at the discretion of the investigator at the same time as the first eye (primary eyes) or after the primary eye treatment.

In addition, subjects were eligible for retreatment no sooner than 3 months after treatment with submission of appropriate clinical data, planned treatment, and agreement of the medical monitor in advance.

All study treatments were conducted using a 6 mm optical zone and an 8 mm ablation zone with intention of full correction to emmetropia. The parameters measured during the study were:

- At 24 hours and 1 week: subjective patient symptoms, UCVA, and anterior segment examination by biomicroscopy. Manifest refraction and BSCVA were also conducted on each subject at the 1-week visit. Adverse events, complications, medications and other clinical findings were also noted.
- At 1 and 3 months: visual acuity (uncorrected, and best spectacle corrected), manifest refraction, keratometry, videokeratography, WaveScan® measurement, contrast sensitivity, reading function, applanation tonometry, anterior segment examination by biomicroscopy, and a subjective questionnaire. Dim pupil size was also conducted on each subject at the 3-month visit only. Adverse events, complications, medications and other clinical findings were also noted.
- At 6, 9, 12, and 24 months: visual acuity (uncorrected and best spectacle corrected), manifest refraction, keratometry, corneal videokeratography, WaveScan measurement, contrast sensitivity, reading function, applanation tonometry, anterior segment examination by biomicroscopy, and a subjective questionnaire. After cycloplegia, a refraction, dilated media and fundoscopic examination were performed. Adverse events, complications, medications, and other clinical findings were noted as appropriate. Stereopsis was also conducted on each subject at the 6-month visit only. During the 9 month post-operative examination, contrast sensitivity, the subjective questionnaire, cycloplegia and post-cycloplegia testing were not required. An assessment of distance glasses was conducted at 9 and 12-months only.

The primary efficacy variables for this study were: improvement of UCVA, predictability of manifest refraction spherical equivalent (MRSE), refractive stability, subject satisfaction, and assessment of spectacle dependence.

E. Study Period and Investigational Sites and Demographics

1. Study Period and Investigational Sites

One hundred and sixty subjects were treated in this study at seven U.S. centers between September 28, 2004 and September 30, 2005. There were 7 investigational sites that provided eligible data for analysis.

2. Demographics

Of the 160 treated subjects, 35.0% (56/160) were from male subjects and 65.0% (104/160) were from female subjects. Furthermore, 81.9% (131/160) were Caucasians, 5.0% (8/160) were African Americans, 4.4% (7/160) were Asian/Pacific Islanders, and 7.5% (12/160) were of other races, reported as Hispanic. The left eye was dominant in 28.8% (46/160) of the cases and the right eye was dominant in 71.3% (114/160) of the cases. The age of the subjects ranged from 40 to 65 years, with a mean of 50.2 years.

Table 1 presents demographic information for all subjects.

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

Category	Classification	n	%
Gender	Male	56	35.0
	Female	104	65.0
Race	Caucasian	131	81.9
	African American	8	5.0
	Native American/ Alaskan Native	2	1.3
	Asian	7	4.4
	Other*	12	7.5
Dominant Eyes	Right	114	71.3
	Left	46	28.8
Contact Lens History**	None	35	21.9
	Soft	115	71.9
	RGP/PMMA	10	6.3
Monovision History	Prior Monovision Contact Lens Use	67	41.9
	No Prior Monovision Contact Lens Use	93	58.1
Age (in Years)	Mean	50.2	
	SD	±5.1	
	Min	40	
	Max	65	

*Other classification of "race" included: Hispanic
**Contact Lens History was not available for three subjects. The percentage for this portion of the analysis is based on non-missing values.

F. Data Analysis and Results

1. Preoperative Characteristics

Tables 2 and 3 contain a summary of the preoperative manifest refractive error stratified by manifest refraction spherical equivalent and cylinder, expressed in minus cylinder notation, for treated dominant and non-dominant eyes, respectively. All refractions were measured at 4 meters and adjusted to a standard vertex distance (12.5 mm) and optical infinity (by subtracting 0.25 D from the spherical component of the refraction) for data analysis and presentation.

Table 2: Pre-Op Refractive Error Stratified by Manifest Spherical Equivalent and Cylinder *Dominant Eyes (N=159)*

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

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

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

2. Postoperative Results

a. Subject Accountability

Of the 292 eyes treated, over 97% accountability was achieved at all postoperative visits. Table 4 presents subject accountability over time.

Table 4: Subject Accountability

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

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

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

b. Stability of Outcome

Stability of outcome was evaluated for dominant eyes with refractions at two consecutive visits. Between all consecutive visits, 100% of dominant eyes experienced a change of 1.0 diopter or less. Between the 3 and 6-month visits, the mean change in MRSE for dominant eyes was -0.03 D. This represents an annualized change in MRSE of -0.12 D. Stability was achieved at 6 months, and maintained through 12 months. The confidence intervals for the mean change in MRSE include zero between the 3 and 6, 6 and 9, and 9 and 12-month visits. Table 5 presents refractive stability data for dominant eyes with two consecutive visits.

Table 5: Stability of MRSE: Two Consecutive Visits
***Dominant Eyes* (N=159)**

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
	(n=155)	(n=155)	(n=150)	(n=145)
Change in MRSE by ≤ 0.5 D 95% CI	148 95.5% (90.9, 98.2)	150 96.8% (92.6, 98.9)	150 100% (98.0, 100)	144 99.3% (96.2, 100)
Change in MRSE by ≤ 1.0 D 95% CI	155 100% (98.1, 100)	155 100% (98.1, 100)	150 100% (98.0, 100)	145 100% (98.0, 100)
Mean Change in MRSE ± SD 95% CI	-0.08 ± 0.25 (-0.12, -0.04)	-0.03 ± 0.23 (-0.07, 0.00)	-0.02 ± 0.18 (-0.05, 0.01)	0.00 ± 0.18 (-0.03, 0.03)

At least 99% of non-dominant eyes experienced a change of 1.0 diopter or less over all consecutive visits. Between the 3 and 6-month visits, the mean change in MRSE for non-dominant eyes was -0.03 D, representing an annualized change in MRSE of -0.12 D. Stability of MRSE for non-dominant eyes was achieved at 6 months and maintained through 12 months. The confidence intervals for the mean change in MRSE for all non-dominant eyes include zero between all consecutive visits.

Table 6 presents refractive stability data for non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism, with two consecutive visits.

Table 6: Stability of MRSE: Two Consecutive Visits
Non-Dominant Eyes (N=137)

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
All Non-Dominant Eyes (NDEs)	**(n=133)**	**(n=133)**	**(n=132)**	**(n=131)**
Change in MRSE by ≤0.5 D	128 96.2%	132 99.2%	131 99.2%	127 96.9%
95% CI	(91.4, 98.8)	(95.9, 100)	(95.9, 100)	(92.4, 99.2)
Change in MRSE by ≤1.0 D	132 99.2%	133 100%	132 100%	131 100%
95% CI	(95.9, 100)	(97.8, 100)	(97.8, 100)	(97.7, 100)
Mean Change in MRSE ± SD	-0.02 ± 0.26	-0.03 ± 0.21	0.00 ± 0.19	-0.03 ± 0.23
95% CI	(-0.06, 0.03)	(-0.07, 0.01)	(-0.03, 0.04)	(-0.07, 0.01)
NDEs w/ Spherical Myopia	**(n=81)**	**(n=81)**	**(n=82)**	**(n=81)**
Change in MRSE by ≤0.5 D	79 97.5%	80 98.8%	81 98.8%	79 97.5%
95% CI	(91.4, 99.7)	(93.3, 100)	(93.4, 100)	(91.4, 99.7)
Change in MRSE by ≤1.0 D	81 100%	81 100%	82 100%	81 100%
95% CI	(96.4, 100)	(96.4, 100)	(96.4, 100)	(96.4, 100)
Mean Change in MRSE ± SD	-0.03 ± 0.23	-0.01 ± 0.21	0.02 ± 0.20	-0.07 ± 0.21
95% CI	(-0.08, 0.02)	(-0.06, 0.04)	(-0.02, 0.07)	(-0.12, -0.03)
NDEs w/ Myopic Astigmatism	**(n=52)**	**(n=52)**	**(n=50)**	**(n=50)**
Change in MRSE by ≤0.5 D	49 94.2%	52 100%	50 100%	48 96.0%
95% CI	(84.1, 98.8)	(94.4, 100)	(94.2, 100)	(86.3, 99.5)
Change in MRSE by ≤1.0 D	51 98.1%	52 100%	50 100%	50 100%
95% CI	(89.7, 100)	(94.4, 100)	(94.2, 100)	(94.2, 100)
Mean Change in MRSE ± SD	0.00 ± 0.31	-0.06 ± 0.20	-0.03 ± 0.18	0.05 ± 0.24
95% CI	(-0.09, 0.09)	(-0.12, -0.01)	(-0.08, 0.02)	(-0.02, 0.12)

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c. Effectiveness Outcomes

The data from one hundred fifty-nine (159) dominant eyes and one hundred thirty-seven (137) non-dominant eyes of one hundred sixty (160) subjects who were enrolled and treated in this study were used to evaluate effectiveness. Effectiveness analyses are also presented separately non-dominant eyes with spherical myopia (eyes with $\leq$ 0.5 D preoperative manifest cylinder, n=83), and myopic astigmatism (eyes with > 0.5 D preoperative manifest cylinder, n=54). Vector Analyses were conducted at the point of defined stability, 6-months, for non-dominant eyes with myopic astigmatism.

1) Binocular Uncorrected Distance Visual Acuity (UCDVA)

Uncorrected distance visual acuity (UCDVA) was measured under photopic lighting conditions in the subject's dominant eye and binocularly at 4 meters, without any lens correction, using the VectorVision CSV-1000 ETDRS test face. Table 7 presents UCDVA results over time for all subjects. At the 6-month point of stability, 86.7% of subjects achieved an outcome of UCDVA of 20/20 or better.

Table 7: Binocular UCDVA Over Time
All Subjects (N=160)

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

2) Binocular Uncorrected Near Visual Acuity Over Time

Uncorrected near visual acuity (UCNVA) was measured under photopic lighting conditions in the subject's non-dominant eye and binocularly at 16 inches without any lens correction, using the ETDRS 40 cm Near card for acuity testing. At least 88% of subjects achieved 20/20 or better near vision at the 3, 6, 9, and 12-month visits. Table 8 presents binocular UCNVA over time.

Table 8: Binocular UCNVA Over Time
All Subjects N=160

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

3) Simultaneous Binocular Uncorrected Distance and Near Visual Acuity Over Time

Approximately 80% of subjects achieved 20/20 or better vision at both distance and near at the 3, 6, 9, and 12-month visits. The percentage of subjects who achieved simultaneous levels of uncorrected visual acuity at both distance and near over time is presented in Table 9.

Table 9: Binocular Simultaneous Uncorrected Distance and Uncorrected Near Visual Acuity
All Subjects (N=160)

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

4) Binocular Uncorrected Intermediate Visual Acuity Over Time

Uncorrected intermediate visual acuity (UCIVA) was measured under photopic lighting conditions binocularly at 60 centimeters without any lens correction, using the ETDRS acuity test for 60 cm. Over 80% of subjects achieved 20/20 or better intermediate vision at the 6, 9, and 12-month visits. Table 10 presents binocular UCIVA over time.

Table 10: Binocular UCIVA Over Time
All Subjects (N=160)

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

5) Monocular Uncorrected Distance Visual Acuity (UCDVA) Over Time

Monocular UCDVA testing was limited to those treated eyes targeted for emmetropia (dominant eyes). Over 85% of dominant eyes achieved 20/20 or better uncorrected distance vision at the 3, 6, 9, and 12-month visits. Table 11 presents UCDVA distance results over time for all treated dominant eyes.

Table 11: Uncorrected Distance Visual Acuity
Dominant Eyes (N=159)

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

6) Monocular Uncorrected Near Visual Acuity (UCNVA) Over Time

Monocular UCNVA testing was limited to those treated eyes targeted for a myopic outcome (non-dominant eyes). Over 80% of non-dominant eyes achieved 20/20 or better uncorrected near vision at the 3, 6, 9, and 12-month visits. Table 12 presents monocular UCNVA distance results over time for all treated non-dominant eyes.

Table 12: Monocular Uncorrected Near Visual Acuity
Non-Dominant Eyes (N=137)

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

Table 13 presents monocular UCNVA distance results over time for all treated non-dominant eyes with spherical myopia.

Table 13: Monocular Uncorrected Near Visual Acuity
Non-Dominant Eyes with Spherical Myopia (N=83)

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

Table 14 presents monocular UCNVA distance results over time for all treated non-dominant eyes with myopic astigmatism.

Table 14: Monocular Uncorrected Near Visual Acuity
Non-Dominant Eyes with Myopic Astigmatism (N=54)

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

Six months postoperatively, one half of the study subjects (50.6%, 80/158) were able to see as well or better at near with no correction as they could see using best correction for near in both eyes preoperatively. Table 15 presents post-operative uncorrected distance near visual acuity compared to pre-operative best-corrected distance near visual acuity over time for all subjects.

Table 15: Post-Operative Binocular UCNVA Compared to Pre-Operative Binocular BCNVA *All Subjects* (N=160)

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

7) Accuracy

Tables 16, 17, 18 and 19 present the accuracy of sphere and cylinder over time for all dominant eyes, all non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism, respectively. Accuracy of cylinder analysis is limited to eyes with myopic astigmatism.

At 6 months post-operatively, 89.8% (141/157) of dominant eyes were within 0.5 D and 98.7% (155/157) were within 1.0 D of attempted sphere correction. Additionally, 83.6% (61/73) of dominant eyes were within 0.5 D and 95.9% (70/73) were within 1.0 D of attempted cylinder correction. Table 16 presents the accuracy of sphere and cylinder over time for all dominant eyes.

Table 16: Accuracy of Sphere and Cylinder Component
Dominant Eyes (N=159)

	Pre-Op	1 Month	3 Months	6 Months	9 Months	12 Months
	n %	n %	n %	n %	n %	n %
Sphere	n=159	n=158	n=156	n=157	n=151	n=148
± 0.50 D 95% CI	0 0.0% (0.0, 1.9)	138 87.3% (81.1, 92.1)	137 87.8% (81.6, 92.5)	141 89.8% (84.0, 94.1)	136 90.1% (84.1, 94.3)	130 87.8% (81.5, 92.6)
± 1.00 D 95% CI	3 1.9% (0.4, 5.4)	153 96.8% (92.8, 99.0)	154 98.7% (95.4, 99.8)	155 98.7% (95.5, 99.8)	149 98.7% (95.3, 99.8)	148 100% (98.0, 100)
Mean ± SD	-3.50 ± 1.24	0.08 ± 0.41	0.00 ± 0.41	-0.03 ± 0.41	-0.09 ± 0.38	-0.11 ± 0.39
Attempted		-3.50 ± 1.24	-3.50 ± 1.25	-3.50 ± 1.24	-3.55 ± 1.23	-3.49 ± 1.26
Achieved		-3.58 ± 1.22	-3.50 ± 1.24	-3.47 ± 1.21	-3.45 ± 1.22	-3.38 ± 1.25
% Achieved		104.0%	100.8%	100.4%	97.8%	97.2%
Cylinder^	n=73	n=73	n=71	n=73	n=67	n=66
± 0.50 D 95% CI	0 0.0% (0.0, 4.0)	65 89.0% (79.5, 95.1)	64 90.1% (80.7, 95.9)	61 83.6% (73.0, 91.2)	56 83.6% (72.5, 91.5)	62 93.9% (85.2, 98.3)
± 1.00 D 95% CI	46 63.0% (50.9, 74.0)	73 100% (96.0, 100)	71 100% (95.9, 100)	70 95.9% (88.5, 99.1)	67 100% (95.6, 100)	66 100% (95.6, 100)
Mean ± SD	-1.10 ± 0.45	-0.27 ± 0.29	-0.27 ± 0.29	-0.28 ± 0.35	-0.26 ± 0.30	-0.19 ± 0.28
Attempted		-1.10 ± 0.45	-1.08 ± 0.44	-1.10 ± 0.45	-1.07 ± 0.45	-1.11 ± 0.46
Achieved		-0.82 ± 0.50	-0.81 ± 0.48	-0.82 ± 0.51	-0.81 ± 0.50	-0.92 ± 0.47
% Achieved		72.7%	72.9%	73.4%	73.9%	83.6%

^ Cylinder analysis limited to those eyes with pre-op manifest cylinder >0.5 D (N=73)

At 6 months post-operatively, 89.6% (121/135) of non-dominant eyes were within 0.5 D and 99.3% (134/135) were within 1.0 D of attempted sphere correction. Additionally, 90.6% (48/53) of non-dominant eyes were within 0.5 D and 98.1% (52/53) were within 1.0 D of attempted cylinder correction. Table 17 presents the accuracy of sphere and cylinder over time for all non-dominant eyes.

Table 17: Accuracy of Sphere and Cylinder Components
Non-Dominant Eyes (N=137)

	Pre-Op (n=137)	1 Month (n=136)	3 Months (n=134)	6 Months (n=135)	9 Months (n=133)	12 Months (n=133)
Sphere	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	7 5.1% (2.1, 10.2)	123 90.4% (84.2, 94.8)	121 90.3% (84.0, 94.7)	121 89.6% (83.2, 94.2)	121 91.0% (84.8, 95.3)	121 91.0% (84.8, 95.3)
± 1.00 D 95% CI	27 19.7% (13.4, 27.4)	135 99.3% (96.0, 100)	132 98.5% (94.7, 99.8)	134 99.3% (95.9, 100)	131 98.5% (94.7, 99.8)	131 98.5% (94.7, 99.8)
Mean ± SD	-3.83 ± 1.06	-1.74 ± 0.45	-1.75 ± 0.45	-1.78 ± 0.46	-1.79 ± 0.46	-1.82 ± 0.46
Attempted		-2.11 ± 1.04	-2.10 ± 1.04	-2.11 ± 1.04	-2.15 ± 1.02	-2.12 ± 1.04
Achieved		-2.10 ± 1.09	-2.07 ± 1.03	-2.05 ± 1.02	-2.09 ± 1.01	-2.01 ± 1.04
% Achieved		98.7%	101.2%	99.7%	98.1%	95.3%
Cylinder^	n=54	n=54	n=52	n=53	n=50	n=52
± 0.50 D 95% CI	0 0.0% (0.0, 5.4)	49 90.7% (79.7, 96.9)	46 88.5% (76.6, 95.6)	48 90.6% (79.3, 96.9)	46 92.0% (80.8, 97.8)	47 90.4% (79.0, 96.8)
± 1.00 D 95% CI	25 46.3% (32.6, 60.4)	53 98.1% (90.1, 100)	51 98.1% (89.7, 100)	52 98.1% (89.9, 100)	50 100% (94.2, 100)	51 98.1% (89.7, 100)
Mean ± SD	-1.20 ± 0.46	-0.26 ± 0.29	-0.27 ± 0.32	-0.24 ± 0.32	-0.24 ± 0.29	-0.23 ± 0.29
Attempted		-1.20 ± 0.46	-1.19 ± 0.45	-1.21 ± 0.46	-1.18 ± 0.45	-1.19± 0.45
Achieved		-0.94 ± 0.54	-0.92 ± 0.49	-0.97 ± 0.55	-0.94 ± 0.53	-0.96 ± 0.52
% Achieved		74.6%	75.0%	76.9%	76.6%	77.6%

^ Cylinder analysis limited to those eyes with pre-op manifest cylinder >0.5 D (N=54).

Table 18 presents the accuracy of sphere and cylinder over time for all treated non-dominant eyes with spherical myopia.

Table 18: Accuracy of Sphere (to Target) and Cylinder (to Zero) Component
Non-Dominant Eyes with Spherical Myopia (N=83)

	Pre-Op (n=83)	1 Month (n=82)	3 Months (n=82)	6 Months (n=82)	9 Months (n=83)	12 Months (n=81)
Sphere	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	1 1.2% (0.0, 6.5)	76 92.7% (84.8, 97.3)	73 89.0% (80.2, 94.9)	70 85.4% (75.8, 92.2)	73 88.0% (79.0, 94.1)	74 91.4% (83.0, 96.5)
± 1.00 D 95% CI	13 15.7% (8.6, 25.3)	82 100% (96.4, 100)	81 98.8% (93.4, 100)	82 100% (96.4, 100)	82 98.8% (93.5, 100)	80 98.8% (93.3, 100)
Mean ± SD	-3.96 ± 1.02	-1.75 ± 0.44	-1.77 ± 0.44	-1.77 ± 0.45	-1.75 ± 0.47	-1.85 ± 0.46
Attempted	-	-2.24 ± 1.04	-2.22 ± 1.03	-2.23 ± 1.04	-2.24 ± 1.04	-2.23 ± 1.04
Achieved	-	-2.21 ± 1.04	-2.17 ± 1.00	-2.18 ± 1.00	-2.21 ± 1.01	-2.10 ± 1.01
% Achieved	-	101.1%	100.4%	100.4%	102.0%	95.2%

Table 19 presents the accuracy of sphere and cylinder over time for all treated non-dominant eyes with myopic astigmatism.

Table 19: Accuracy of Sphere (to Target) and Cylinder (to Zero) Component
Non-Dominant Eyes with Myopic Astigmatism (N=54)

	Pre-Op n=54	1 Month n=54	3 Months n=52	6 Months n=53	9 Months n=50	12 Months n=52
Sphere	n %	n %	n %	n %	n %	n %
± 0.50 D 95% CI	6 11.1% (4.2, 22.6)	47 87.0% (75.1, 94.6)	48 92.3% (81.5, 97.9)	51 96.2% (87.0, 99.5)	48 96.0% (86.3, 99.5)	47 90.4% (79.0, 96.8)
± 1.00 D 95% CI	14 25.9% (15.0, 39.7)	53 98.1% (90.1, 100)	51 98.1% (89.7, 100)	52 98.1% (89.9, 100)	49 98.0% (89.4, 99.9)	51 98.1% (89.7, 100)
Mean ± SD	-3.63 ± 1.09	-1.71 ± 0.48	-1.71 ± 0.47	-1.79 ± 0.48	-1.85 ± 0.43	-1.78 ± 0.48
Attempted	-	-1.91 ± 1.02	-1.92 ± 1.03	-1.93 ± 1.02	-2.01 ± 0.99	-1.94 ± 1.03
Achieved	-	-1.91 ± 1.15	-1.92 ± 1.06	-1.86 ± 1.02	-1.89 ± 1.00	-1.87 ± 1.08
% Achieved	-	95.1%	102.6%	98.6%	91.7%	95.4%
Cylinder	n=54	n=54	n=52	n=53	n=50	n=52
± 0.50 D 95% CI	0 0.0% (0.0, 5.4)	49 90.7% (79.7, 96.9)	46 88.5% (76.6, 95.6)	48 90.6% (79.3, 96.9)	46 92.0% (80.8, 97.8)	47 90.4% (79.0, 96.8)
± 1.00 D 95% CI	25 46.3% (32.6, 60.4)	53 98.1% (90.1, 100)	51 98.1% (89.7, 100)	52 98.1% (89.9, 100)	50 100% (94.2, 100)	51 98.1% (89.7, 100)
Mean ± SD	-1.20 ± 0.46	-0.26 ± 0.29	-0.27 ± 0.32	-0.24 ± 0.32	-0.24 ± 0.29	-0.23 ± 0.29
Attempted		-1.20 ± 0.46	-1.19 ± 0.45	-1.21 ± 0.46	-1.18 ± 0.45	-1.19 ± 0.45
Achieved		-0.94 ± 0.54	-0.92 ± 0.49	-0.97 ± 0.55	-0.94 ± 0.53	-0.96 ± 0.52
% Achieved		74.6%	75.0%	76.9%	76.6%	77.6%

Tables 20, 21, 22 an 23 present the accuracy of manifest refraction spherical equivalent over time for all dominant eyes, all non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism, respectively.

At 6-months, 88.5% of dominant eyes were within 0.50 D and 98.1% of eyes were within 1.0 D of intended correction. Table 20 provides the accuracy of the intended treatment in dominant eyes.

Table 20: Accuracy of MRSE: Intended vs. Achieved
Dominant Eyes (N=159)

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

All non-dominant eyes were intentionally undercorrected to achieve good near vision. At 6 months post-operatively, 87.4% (118/135) of eyes were within 0.5 D and 99.3% (134/135) were within 1.0 D of attempted correction. No eye was overcorrected or undercorrected by more than 2.0 diopters. Table 21 presents the accuracy of MRSE results in treated non-dominant eyes.

Table 21: Accuracy of MRSE: Intended vs. Achieved
Non-Dominant Eyes (N=137)

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

Table 22 presents the accuracy of MRSE results in treated non-dominant eyes with spherical myopia.

Table 22: Accuracy of MRSE: Intended vs. Achieved
Non-Dominant Eyes with Spherical Myopia (N=83)

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

Table 23 presents the accuracy of MRSE results in treated non-dominant eyes with myopic astigmatism.

Table 23: Accuracy of MRSE: Intended vs. Achieved
Non-Dominant Eyes with Myopic Astigmatism (N=54)

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

Table 24 presents the accuracy of MRSE results for achieved anisometropia with over 90% of eyes within 0.50 D of intended outcome.

Table 24: Accuracy of MRSE: Attempted vs. Achieved Anisometropia
All Subjects (N=160)

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

8) Summary of Key Safety and Effectiveness Variables

Summaries of the key safety and effectiveness variables at Stability Endpoint of 6 months stratified by pre-operative MRSE are presented in Tables 25, 26, 27 and 28 for all dominant eyes, non-dominant eyes, non-dominant eyes with spherical myopia, and non-dominant eyes with myopic astigmatism, respectively.

Table 25: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months: *Dominant Eyes Stratified by Preoperative MRSE* (N=157)

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

Table 25 (continued): Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months: *Dominant Eyes Stratified by Preoperative MRSE* (N=157)

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

Table 26: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months: *Non-Dominant Eyes Stratified by Preoperative MRSE* (N=135)

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

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

Table 26 (continued): Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months: *Non-Dominant Eyes Stratified by Preoperative MRSE* (N=135)

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

Table 27: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months:
***Non-Dominant Eyes with Spherical Myopia Stratified by Preoperative MRSE* (N=82)**

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

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

Table 27 (continued): Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months: *Non-Dominant Eyes with Spherical Myopia Stratified by Preoperative MRSE* (N=82)

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

Table 28: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months:
***Non-Dominant Eyes with Myopic Astigmatism Stratified by Preoperative MRSE* (N=53)**

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

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

Table 28 (continued): Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months:
***Non-Dominant Eyes with Myopic Astigmatism Stratified by Preoperative MRSE* (N=53)**

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

d. 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 significantly change after CustomVue™ treatment. Table 29 presents wavefront root-mean-square (RMS) values over time for dominant and non-dominant eyes with 5 mm minimum diameter wavefront measurements, as aberration analyses are standardized at and calculated over a 5 mm pupil diameter.

Table 29: Higher Order Wavefront Aberration RMS Over Time
Dominant and Non- Dominant Eyes

	Pre-Op Mean ± SD	**1 Month Mean ± SD**	**3 Months Mean ± SD**	**6 Months Mean ± SD**	**9 Months Mean ± SD**	**12 Months Mean ± SD**
Dominant Eyes	n=156	n=144	n=148	n=142	n=139	n=133
All higher order	0.19 ±0.06	0.22 ±0.07	0.22 ±0.06	0.22 ±0.06	0.22 ±0.07	0.21 ± 0.06
Coma	0.11 ±0.06	0.13 ±0.06	0.13 ±0.07	0.12 ±0.06	0.13 ±0.07	0.13 ± 0.06
Trefoil	0.09 ±0.05	0.09 ±0.05	0.10 ±0.05	0.10 ±0.05	0.10 ±0.05	0.09 ± 0.05
Spherical Aberration	0.07 ±0.04	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08 ± 0.05
Secondary Astigmatism	0.04 ±0.02	0.05 ±0.03	0.05 ±0.02	0.05 ±0.02	0.05 ±0.03	0.05 ± 0.02
Tetrafoil	0.04 ±0.02	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ± 0.03
5^{th} order	0.03 ±0.02	0.05 ±0.03	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ± 0.02
6^{th} order	0.02 ±0.02	0.04 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ± 0.02
Signed Value of Spherical Aberration	0.06 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07±0.06	0.07 ±0.06	0.07 ± 0.06
Min, Max	(-0.16,0.22)	(-0.13,0.21)	(-0.11,0.22)	(-0.12,0.20)	(-0.08,0.24)	(-0.10,0.22)
Non-Dominant Eyes	n=135	n=124	n=123	n=126	n=122	n=122
All higher order	0.20 ±0.06	0.20 ±0.08	0.20 ±0.07	0.20 ±0.06	0.20 ±0.06	0.20±0.06
Coma	0.11 ±0.06	0.11 ±0.07	0.10 ±0.06	0.11 ±0.06	0.11 ±0.06	0.10±0.06
Trefoil	0.10 ±0.05	0.09 ±0.05	0.09 ±0.05	0.08 ±0.05	0.09 ±0.05	0.09±0.05
Spherical Aberration	0.07 ±0.05	0.07 ±0.04	0.08 ±0.05	0.08 ±0.05	0.08 ±0.05	0.08±0.05
Secondary Astigmatism	0.04 ±0.02	0.05 ±0.03	0.04 ±0.03	0.05 ±0.03	0.05 ±0.02	0.04±0.02
Tetrafoil	0.04 ±0.02	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05 ±0.03	0.05±0.02
5th order	0.03 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04 ±0.02	0.04±0.02
6th order	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03 ±0.02	0.03±0.02
Signed Value of Spherical Aberration	0.06 ±0.06	0.06 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07 ±0.06	0.07 ±0.06
Min, Max	(-0.15,0.20)	(-0.09,0.22)	(-0.10,0.22)	(-0.09,0.27)	(-0.08,0.24)	(-0.11,0.26)

Table 30 presents wavefront-derived refraction values over time for dominant and non-dominant eyes with 4 mm minimum diameter wavefront measurements, as wavefront refraction analyses are standardized at and calculated over a 4 mm pupil diameter.

Table 30: WaveScan Spherical Equivalent and Cylinder Over Time
Dominant and Non-Dominant Eyes

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

e. Safety Outcomes

Data from the clinical study provided reasonable assurance of device safety. The benchmark for each adverse event is a rate of less than 1 % per type of event. There were no deaths in this study. There were twelve (12) instances of diffuse lamellar keratitis (DLK), eleven (11) that occurred prior to the 1-month visit, one corneal infiltrate and two instances of elevated IOP, also prior to the 1-month visit, as presented in Table 31. Complications that occurred during the clinical trial are summarized in Table 32. Analyses of contrast sensitivity outcomes are presented in Tables 33, 34, 35, 36, and 37.

Table 31: Summary of Adverse Events
***All Treated Eyes* (N=296)**

	<1 Month (n=296)		1 Month (n=294)		3 Months (n=290)		6 Months (n=292)		9 Months (n=284)		12 Months (n=281)	
	n	%	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal epithelial defect involving the keratectomy at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema at 1 month or later (specify "flap" or "bed" or both)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface with loss of 2 or more lines of BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Miscreated Flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Melting of the flap (LASIK only)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Uncontrolled IOP >10 mm Hg or any reading > 25 mm Hg	2	0.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease in BSCVA of > 10 letter 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

Other: One instance of iritis reported at interim visit between 9 and 12 months and twelve (12) instances of DLK (11 occurred prior to the 1-month visit) were reported as adverse events during the course of the study.

Table 32: Summary of Complications
***All Treated Eyes* (N=296)**

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

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

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

Subjects reported the frequency of both ghost (or shadow) images and diplopia (two distinct images) on their periodic questionnaire. No subjects with diplopia reported the diplopia as occurring "often" or "always". Ghost images were reported as occurring "often" by four subjects and "always" by one subject.

Distance contrast sensitivity testing was conducted binocularly at 8 feet under photopic, mesopic, and mesopic with glare test conditions pre-operatively and at 1, 3, 6, 9, and 12-months post-operatively. Near contrast sensitivity testing was conducted binocularly at

[1] Overall, 1.0% of eyes (3/296) experienced epithelium in the interface
[2] Overall, 17.5% of subjects (28/160) were reported with the Complication of ghost images or diplopia for at least one visit.

16 inches under photopic test conditions pre-operatively and at 6-months post-operatively.

Subject responses to the five spatial frequencies (1.5 (near only), 3, 6, 12 and 18 cycles per degree (CPD)) were measured with the subject's best corrected vision using the VectorVision CSV-1000E and converted from contrast levels to log units. The data is sorted to allow for a two-tailed paired-t for the means analysis. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease.

Tables 33 and 34 present the results of the best-corrected binocular contrast sensitivity analysis for all subjects (N=160). Tables 35, 36 and 37 present the results of a sub-study (n=30) of uncorrected binocular contrast sensitivity at 24 months postoperatively compared to best-corrected binocular contrast sensitivity preoperatively.

Table 33: Best-Corrected Contrast Sensitivity
All Subjects (N=160)

	Pre-Op					Change from Pre-Op to 1 Month				Change from Pre-Op to 3 Months			
CPD	1.5	3	6	12	18	3	6	12	18	3	6	12	18
Distance Photopic													
		n=160	n=160	n=160	n=160	n=157	n=157	n=157	n=157	n=157	n=157	n=157	n=157
Mean		1.82	2.04	1.69	1.22	-0.02	-0.03	-0.02	-0.03	0.00	0.01	0.04	0.03
(SE)		0.012	0.015	0.018	0.019	0.013	0.015	0.018	0.022	0.012	0.014	0.017	0.019
P-Value		-	-	-	-	0.135	0.036	0.253	0.186	0.759	0.347	0.030	0.125
Distance Mesopic													
		n=160	n=160	n=160	n=160	n=157	n=157	n=157	n=157	n=157	n=157	n=157	n=157
Mean		1.67	1.75	1.27	0.76	-0.02	-0.03	-0.08	-0.02	0.02	0.02	-.01	0.03
(SE)		0.015	0.023	0.032	0.035	0.016	0.021	0.029	0.031	0.016	0.024	0.032	0.035
P-Value		-	-	-	-	0.342	0.115	0.006	0.524	0.256	0.464	0.844	0.455
Distance Mesopic with Glare													
		n=160	n=160	n=160	n=160	n=157	n=157	n=157	n=157	n=157	n=157	n=157	n=157
Mean		1.65	1.67	1.15	0.69	-0.03	-0.04	-0.07	-0.02	-0.02	0.01	0.04	0.07
(SE)		0.015	0.022	0.034	0.034	0.018	0.024	0.027	0.031	0.018	0.028	0.035	0.036
P-Value		-	-	-	-	0.090	0.062	0.008	0.428	0.193	0.677	0.310	0.066
Near Photopic													
	n=160	n=160	n=160	n=160	n=157*								
Mean	1.72	1.95	1.99	1.67	1.32								
(SE)	0.014	0.013	0.015	0.018	0.022								
P-Value	-	-	-	-	-								

* The data from 3 eyes was not available for near contrast sensitivity at pre-op

Table 33 (continued): Best-Corrected Contrast Sensitivity
All Subjects (N=160)

	Change from Pre-Op to 6 Months					Change from Pre-Op to 9 Months				Change from Pre-Op to 12-Months			
CPD	1.5	3	6	12	18	3	6	12	18	3	6	12	18
Distance Photopic													
		n=156	n=156	n=156	n=156	n=151	n=151	n=151	n=151	n=149	n=149	n=149	n=149
Mean		0.02	0.03	0.05	0.05	0.04	0.05	0.07	0.07	0.03	0.05	0.07	0.06
(SE)		0.013	0.016	0.018	0.020	0.012	0.015	0.019	0.019	0.013	0.016	0.020	0.021
P-Value		0.179	0.114	0.011	0.008	0.001	0.001	0.001	0.000	0.009	0.004	0.000	0.004
Distance Mesopic													
		n=156	n=156	n=156	n=156	n=151	n=151	n=151	n=151	n=149	n=149	n=149	n=149
Mean		0.02	0.01	0.03	0.05	0.02	0.05	0.03	0.06	0.04	0.04	0.08	0.12
(SE)		0.016	0.023	0.031	0.033	0.017	0.023	0.031	0.033	0.017	0.023	0.035	0.034
P-Value		0.221	0.591	0.393	0.164	0.205	0.021	0.322	0.073	0.023	0.061	0.020	0.001
Distance Mesopic with Glare													
		n=156	n=156	n=156	n=156	n=151	n=151	n=151	n=151	n=149	n=149	n=149	n=149
Mean		-0.01	0.05	0.07	0.10	0.02	0.06	0.11	0.12	0.04	0.10	0.16	0.16
(SE)		0.018	0.023	0.034	0.035	0.016	0.026	0.033	0.034	0.017	0.023	0.034	0.035
P-Value		0.740	0.050	0.030	0.006	0.351	0.015	0.001	0.001	0.010	0.000	0.000	0.000
Near Photopic													
	n=155	n=155	n=155	n=155	n=149								
Mean	0.03	0.00	0.00	0.02	0.02								
(SE)	0.015	0.015	0.018	0.020	0.023								
P-Value	0.035	0.932	0.856	0.395	0.388								

Table 34 presents the change in best-corrected contrast sensitivity from baseline of more than 2 lines (>0.30 log units) at 2 or more spatial frequencies at 3, 6, 9, and 12-months post-operatively for all subjects.

Table 34: Change in Best-Corrected Contrast Sensitivity *All Subjects (N=160)*

	3 Months n=157				6 Months n=158				9 Months n=152				12 Months n=149			
	Decrease	No Change	Increase	Not Reported	Decrease	No Change	Increase	Not Reported	Decrease	No Change	Increase	Not Reported	Decrease	No Change	Increase	Not Reported
	n %	n %	n %	n	n %	n %	n %	n	n %	n %	n %	n	n %	n %	n %	n
Distance Photopic	2 1.3%	148 94.3%	7 4.5%	0	2 1.3%	147 94.2%	7 4.5%	2	1 0.7%	141 93.4%	9 6.0%	1	2 1.3%	138 92.6%	9 6.0%	0
Distance Mesopic	16 10.2%	131 83.4%	10 6.4%	0	16 10.3%	126 80.8%	14 9.0%	2	11 7.3%	124 82.1%	16 10.6%	1	11 7.4%	118 79.2%	20 13.4%	0
Distance Mesopic w/Glare	14 8.9%	129 82.2%	14 8.9%	0	16 10.3%	117 75.0%	23 14.7%	2	11 7.3%	119 78.8%	21 13.9%	1	10 6.7%	115 77.2%	24 16.1%	0
Near Photopic					8 5.2%	137 88.4%	10 6.5%	3								

Table 35 presents the change in contrast sensitivity from baseline (with correction) of more than 2 lines (>0.30 log units) at 2 or more spatial frequencies at 3, 6, 9, and 12-months post-operatively (without correction).

Table 35: Change in Uncorrected Contrast Sensitivity *(N=30)*

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

*Two tailed paired t-test for the means.
^One subject did not have preoperative near photopic testing at 18 cpd.

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

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

^One subject did not have preoperative near photopic testing at 18 cpd.

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

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

^One subject did not have preoperative near photopic testing at 18 cpd.

f. Retreatment

As of the database lock on August 30, 2005 eight (8) eyes of seven subjects had undergone retreatment. Seven (7) dominant eyes were treated for improved distance vision, and one (1) non-dominant eye was retreated for improved near vision. Five eyes were retreated after the 6 month exam and two eyes were retreated after the 9 month exam. Data from these eyes, prior to retreatment, are included in all analyses. Eight retreatments are insufficient to yield clinically useful information; however, caution should be taken to assure refractive stability before performing additional procedures.

g. Factors Associated with Outcomes

To evaluate the consistency of results and effect of treatment by study site and baseline characteristics, results at the 6 month (post-operative) point of stability were analyzed. The observed outcomes for key safety and effectiveness variables were calculated and compared to target percentages to determine if the results were significantly different.

For each category, the observed percentage was calculated and compared to the target percentage using a chi-square goodness-of-fit test. The p-value from the chi-square test was reported below the percentage. Exact confidence intervals were also calculated. Specifically, the analyses of effect included: sex (female and male), race (white and other), investigational site, age group (40 to 49, 50 to 59, and ≥60), pre-operative contact lens use (none, soft, and GP/PMMA), pre-operative MRSE (<0 to -1.0, < -1.0 to -2.0, < -2.0 to -3.0, < -3.0 to -4.0, < -4.0 to -5.0, < -5.0 to -6.0, and < -6.0 to -7.0), laser room temperature (< 70°, 70°, 71°, 72° to 73°, 74°, and > 75°), laser room humidity (< 30%, 30% to 35%, 36% to 40%, 41% to 45%, and > 45%), surgeon, iris registration status, and microkeratome model.

A Mantel-Haenszel one degree of freedom chi-square test was used to compare the observed percentages across categories for ordinal data. To compare the observed percentages across non-ordinal categories, Cochran- Mantel-Haenszel test was

employed. Those p-values were employed to identify situations where there were differences between categories.

Depending on the treatment cohort, the appropriate outcomes observed at the 6 month post-operative visit were compared against target values to identify statistically significant differences. The outcome measures and the target percentage(s) for the outcomes are as follows:

- MRSE (intended vs. achieved) ± 0.50 D, target ≥ 50%,
- MRSE (intended vs. achieved) ± 1.00 D, target ≥ 75%,
- UCDVA 20/40 or better, target ≥ 85% (Dominant eyes only)
- UCNVA 20/40 or better, target ≥ 85% (Non-Dominant eyes only)
- BCDVA worse than 20/40, target < 1%
- Loss of >2 lines BCDVA, target < 5%
- BCNVA worse than 20/40, target < 1%
- Loss of >2 lines BCNVA, target < 5%

Throughout these analyses, in all cases the observed value met the target value. In many of these subcategories, the observed value was statistically significantly superior ($p < 0.05$) to the target value.

Because no eye had a BCDVA or BCNVA loss of > 2 lines, and no eye had a BCDVA or BCNVA worse than 20/40, there were no detectable differences between study sites and baseline characteristics relative to these safety outcomes.

<u>All Treated Dominant Eyes with 6-month data (N=157)</u>
Microkeratome model, age group, pre-study MRSE, temperature, sex, iris registration, site, contact lens, surgeon, and relative humidity had no statistically significant differences between subcategories for all outcomes.

There was a significant difference in race between white and "other" for achieved MRSE within ± 1.00 D of intended (p=0.0188). Dominant eyes of white subjects had a higher proportion of achieved MRSE within ± 1.00 of intended than those of non-white subjects (99.2% versus 92.3%).

<u>All Treated Non-Dominant Eyes with 6-month data (N=135)</u>
Microkeratome model, age group, pre-study MRSE, temperature, sex, site, contact lens, surgeon, and relative humidity had no statistically significant differences between subcategories for all outcomes.

There was a significant difference in race between white and non-white for achieved MRSE within ± 0.50 D of intended (p=0.0329) and achieved MRSE within ± 1.00 D of intended (p=0.0273). Non-dominant eyes of white subjects had a higher proportion of achieved MRSE within ± 0.50 D of intended than eyes of non-white subjects (90.2% versus 73.9%). Non-dominant eyes of white subjects also had a higher proportion of achieved MRSE within ± 1.00 D of intended than those of non-white subjects (100% versus 95.7%).

There was also a significant difference in iris registration for achieved MRSE within ± 0.50 of intended (p=0.0249). Non-dominant eyes treated without iris registration enabled had a higher proportion of achieved MRSE within ± 0.50 of intended than

eyes treated with iris registration enabled (91.6% versus 77.5%). An analysis by site revealed two sites which did not perform any procedures using iris registration (sites 1 and 5). In order to control for the site differences, a Cochran-Mantel-Haenszel test was performed. The results for this test indicate that when controlling for site difference, none of the sites showed a statistically significant difference in the proportion of non-dominant eyes achieving MRSE within ± 0.50 D of intended between eyes treated with and without iris registration (p=0.3478 for site 2, p=0.1923 for site 3, p=0.1479 for site 4, p=1.000 for site 6, and p=0.1818 for site 9).

Conclusion: While some statistically significant differences between accuracy of MRSE outcomes were noted for race, the differences are not considered to be clinically significant. The differences in accuracy of MRSE outcomes in non-dominant eyes that were associated with iris registration were not found to be significant when analyzed by site. Across all analyses, all target values were met or exceeded.

h. Subject Satisfaction

Subjects were asked to complete a questionnaire to evaluate satisfaction with visual quality pre-operatively and post-operatively. Subjects were asked to provide their level of satisfaction (Very Satisfied, Satisfied, Not Sure, Somewhat Dissatisfied, or Very Dissatisfied) with ten (10) different visual conditions as well as an overall rating of satisfaction with their vision. Table 38 presents a summary of this satisfaction pre-operatively with their usual correction, and at 6 and 12-months post-operatively without correction, and Table 39 presents change in satisfaction. Table 40 presents overall satisfaction with monovision correction.

Subjects also rated their use of spectacle correction on questionnaires pre- and postoperatively, as summarized in Table 41.

Subjects were asked to provide the frequency (Never, Rarely, Sometimes, Often, or Always) they experienced eleven (11) different visual symptoms. Table 42 summarizes these results pre-operatively with their usual correction, and at 6 and 12-months post-operatively without correction, and Table 43 presents change in symptoms.

Table 38: Summary of Subject Satisfaction with Visual Quality
***All Subjects* (N=160)**

	Very Satisfied			Satisfied			Not Sure			Somewhat Dissatisfied			Very Dissatisfied		
	Pre^ n=155	6M n=157	12M n=149	Pre^ n=155	6M n=157	12M n=149	Pre^ n=155	6M n=157	12M n=149	Pre^ n=155	6M n=157	12M n=149	Pre^ n=155	6M n=157	12M n=149
Activity	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
Intermediate Vision	37 23.9	109 69.4	112 75.2	89 57.4	38 24.2	30 20.1	0 0.0	2 1.3	2 1.3	24 15.5	7 4.5	4 2.7	5 3.2	1 0.6	1 0.7
Depth Perception	57 36.8	112 71.3	108 72.5	83 53.5	42 26.8	39 26.2	1 0.6	0 0.0	1 0.7	14 9.0	2 1.3	1 0.7	0 0.0	1 0.6	0 0.0
Peripheral Vision	55 35.5	113 72.0	108 72.5	76 49.0	39 24.8	38 25.5	5 3.2	1 0.6	2 1.3	16 10.3	3 1.9	1 0.7	3 1.9	1 0.6	0 0.0
Near Vision (sustained)	33 21.3	92 58.6	94 63.1	84 54.2	54 34.4	48 32.2	2 1.3	3 1.9	0 0.0	23 14.8	7 4.5	5 3.4	13 8.4	1 0.6	2 1.3
Near Vision (brief)	41 26.5	112 71.3	102 68.5	76 49.0	38 24.2	42 28.2	3 1.9	2 1.3	0 0.0	27 17.4	3 1.9	4 2.7	8 5.2	2 1.3	1 0.7
Near Vision (small print)	23 14.8	67 42.7	75 50.3	59 38.1	67 42.7	53 35.6	13 8.4	7 4.5	4 2.7	38 24.5	11 7.0	13 8.7	22 14.2	5 3.2	4 2.7
Distance Vision at Night	21 13.5	59 37.6	67 45.0	90 58.1	73 46.5	55 36.9	9 5.8	9 5.7	9 6.0	31 20.0	11 7.0	16 10.7	4 2.6	5 3.2	2 1.3
Distance Vision at Night w/ Glare	13 8.4	60 38.2	58 38.9	85 54.8	68 43.3	62 41.6	15 9.7	9 5.7	9 6.0	35 22.6	18 11.5	17 11.4	7 4.5	2 1.3	3 2.0
Distance Vision at Dusk	26 16.8	76 48.4	82 55.0	95 61.3	64 40.8	56 37.6	14 9.0	4 2.5	2 1.3	18 11.6	10 6.4	7 4.7	2 1.3	3 1.9	2 1.3
Distance Vision Under Active Conditions	42 27.3	107 68.6	111 74.5	72 46.8	39 25.0	34 22.8	5 3.2	2 1.3	2 1.3	29 18.8	5 3.2	2 1.3	6 3.9	3 1.9	0 0.0
Overall Satisfaction	26 16.8	105 66.9	106 71.1	76 49.0	42 26.8	38 25.5	8 5.2	4 2.5	1 0.7	42 27.1	6 3.8	3 2.0	3 1.9	0 0.0	1 0.7

^ 5 subjects did not complete a preoperative questionnaire.

Table 39: Change in Subject Satisfaction: Comparison of Pre-Op with Correction to Post-Op without Correction
All Subjects (N=155^)

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

^5 subjects did not complete a pre-operative questionnaire and are excluded from this analysis.

Subjects were asked if given the opportunity, whether they would elect to have a monovision treatment again. Responses to this question are provided in Table 40.

Table 40: Overall Satisfaction with Monovision Correction
All Subjects (N=160)

	6 Months (n=157)			12 Months (n=149)		
	Yes	No	Not Sure	Yes	No	Not Sure
	N %	n %	n %	n %	n %	n %
Overall Satisfaction with Monovision	152 96.8	0 0.0	5 3.2	146 98.0	1 0.7	2 1.3

Subjects were also asked to specify how frequently they used corrective lenses (never, rarely, sometimes, often, or always). Table 41 reflects the change in use of corrective lenses, of at least 2 levels, at 6 and 12 months postoperatively.

Table 41: Change in Frequency of Use of Corrective Lenses from Pre-Op
All Subjects (N=155^)

	6 Months (n=152)						12 Months (n=145)					
	Decrease in Use		No Change		Increase in Use		Decrease in Use		No Change		Increase in Use	
	n	%	n	%	n	%	n	%	n	%	n	%
Change in use of Corrective Lenses from Pre-op	146	96.1	6	3.9	0	0.0	132	91.0	12	8.3	1	0.7

^5 subjects did not complete a pre-operative questionnaire and are excluded from this analysis.

Table 42: Summary of Visual Symptoms
All Subjects (N=160)

	Never			Rarely			Sometimes			Often			Always		
	Pre^ n=155	6M n=157	12M n=112	Pre^ n=155	6M n=157	12M n=112	Pre^ n=155	6M n=157	12M n=112	Pre^ n=155	6M n=157	12M n=112	Pre^ n=155	6M n=157	12M n=112
Symptoms	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
Dryness	24 15.5	24 15.3	24 16.1	53 34.2	53 33.8	65 43.6	68 43.9	62 39.5	50 33.6	9 5.8	15 9.6	9 6.0	1 0.6	3 1.9	1 0.7
Blurry vision	47 30.3	44 28.0	50 33.6	52 33.5	73 46.5	75 50.3	52 33.5	35 22.3	21 14.1	3 1.9	3 1.9	3 2.0	1 0.6	2 1.3	0 0.0
Fluctuation of vision	55 35.5	66 42.0	65 43.6	52 33.5	58 36.9	55 36.9	44 28.4	30 19.1	26 17.4	4 2.6	3 1.9	3 2.0	0 0.0	0 0.0	0 0.0
Glare	41 26.5	67 42.7	63 42.3	59 38.1	52 33.1	60 40.3	50 32.3	31 19.7	21 14.1	3 1.9	4 2.5	5 3.4	2 1.3	3 1.9	0 0.0
Halos around lights	54 34.8	74 47.1	76 51.0	51 32.9	36 22.9	43 28.9	38 24.5	31 19.7	22 14.8	10 6.5	13 8.3	5 3.4	2 1.3	3 1.9	3 2.0
Difficulty at night	23 14.8	53 33.8	51 34.2	70 45.2	45 28.7	48 32.2	42 27.1	44 28.0	40 26.8	14 9.0	10 6.4	5 3.4	6 3.9	5 3.2	5 3.4
Ghosting or shadowing of images	101 65.2	108 68.8	116 77.9	39 25.2	33 21.0	22 14.8	12 7.7	10 6.4	5 3.4	3 1.9	3 1.9	5 3.4	0 0.0	3 1.9	1 0.7
Double images	139 89.7	136 86.6	136 91.3	14 9.0	15 9.6	8 5.4	1 0.6	4 2.5	4 2.7	1 0.6	2 1.3	0 0.0	0 0.0	0 0.0	1 0.7
Things appear distorted	132 85.2	131 83.4	130 87.2	17 11.0	21 13.4	12 8.1	5 3.2	5 3.2	7 4.7	1 0.6	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
My vision makes me dizzy	130 83.9	150 95.5	141 94.6	20 12.9	7 4.5	8 5.4	5 3.2	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
My vision gives me headaches	106 68.4	143 91.1	131 87.9	36 23.2	11 7.0	14 9.4	11 7.1	3 1.9	4 2.7	2 1.3	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

^subjects did not complete a preoperative questionnaire.

Table 43: Change in Symptoms: Comparison of Pre-Op with Correction to Post-Op without Correction *All Subjects (N=155^)*

	6 Months (n=152)				12 Months (n=145)			
	Improve	No Change	Worsen	NR	Improve	No Change	Worsen	NR
Symptoms	n %	n %	n %	n	n %	n %	n %	n
Dryness	14 9.2	117 77.0	21 13.8	0	13 9.0	122 84.1	10 6.9	0
Blurry vision	9 5.9	136 89.5	7 4.6	0	13 9.0	128 88.3	4 2.8	0
Fluctuation of vision	18 11.8	127 83.6	7 4.6	0	15 10.3	123 84.8	7 4.8	0
Glare	14 9.2	126 82.9	12 7.9	0	14 9.7	124 85.5	7 4.8	0
Halos around lights	18 11.8	117 77.0	17 11.2	0	22 15.2	111 76.6	12 8.3	0
Difficulty at night	21 13.8	115 75.7	16 10.5	0	22 15.2	112 77.2	11 7.6	0
Ghosting or shadowing of images	9 5.9	134 88.2	9 5.9	0	7 4.8	132 91.0	6 4.1	0
Double images	2 1.3	147 96.7	3 2.0	0	2 1.4	140 96.6	3 2.1	0
Things appear distorted	4 2.6	143 94.1	5 3.3	0	4 2.8	134 92.4	7 4.8	0
My vision makes me dizzy	4 2.6	148 97.4	0 0.0	0	4 2.8	141 97.2	0 0.0	0
My vision gives me headaches	7 4.6	144 94.7	1 0.7	0	6 4.1	138 95.2	1 0.7	0

^5 subjects did not complete a pre-op questionnaire and are excluded in this table.

i. Device Failure

There were no device failures reported during this study.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

Preclinical studies completed for this device did not raise any new safety or effectiveness concerns. Data from the clinical study provided reasonable assurance of device safety and effectiveness, when used in accordance with the directions for use, for wavefront-guided LASIK treatment with the VISX STAR S4 IR™ Excimer Laser System with Variable Spot Scanning and WaveScan®-derived ablation targets for the correction presbyopia patients with low to moderate myopia, with and without astigmatism, by targeting a monovision outcome.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

CDRH issued an approval order on July 11, 2007.

The sponsor will conduct a multi-center (minimum of 15 clinical sites) prospective post-approval study with 6-month follow-up enrolling 500 new presbyopic patients interested in and eligible to receive monovision LASIK. The sponsor will submit a full post-approval study protocol (that CDRH's Office of Surveillance and Biometrics [OSB]) has agreed to) in a PMA supplement within 30 days of the above approval date. The sponsor will select a group of surgeons diverse with respect to demographic characteristics, geographic location, practice setting, and other relevant characteristics from their current surgeon base.

The objective of the study is to estimate the proportion of monovision LASIK patients who experience visual disturbances, especially those associated with monovision, that are severe enough to limit activities or adversely affect a patient's quality of life. Specific questions to be answered by the study are: (1) What proportion of subjects who undergo monovision LASIK have poor outcomes as measured by 6-month post-operative National Eye Institute Refractive Quality of Life (NEI-RQL-42) scores and the NEI Visual Function Questionnaire (NEI-VFQ-25) driving subscale score consistent with severe difficulties? (2) What proportion of subjects with pre-operation scores above the NEI-RQL-42 and NEI-VFQ-25 driving subscale scores consistent with severe difficulties have 6-month post-operative scores below the severity threshold score? and (3) What baseline patient characteristics are associated with poor outcomes?

The results of this study must be reflected in the labeling (via supplement) when the post-approval study is completed.

The applicant's manufacturing facility was inspected and found to be in compliance with the Quality System regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

- Postapproval Requirements and Restriction: see Approval Order.

- Hazards to Health from Use of the Device: see Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.

- Directions for use: see labeling.