I. GENERAL INFORMATION

Device Generic Name:	Excimer Laser
Device Trade Name:	Bausch & Lomb TECHNOLAS®217A Excimer Laser System
Applicant's Name and Address:	Bausch & Lomb, Inc. 180 E. Via Verde Drive San Dimas, California 91773 USA
Date of Panel Recommendation:	None
PMA Number:	P990027/S4
Date of Notice of Approval to Applicant:	February 25, 2003

The Bausch & Lomb TECHNOLASÒ 217A Excimer Laser System was approved on February 23, 2000 under PMA 990027/S2 for the indication of photorefractive keratectomy for the reduction or elimination of myopia ranging from –1.00 D to –7.00 D spherical myopia with our without ≤ -3.00 astigmatism. An expansion of the indication statement was approved on May 17, 2002 for the reduction or elimination of myopic astigmatism up to –12.00 D MRSE, with sphere between > -7.00 D to –10.99 D and cylinder between 0.00 and <03.00. The sponsor submitted the current supplement to request expansion of the indication statement to include hyperopia and hyperopic astigmatism. Clinical data to support this indication are provided in this summary. The pre-clinical test results were presented in the original PMA application. For more information on the data that supported the approved indication, the summary of safety and effectiveness data (SSED) for P990027/S4 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, Room 1061, Rockville, Maryland 20857. The summary can also be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html.

II. INDICATIONS FOR USE

The Bausch & Lomb TECHNOLAS 217A Excimer Laser System is indicated for use in laser assisted in-situ keratomileusis (LASIK) treatments for:

- The reduction or elimination of low-to-moderate naturally occurring hyperopia up to +4.00 dipoters (D) MRSE, with sphere between +1.00 to +4.00 D with or without refractive astigmatism up to +2.00 D at the spectacle plane.
- In patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination.
- In patients who are 21 years of age or older.

III. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

A. Contraindications

LASIK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune, or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane), or amiodarone hydrochloride (Cordarone).

B. Warning and Precautions

Please refer to the Professional Use information and the Patient Information booklet for a complete list of warning and precautions.

IV. DEVICE DESCRIPTION

The TECHNOLAS®217A Excimer Laser System is designed for the correction of refractive error by reshaping the surface of the cornea. Corneal reshaping is accomplished by ablating precise amounts of corneal tissue with high-energy ultraviolet light from a pulsed Argon-Fluoride excimer laser system. The desired ablation profile is based upon the thin lens equations. The TECHNOLAS®217A uses a small diameter spot in a scanning mode to create the type of correction desired hyperopia or astigmatism.

The TECHNOLAS 217A Excimer Laser system for hyperopic astigmatism uses an optical zone that is selectable between 5.0 mm and 6.0 mm and a blend zone of 1.90mm for spherical hyperopia and 1.75 mm for hyperopic astigmatism. and the Laser is locked out for refractive corrections greater 4.00D sphere and greater than 2.00D cylinder. The software used in the clinical trial was 2.9994A. The final commercial release version for

hyperopic astigmatism, incorporating the changes made during PMA review, is software version 3.14A.

The TECHNOLAS®217A Excimer Laser System consists of the following components:

A. Laser System

Laser Unit	The laser unit consists of the laser head (discharge system), which contains the optical resonator and a discharge chamber, which is filled with a premix of argon, fluorine, and a buffer of other noble gases.
Control Unit	The control unit contains the personal computer that uses a software algorithm to calculate the number and location of laser pulses required to achieve the desired correction.
Tower Unit	The tower unit provides the stable holding construction for the optical system of the TECHNOLAS®217A Excimer Laser. The tower unit contains the optical elements that condition the laser beam to the appropriate characteristics. The tower also contains the visualization optics (the operating microscope) and the positioning and fixation optics for properly locating and monitoring the progress of the ablation. There is a distance of 21 cm ("working distance") between the focusing point on the cornea and the laser arm.
Operating Elements	The operating elements of the TECHNOLAS®217A Excimer Laser System consist of two joysticks for movement of the patient bed in all axes and other operating elements and external connectors.
Bed Unit and Chair	The bed unit allows for accurate positioning of the patient during the surgical procedure while the operating chair allows the surgeon to adjust his/her position at the operating microscope.

TECHNOLAS®217A Excimer Laser Specifications

Laser Type	Argon Fluoride
Laser Wavelength	193 nm
Laser Pulse Duration	18 nanoseconds
Laser Head Repetition Rate	50 Hz
Effective Corneal Repetition Rate	12.5 Hz
Fluence (at the eye)	120 mJ/cm^2
Range of Ablation Diameter	2.0 to 2.05 mm

B. Microkeratome

The microkeratome is an instrument that creates a hinged corneal flap (lamellar flap) prior to the laser ablation procedure. The microkeratome is commercially available and cleared for marketing via premarket notification. The device used in this study consists of a sterilization/storage tray which includes the microkeratome head, a left/right eye adapter, suction ring, suction handle, and blade insertion tool. The microkeratome motor, tonometer, cleaning brush, disposable blades, black suction ball, power/suction supply unit with vacuum and motor footswitch and power cords are provided as separate components and accessory stand and equipment suitcase which complete the system.

V. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative methods of correcting farsightedness (hyperopia) include: glasses, contact lenses, photorefractive keratectomy (PRK), incisional refractive keratotomy (RK), lamellar refractive keratotomy, or other types of refractive surgery.

VI. MARKETING HISTORY

Over 500 TECHNOLAS®217 Excimer Laser Systems have been installed in the following countries: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Czech Republic, Finland, France, Germany, Greece, Hong Kong, India, Indonesia, Israel, Italy, Japan, Jordan, Korea, Malaysia, Mexico, New Zealand, Philippines, Portugal, Qatar, Russia, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, United States and Venezuela.

The TECHNOLAS®217A Excimer Laser System has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse reactions associated with LASIK include: loss of best spectacle corrected visual acuity, worsening of patient complaints such as dry eyes, 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.

VIII. SUMMARY OF PRECLINICAL STUDIES

Please refer to the SSED of the original PMA P990027

IX. SUMMARY OF CLINICAL STUDIES

A. Objectives

The objective of this study was to demonstrate the safety and effectiveness of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System for the reduction or elimination of low-to-moderate naturally occurring hyperopia of +1.00 to +4.00 diopters with or without refractive astigmatism up to +2.00 diopters when used as part of the LASIK surgical procedure. In this study, the maximum amount of sphere treated was +4.00 D, and the maximum amount of cylinder treated was +2.00 D.

B. Study Design

The data for this report were gathered from a prospective, open-label, non-randomized, multi-center clinical evaluation conducted in the United States of America for the indications of +1.00 to +4.00 D of hyperopia and up to +2.00 D of astigmatism when used in the procedure known as LASIK. Since the TECHNOLAS 217A laser already had PMA approval for marketing based on previously submitted safety and effectiveness data for myopia and astigmatic myopia, the sample size was based on the demonstration of effectiveness for hyperopia treatments rather than on primary safety outcomes. A total of 358 eyes were enrolled (357 actually treated). There were 290 eyes (233 non-monovision and 57 monovision) with 6 months of follow-up data. Based on the sample size calculations provided in the original protocol, at least 196 non-monovision-treated eyes would be required to demonstrate effectiveness. In this report, effectiveness results are provided for 233 non-monovision-treated eyes with at least 6 months of follow-up data. Safety data are provided for all 358 eyes enrolled in the study.

C. Inclusion and Exclusion Criteria

Study Inclusion Criteria:

To be enrolled in the study, patients needed to meet these conditions: have +1.00 to +4.00D of hyperopia with +2.00D or less of refractive astigmatism; less than 0.75D of latent hyperopia as determined by the difference between preoperative manifest and cycloplegic refractions; be willing to have full distance correction or monovision; presbyopic patients must tolerate and accept monovision during a trial monovision correction using either contact lenses or spectacles, have a white to white measurement of not less than 11.0mm; have a stable refraction for the past year; discontinue use of contact lenses at least 2 weeks for hard contracts and 1 week for soft lenses prior to surgery; hard contact wearers must have two central keratometry readings and two manifest refractions taken at least one week apart that do not differ by more than 0.50D; with visual acuity correctable to at least 20/40; be at least 21 years of age, be willing and able to return for scheduled follow-up examinations; provide written informed consent.

Exclusion Criteria – All eyes to be Treated

Patients not meeting the above inclusion criteria were excluded from the study,in addition, subjects who exhibited any of the following conditions were excluded: history of anterior segment pathology, including cataracts; patients co-managed by ophthalmologist or optometrist not approved as a B&L laser investigator; residual, recurrent, active ocular or uncontrolled eyelid disease, or any corneal abnormality (specifically, recurrent corneal erosion, severe basement membrane disease); ophthalmoscopic signs of keratoconus (or keratoconus suspect); unstable (distorted/not clear) corneal mires on central keratometry readings; blind in the fellow eye; previous intraocular or corneal surgery; history of herpes zoster or herpes simplex keratitis; history of steroid-responsive rise in intraocular pressure, glaucoma, or preoperative IOP >21 mm Hg; diabetes, diagnosed autoimmune disease, connective tissue disease or clinically significant atopic syndrome; chronic systemic corticosteroid or other immunosuppresive therapy, and immunocompromised patients; pregnant, lactating, or child-bearing potential and not practicing a medically approved method of birth control; sensitivity to planned study medications; simultaneous participation in other ophthalmic drug or device clinical trial.

D. Study Plan, Patient Assessments and Efficacy Criteria

All subjects were expected to return for follow-up examinations at 1 day, 1 week, 1 month, 3 months, 6 months, 9 months, 12 months, 18 months and 24 months postoperatively.

Subjects were permitted to have second eyes (fellow eyes) treated no sooner than 7 days after the first eye surgery. In, addition, subjects were eligible for retreatment no sooner than 3 months after the original surgery and only if refraction was stable after treatment. Retreatment would not be performed as a part of the protocol.

Preoperatively, the subjects' medical and ocular histories were recorded. The objective parameters measured during the study included: uncorrected visual acuity, best spectacle corrected visual acuity, manifest refraction, intraocular pressure, corneal pachymetry, slit lamp examination of the anterior segment, fundus examination, computerized corneal topography and subjective self evaluation questionnaire.

The primary efficacy variables for this study were improvement of UCVA based on the pre-treatment goal of the procedure and predictability of manifest refraction.

E. Study Period, Investigational Sites, and Demographics Data

1. Study Period and Investigational Sites

Subjects were treated between May 1999 to August 2001. The database for this PMA supplement reflected data collected through March 18. 2002. A total of 358 eyes were treated at eight sites.

2. Demographics

Demographic data for all treated eyes grouped by treatment type are presented below in Table 1.

Table 1
Demographics — All Treated Eyes

Demographics	Treated for Spherical Hyperopia Only		Treated for Astigmatic Hyperopia		All Treated Eyes	
	Number	Percentage	Number	Percentage	Number	Percentage
NUMBER OF EYES & SUBJECTS	211 Eyes of 128 Enrolled Subjects		147 Eyes of 96 Enrolled Subjects		358 Eyes of 194 Enrolled Subjects	
GENDER						
Male	104	49.3%	74	50.3%	178	49.7%
Female	107	50.7%	73	49.7%	180	50.3%
RACE						
White	208	98.6%	142	96.6%	350	97.8%
Black	1	0.5%	3	2.0%	4	1.1%
Other	2	0.9%	2	1.4%	4	1.1%
SURGICAL EYE						
Right	100	47.4%	79	53.7%	179	50.0%
Left	111	52.6%	68	46.3%	179	50.0%
AGE (in years)						
Mean	52.8 (7.5)		53.6 (9.5)		53.1 (8.4)	
Minimum, Maximum	23.4, 68.9		23.9, 69.0		23.4, 69.0	

F. Data Analysis and Results

1. Preoperative Characteristics

Presented in Table 2 are the preoperative refraction parameters for all treated eyes.

Table 2
Preoperative Refraction Parameters
All Treated Eyes
Stratified by Sphere and Cylinder Components

Manifest Sphere Mean (SD): 1.92 (0.79) Range: 0.50 to 4.00	Manifest Cylinder Mean (SD): 0.50 (0.46), Range: 0.00 to 2.00						Total	
	0.00-0.99 D		1.00-1.74 D		1.75-2.00 D			
	n/N	%	n/N	%	n/N	%	n/N	%
0.00-0.50 D	2/358	(0.6)	1/358	(0.3)	0/358	(0.0)	3/358	(0.8)
0.51-1.00 D	40/358	(11.2)	8/358	(2.2)	1/358	(0.3)	49/358	(13.7)
1.01-1.50 D	85/358	(23.7)	21/358	(5.9)	3/358	(0.8)	109/358	(30.4)
1.51-2.00 D	56/358	(15.6)	9/358	(2.5)	4/358	(1.1)	69/358	(19.3)
2.01-2.50 D	53/358	(14.8)	8/358	(2.2)	0/358	(0.0)	61/358	(17.0)
2.51-3.00 D	28/358	(7.8)	3/358	(0.8)	2/358	(0.6)	33/358	(9.2)
3.01-3.50 D	21/358	(5.9)	1/358	(0.3)	1/358	(0.3)	23/358	(6.4)
3.51-4.00 D	9/358	(2.5)	1/358	(0.3)	1/358	(0.3)	11/358	(3.1)
Total	294/358	(82.1)	52/358	(14.5)	12/358	(3.4)	358/358	(100.0)

N = Total number of eyes treated for astigmatic hyperopia.
1 eye (3.500.75x15) was reported with an aborted procedure.
79 eyes were treated for monovision.

2. Post-operative Characteristics and Results

a. Accountability

Accountability for all treated eyes across the study visit schedule is presented in Table 3.

Table 3
Accountability — All Treated Eyes

Status		1 Month	3 Months	6 Months	9 Months	[3] 12 Months
Available for Analysis	n/N (%)	333/358 (93.0%)	343/358 (95.8%)	290/358 (81.0%)	222/358 (62.0%)	178/358 (49.7%)
Discontinued*	n/N (%)	1/358 (0.3%)	1/358 (0.3%)	1/358 (0.3%)	13/358 (3.6%)	19/358 (5.3%)
Active (Not yet eligible for the interval)	n/N (%)	0/358 (0.0%)	0/358 (0.0%)	48/358 (13.4%)	50/358 (14.0%)	152/358 (42.5%)
Lost to Follow-up†	n/N (%)	0/358 (0.0%)	0/358 (0.0%)	0/358 (0.0%)	6/358 (1.7%)	6/358 (1.7%)
Missed Visit‡	n/N (%)	24/358 (6.7%)	14/358 (3.9%)	19/358 (5.3%)	67/358 (18.7%)	3/358 (0.8%)
% Accountability = Available for Analysis ÷ (Enrolled - Discontinued - Not yet eligible)		333/357 (93.3%)	343/357 (96.1%)	290/309 (93.9%)	222/295 (75.3%)	178/187 (95.2%)

N = Total eyes enrolled.

* Discontinued = Exited due to Technolas laser retreatment (0 eye) or non-Technolas laser retreatment (18 eyes) or aborted procedure (1 eye) or death (0 eye).

† Loss to follow-up: Eyes not examined at the 24-month visit, and not considered active or discontinued.

‡ Missed visit: Eyes not examined at the scheduled visit, but were then seen at a subsequent visit.

b. Stability of outcome

Table 4 presents the results for the stability of the manifest refraction spherical equivalent for the consistent cohort (all treated eyes examined at 1, 3, and 6 months). The results indicate that at least 95% of eyes were within 1.00 D of the previous visit's spherical equivalent refraction value during the 1 to 3 months interval. The mean of the paired-differences of MRSE reached $\leq |0.12|$ D in the 3 to 6 months interval. Thus, stability was demonstrated by 6 months postoperative.

Table 4
Stability of Manifest Refraction Spherical Equivalent (MRSE)
6-Month Consistent Cohort

Change in Spherical Refraction	Between 1 and 3 Months			Between 3 and 6 Months		
	Full Cohort	Treated For Sphere Only	Treated For Sphere & Cylinder	Full Cohort	Treated For Sphere Only	Treated For Sphere & Cylinder
Change of **MRSE** by ≤ 1.00 D						
n/N (%)	258/267 (96.6%)	151/157 (96.2%)	107/110 (97.3%)	262/269 (97.4%)	154/159 (96.9%)	108/110 (98.2%)
95% CI for %	(94.5%, 98.8%)	(93.2%, 99.1%)	(94.3%, 99.9%)	(95.3%, 99.5%)	(93.5%, 99.9%)	(95.1%, 99.9%)
Change of **MRSE** (Paired-Differences) in Diopters						
Mean	0.127	0.147	0.098	0.081	0.088	0.070
SD	0.483	0.508	0.448	0.408	0.420	0.390
95% CI for Mean	(0.065, 0.189)	(0.063, 0.231)	(0.007, 0.188)	(0.032, 0.130)	(0.021, 0.155)	(-0.000, 0.141)
Change in Spherical Refraction	**Between 6 and 9 Months**			**Between 9 and [3] 12 Months**		
	Full Cohort	**Treated For Sphere Only**	**Treated For Sphere & Cylinder**	**Full Cohort**	**Treated For Sphere Only**	**Treated For Sphere & Cylinder**
Change of **MRSE** by ≤ 1.00 D						
n/N (%)	205/210 (97.6%)	106/109 (97.2%)	99/101 (98.0%)	111/112 (99.1%)	69/70 (98.6%)	42/42 (100.0%)
95% CI for %	(95.2%, 99.9%)	(93.3%, 99.9%)	(94.7%, 99.9%)	(96.1%, 99.9%)	(93.8%, 99.9%)	(92.2%, 100.0%)
Change of **MRSE** (Paired-Differences) in Diopters						
Mean	-0.015	-0.024	-0.005	0.041	0.043	0.039
SD	0.388	0.429	0.338	0.352	0.351	0.363
95% CI for Mean	(-0.074, 0.044)	(-0.113, 0.065)	(-0.081, 0.071)	(-0.031, 0.113)	(-0.042, 0.128)	(-0.090, 0.167)

The 95% confidence interval was adjusted for the correlation between eyes.
6-Month Consistent Cohort: All eyes examined at 1, 3, and 6 months.

c. Effectiveness Outcomes

Table 5 presents the key effectiveness variables outcomes for all treated eyes. Key efficacy outcomes stratified by each 0.50 diopter of preoperative MRSE for all treated eyes, eyes treated for spherical hyperopia and eyes treated for hyperopic astigmatism are presented in Tables 6, 7 and 8 respectively.

It will be noted from Table 6 that the three primary outcomes for percent of eyes with 20/40 or better uncorrected visual acuity and percent of eyes within ±0.50 D and ±1.00 D of attempted correction are all well above the suggested minimum FDA Guidance values for hyperopia.

The accuracy of the refractive outcomes and the rate of 20/20 UCVA or better are seen to decrease with increasing preoperative MRSE. This is due in part to the increased rate of undercorrections with increasing baseline MRSE as seen in Table 9. Accuracy within 0.50D of intended refractive outcome fell below the target rate of 50% for treatment of MRSE greater than +3.50D. Table 10 shows that undercorrections of greater than 1.00D occurred at a rate of 12.4% and 13.0% at month 6 and month 12 respectively and that the average undercorrections were 0.31D and 0.37D at these visits.

The accuracy of the refractive outcomes and the rate of 20/20 or better UCVA are seen to decrease with increasing preoperative manifest refractive cylinder as shown in Tables 11 and 12. The impact of preoperative cylinder on UCVA is especially noticeable in the group of eyes with 0.50 to 0.75 D cylinder that received spherical treatments.

Table 5
Summary of Key Effectiveness Variables
All Treated Eyes

Key Effectiveness Variables	1 Month		3 Months		6 Months		9 Months		[3] 12 Months	
	n/N (%)	95%* CI	n/N (%)	95%* CI	n/N (%)	95%* CI	n/N (%)	95%* CI	n/N (%)	95%* CI
UCVA 20/20 or better†	131/258 (50.8%)	(44.5, 57.0)	159/265 (60.0%)	(53.6, 66.4)	143/233 (61.4%)	(54.5, 68.3)	100/168 (59.5%)	(51.6, 67.4)	83/141 (58.9%)	(50.7, 67.0)
UCVA 20/40 or better†	243/258 (94.2%)	(91.4, 97.0)	255/265 (96.2%)	(94.0, 98.5)	221/233 (94.8%)	(91.6, 98.1)	161/168 (95.8%)	(92.8, 98.8)	134/141 (95.0%)	(91.3, 98.8)
MRSE‡, Attempted vs. Achieved, ± 0.50 D	225/331 (68.0%)	(62.6, 73.3)	222/343 (64.7%)	(59.2, 70.2)	174/290 (60.0%)	(53.7, 66.3)	142/222 (64.0%)	(56.7, 71.3)	109/177 (61.6%)	(53.8, 69.3)
MRSE‡, Attempted vs. Achieved, ± 1.00 D	294/331 (88.8%)	(85.2, 92.4)	314/343 (91.5%)	(88.4, 94.7)	251/290 (86.6%)	(81.9, 91.2)	191/222 (86.0%)	(80.8, 91.3)	151/177 (85.3%)	(79.5, 91.1)
MRSE‡, Attempted vs. Achieved, ± 2.00 D	328/331 (99.1%)	(97.8, 99.9)	340/343 (99.1%)	(98.0, 99.9)	287/290 (99.0%)	(97.6, 99.9)	220/222 (99.1%)	(97.6, 99.9)	175/177 (98.9%)	(97.0, 99.9)
MRSE‡, from Emmetropia, ± 0.50 D†	180/256 (70.3%)	(64.7, 75.9)	193/265 (72.8%)	(67.2, 78.4)	155/233 (66.5%)	(59.9, 73.1)	120/168 (71.4%)	(63.8, 79.1)	95/141 (67.4%)	(58.9, 75.9)
MRSE‡, from Emmetropia, ± 1.00 D†	238/256 (93.0%)	(89.7, 96.2)	246/265 (92.8%)	(89.5, 96.2)	209/233 (89.7%)	(85.5, 93.9)	147/168 (87.5%)	(81.9, 93.1)	120/141 (85.1%)	(78.9, 91.4)
MRSE‡, from Emmetropia, ± 2.00 D†	254/256 (99.2%)	(97.7, 99.9)	263/265 (99.2%)	(98.0, 99.9)	232/233 (99.6%)	(98.1, 99.9)	167/168 (99.4%)	(97.4, 99.9)	140/141 (99.3%)	(96.9, 99.9)

N = Number of CRFs received with non-missing values at each visit.

* The 95% confidence interval was adjusted for the correlation between eyes.

† For all eyes minus those treated for monovision.

‡ MRSE = Manifest Spherical Equivalent = Manifest Sphere + 0.5 × Manifest Cylinder.

One eye (170-7015-B0) received a treatment (+0.75/+0.75 x 180) outside the approved range for sphere.

Table 6
Summary of Key Effectiveness Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE
All Treated Eyes

Key Effectiveness Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
UCVA 20/20 or better†	8/9 (88.9%)	33/49 (67.3%)	42/62 (67.7%)	23/39 (59.0%)	22/38 (57.9%)	5/15 (33.3%)	8/17 (47.1%)	2/3 (66.7%)	0/1 (0.0%)	143/233 (61.4%)
UCVA 20/25 or better†	9/9 (100.0%)	44/49 (89.8%)	51/62 (82.3%)	29/39 (74.4%)	31/38 (81.6%)	8/15 (53.3%)	11/17 (64.7%)	2/3 (66.7%)	0/1 (0.0%)	185/233 (79.4%)
UCVA 20/40 or better†	9/9 (100.0%)	49/49 (100.0%)	57/62 (91.9%)	36/39 (92.3%)	37/38 (97.4%)	14/15 (93.3%)	15/17 (88.2%)	3/3 (100.0%)	1/1 (100.0%)	221/233 (94.8%)
MRSE*, Attempted vs. Achieved, ± 0.50 D	10/14 (71.4%)	54/70 (77.1%)	42/71 (59.2%)	28/51 (54.9%)	22/44 (50.0%)	10/18 (55.6%)	7/17 (41.2%)	1/4 (25.0%)	0/1 (0.0%)	174/290 (60.0%)
MRSE*, Attempted vs. Achieved, ± 1.00 D	14/14 (100.0%)	66/70 (94.3%)	63/71 (88.7%)	42/51 (82.4%)	36/44 (81.8%)	15/18 (83.3%)	13/17 (76.5%)	2/4 (50.0%)	0/1 (0.0%)	251/290 (86.6%)
MRSE*, Attempted vs. Achieved, ± 2.00 D	14/14 (100.0%)	70/70 (100.0%)	70/71 (98.6%)	51/51 (100.0%)	43/44 (97.7%)	18/18 (100.0%)	16/17 (94.1%)	4/4 (100.0%)	1/1 (100.0%)	287/290 (99.0%)
MRSE*, from Emmetropia, ± 0.50 D†	8/9 (88.9%)	42/49 (85.7%)	43/62 (69.4%)	23/39 (59.0%)	23/38 (60.5%)	8/15 (53.3%)	8/17 (47.1%)	0/3 (0.0%)	0/1 (0.0%)	155/233 (66.5%)
MRSE*, from Emmetropia, ± 1.00 D†	9/9 (100.0%)	49/49 (100.0%)	57/62 (91.9%)	34/39 (87.2%)	32/38 (84.2%)	13/15 (86.7%)	14/17 (82.4%)	1/3 (33.3%)	0/1 (0.0%)	209/233 (89.7%)
MRSE*, from Emmetropia, ± 2.00 D†	9/9 (100.0%)	49/49 (100.0%)	62/62 (100.0%)	39/39 (100.0%)	38/38 (100.0%)	15/15 (100.0%)	16/17 (94.1%)	3/3 (100.0%)	1/1 (100.0%)	232/233 (99.6%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

One eye (170-7015-B0) received a treatment (+0.75/+0.75 x 180) outside the approved range for sphere.

Table 7
Summary of Key Effectiveness Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE
Eyes Treated for Spherical Hyperopia Only

Key Effectiveness Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
UCVA 20/20 or better†	8/9 (88.9%)	20/34 (58.8%)	25/35 (71.4%)	14/27 (51.9%)	11/22 (50.0%)	2/8 (25.0%)	6/10 (60.0%)	NA	NA	86/145 (59.3%)
UCVA 20/25 or better†	9/9 (100.0%)	29/34 (85.3%)	29/35 (82.9%)	18/27 (66.7%)	17/22 (77.3%)	3/8 (37.5%)	7/10 (70.0%)	NA	NA	112/145 (77.2%)
UCVA 20/40 or better†	9/9 (100.0%)	34/34 (100.0%)	32/35 (91.4%)	25/27 (92.6%)	22/22 (100.0%)	7/8 (87.5%)	10/10 (100.0%)	NA	NA	139/145 (95.9%)
MRSE*, Attempted vs. Achieved, ± 0.50 D	9/13 (69.2%)	35/44 (79.5%)	25/43 (58.1%)	17/32 (53.1%)	13/27 (48.1%)	3/9 (33.3%)	3/10 (30.0%)	NA	NA	105/178 (59.0%)
MRSE*, Attempted vs. Achieved, ± 1.00 D	13/13 (100.0%)	42/44 (95.5%)	37/43 (86.0%)	26/32 (81.3%)	21/27 (77.8%)	6/9 (66.7%)	8/10 (80.0%)	NA	NA	153/178 (86.0%)
MRSE*, Attempted vs. Achieved, ± 2.00 D	13/13 (100.0%)	44/44 (100.0%)	42/43 (97.7%)	32/32 (100.0%)	27/27 (100.0%)	9/9 (100.0%)	9/10 (90.0%)	NA	NA	176/178 (98.9%)
MRSE*, from Emmetropia, ± 0.50 D†	8/9 (88.9%)	30/34 (88.2%)	26/35 (74.3%)	14/27 (51.9%)	14/22 (63.6%)	2/8 (25.0%)	4/10 (40.0%)	NA	NA	98/145 (67.6%)
MRSE*, from Emmetropia, ± 1.00 D†	9/9 (100.0%)	34/34 (100.0%)	31/35 (88.6%)	24/27 (88.9%)	17/22 (77.3%)	6/8 (75.0%)	9/10 (90.0%)	NA	NA	130/145 (89.7%)
MRSE*, from Emmetropia, ± 2.00 D†	9/9 (100.0%)	34/34 (100.0%)	35/35 (100.0%)	27/27 (100.0%)	22/22 (100.0%)	8/8 (100.0%)	9/10 (90.0%)	NA	NA	144/145 (99.3%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

Table 8
Summary of Key Effectiveness Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE
Eyes Treated for Astigmatic Hyperopia

Key Effectiveness Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
UCVA 20/20 or better†	NA	13/15 (86.7%)	17/27 (63.0%)	9/12 (75.0%)	11/16 (68.8%)	3/7 (42.9%)	2/7 (28.6%)	2/3 (66.7%)	0/1 (0.0%)	57/88 (64.8%)
UCVA 20/25 or better†	NA	15/15 (100.0%)	22/27 (81.5%)	11/12 (91.7%)	14/16 (87.5%)	5/7 (71.4%)	4/7 (57.1%)	2/3 (66.7%)	0/1 (0.0%)	73/88 (83.0%)
UCVA 20/40 or better†	NA	15/15 (100.0%)	25/27 (92.6%)	11/12 (91.7%)	15/16 (93.8%)	7/7 (100.0%)	5/7 (71.4%)	3/3 (100.0%)	1/1 (100.0%)	82/88 (93.2%)
MRSE*, Attempted vs. Achieved, ± 0.50 D	1/1 (100.0%)	19/26 (73.1%)	17/28 (60.7%)	11/19 (57.9%)	9/17 (52.9%)	7/9 (77.8%)	4/7 (57.1%)	1/4 (25.0%)	0/1 (0.0%)	69/112 (61.6%)
MRSE*, Attempted vs. Achieved, ± 1.00 D	1/1 (100.0%)	24/26 (92.3%)	26/28 (92.9%)	16/19 (84.2%)	15/17 (88.2%)	9/9 (100.0%)	5/7 (71.4%)	2/4 (50.0%)	0/1 (0.0%)	98/112 (87.5%)
MRSE*, Attempted vs. Achieved, ± 2.00 D	1/1 (100.0%)	26/26 (100.0%)	28/28 (100.0%)	19/19 (100.0%)	16/17 (94.1%)	9/9 (100.0%)	7/7 (100.0%)	4/4 (100.0%)	1/1 (100.0%)	111/112 (99.1%)
MRSE*, from Emmetropia, ± 0.50 D†	NA	12/15 (80.0%)	17/27 (63.0%)	9/12 (75.0%)	9/16 (56.3%)	6/7 (85.7%)	4/7 (57.1%)	0/3 (0.0%)	0/1 (0.0%)	57/88 (64.8%)
MRSE*, from Emmetropia, ± 1.00 D†	NA	15/15 (100.0%)	26/27 (96.3%)	10/12 (83.3%)	15/16 (93.8%)	7/7 (100.0%)	5/7 (71.4%)	1/3 (33.3%)	0/1 (0.0%)	79/88 (89.8%)
MRSE*, from Emmetropia, ± 2.00 D†	NA	15/15 (100.0%)	27/27 (100.0%)	12/12 (100.0%)	16/16 (100.0%)	7/7 (100.0%)	7/7 (100.0%)	3/3 (100.0%)	1/1 (100.0%)	88/88 (100.0%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision
One eye (170-7015-B0) received a treatment (+0.75/+0.75 x 180) outside the approved range for sphere.

Table 9
Accuracy of Manifest Spherical Equivalent at 6 Months — Attempted vs Achieved
Stratified By Preoperative MRSE
All Treated Eyes

Deviation	0.51 to 1.00 D‡ n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D‡ n/N (%)
±0.50 D	10/14 (71.4%)	54/70 (77.1%)	42/71 (59.2%)	28/51 (54.9%)	22/44 (50.0%)	10/18 (55.6%)	7/17 (41.2%)	1/4 (25.0%)	0/1 (0.0%)
±1.00 D	14/14 (100.0%)	66/70 (94.3%)	63/71 (88.7%)	42/51 (82.4%)	36/44 (81.8%)	15/18 (83.3%)	13/17 (76.5%)	2/4 (50.0%)	0/1 (0.0%)
±2.00 D	14/14 (100.0%)	70/70 (100.0%)	70/71 (98.6%)	51/51 (100.0%)	43/44 (97.7%)	18/18 (100.0%)	16/17 (94.1%)	4/4 (100.0%)	1/1 (100.0%)
Mean (SD)	*0.30 (0.28)*	*0.19 (0.48)*	*0.36 (0.63)*	*0.24 (0.70)*	*0.52 (0.70)*	*0.09 (0.74)*	*0.46 (0.95)*	*0.56 (1.25)*	*1.13 (.)*
Range	*0.00 to 0.75*	*-1.13 to 1.38*	*-1.00 to 2.38*	*-1.25 to 1.63*	*-0.75 to 2.75*	*-1.00 to 1.50*	*-0.75 to 2.50*	*-0.75 to 1.75*	*1.13 to 1.13*
Not reported*	0	0	0	0	0	0	0	0	0
Total†	14	70	71	51	44	18	17	4	1
Overcorrected > 1	0/14 (0.0%)	1/70 (1.4%)	0/71 (0.0%)	2/51 (3.9%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)
Overcorrected > 2	0/14 (0.0%)	0/70 (0.0%)	0/71 (0.0%)	0/51 (0.0%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)
Undercorrected > 1	0/14 (0.0%)	3/70 (4.3%)	8/71 (11.3%)	7/51 (13.7%)	8/44 (18.2%)	3/18 (16.7%)	4/17 (23.5%)	2/4 (50.0%)	1/1 (100.0%)
Undercorrected > 2	0/14 (0.0%)	0/70 (0.0%)	1/71 (1.4%)	0/51 (0.0%)	1/44 (2.3%)	0/18 (0.0%)	1/17 (5.9%)	0/4 (0.0%)	0/1 (0.0%)
Mean (SD)	*0.30 (0.28)*	*0.19 (0.48)*	*0.36 (0.63)*	*0.24 (0.70)*	*0.52 (0.70)*	*0.09 (0.74)*	*0.46 (0.95)*	*0.56 (1.25)*	*1.13 (.)*
Range	*0.00 to 0.75*	*-1.13 to 1.38*	*-1.00 to 2.38*	*-1.25 to 1.63*	*-0.75 to 2.75*	*-1.00 to 1.50*	*-0.75 to 2.50*	*-0.75 to 1.75*	*1.13 to 1.13*
Not reported*	0	0	0	0	0	0	0	0	0
Total†	14	70	71	51	44	18	17	4	1

N = Number of CRFs received with non-missing values at each visit.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.

‡ Lowest Preoperative MRSE = 0.75D. Highest Preoperative MRSE = 4.875D.

Table 10
Accuracy of Manifest Spherical Equivalent — Attempted vs Achieved
All Treated Eyes

Deviation	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	[3] 12 Months n/N (%)
±0.50 D	225/331 (68.0%)	222/343 (64.7%)	174/290 (60.0%)	142/222 (64.0%)	109/177 (61.6%)
±1.00 D	294/331 (88.8%)	314/343 (91.5%)	251/290 (86.6%)	191/222 (86.0%)	151/177 (85.3%)
±2.00 D	328/331 (99.1%)	340/343 (99.1%)	287/290 (99.0%)	220/222 (99.1%)	175/177 (98.9%)
Mean (SD)	*0.09 (0.67)*	*0.20 (0.62)*	*0.31 (0.66)*	*0.29 (0.65)*	*0.37 (0.66)*
Range	*-2.25 to 2.63*	*-1.50 to 2.75*	*-1.25 to 2.75*	*-1.75 to 3.13*	*-1.38 to 3.38*
Not reported*	2	0	0	0	1
Total†	333	343	290	222	178
Overcorrected > 1	13/331 (3.9%)	6/343 (1.7%)	3/290 (1.0%)	5/222 (2.3%)	3/177 (1.7%)
Overcorrected > 2	2/331 (0.6%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/177 (0.0%)
Undercorrected > 1	24/331 (7.3%)	23/343 (6.7%)	36/290 (12.4%)	26/222 (11.7%)	23/177 (13.0%)
Undercorrected > 2	1/331 (0.3%)	3/343 (0.9%)	3/290 (1.0%)	2/222 (0.9%)	2/177 (1.1%)
Mean (SD)	*0.09 (0.67)*	*0.20 (0.62)*	*0.31 (0.66)*	*0.29 (0.65)*	*0.37 (0.66)*
Range	*-2.25 to 2.63*	*-1.50 to 2.75*	*-1.25 to 2.75*	*-1.75 to 3.13*	*-1.38 to 3.38*
Not reported*	2	0	0	0	1
Total†	333	343	290	222	178

N = Number of CRFs received with non-missing values at each visit.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.

Table 11
Summary of Key Effectiveness Variables at 6 Months
Stratified By Preoperative MRCYL*
Eyes Treated for Spherical Hyperopia Only

Key Effectiveness Variables	0.00 D n/N (%)	0.25 D n/N (%)	0.50 to 0.75 D n/N (%)	Total n/N (%)
UCVA 20/20 or better†	39/52 (75.0%)	30/43 (69.8%)	17/50 (34.0%)	86/145 (59.3%)
UCVA 20/40 or better†	50/52 (96.2%)	43/43 (100.0%)	46/50 (92.0%)	139/145 (95.9%)
MRSE, Attempted vs. Achieved, ± 0.50 D	42/65 (64.6%)	32/57 (56.1%)	31/56 (55.4%)	105/178 (59.0%)
MRSE, Attempted vs. Achieved, ± 1.00 D	58/65 (89.2%)	47/57 (82.5%)	48/56 (85.7%)	153/178 (86.0%)
MRSE, Attempted vs. Achieved, ± 2.00 D	65/65 (100.0%)	56/57 (98.2%)	55/56 (98.2%)	176/178 (98.9%)
MRSE, from Emmetropia, ±0.50 D†	36/52 (69.2%)	29/43 (67.4%)	33/50 (66.0%)	98/145 (67.6%)
MRSE, from Emmetropia, ±1.00 D†	48/52 (92.3%)	38/43 (88.4%)	44/50 (88.0%)	130/145 (89.7%)
MRSE, from Emmetropia, ±2.00 D†	52/52 (100.0%)	43/43 (100.0%)	49/50 (98.0%)	144/145 (99.3%)

N = Number of CRFs received with non-missing values at each visit.

* MRCYL = Manifest Refraction Cylinder Power

† For all eyes minus those treated for monovision

Table 12
Summary of Key Effectiveness Variables at 6 Months
Stratified By Preoperative MRCYL*
Eyes Treated for Astigmatic Hyperopia

Key Effectiveness Variables	0.25 to 0.99 D n/N (%)	1.00 to 1.74 D n/N (%)	1.75 to 2.00 D n/N (%)	Total n/N (%)
UCVA 20/20 or better†	35/48 (72.9%)	16/29 (55.2%)	6/11 (54.5%)	57/88 (64.8%)
UCVA 20/40 or better†	46/48 (95.8%)	27/29 (93.1%)	9/11 (81.8%)	82/88 (93.2%)
MRSE, Attempted vs. Achieved, ± 0.50 D	39/60 (65.0%)	25/41 (61.0%)	5/11 (45.5%)	69/112 (61.6%)
MRSE, Attempted vs. Achieved, ± 1.00 D	53/60 (88.3%)	37/41 (90.2%)	8/11 (72.7%)	98/112 (87.5%)
MRSE, Attempted vs. Achieved, ± 2.00 D	60/60 (100.0%)	40/41 (97.6%)	11/11 (100.0%)	111/112 (99.1%)
MRSE, from Emmetropia, ±0.50 D†	33/48 (68.8%)	19/29 (65.5%)	5/11 (45.5%)	57/88 (64.8%)
MRSE, from Emmetropia, ±1.00 D†	43/48 (89.6%)	28/29 (96.6%)	8/11 (72.7%)	79/88 (89.8%)
MRSE, from Emmetropia, ±2.00 D†	48/48 (100.0%)	29/29 (100.0%)	11/11 (100.0%)	88/88 (100.0%)

N = Number of CRFs received with non-missing values at each visit.

* MRCYL = Manifest Refraction Cylinder Power

† For all eyes minus those treated for monovision

One eye (170-7015-B0) received a treatment (+0.75/+0.75 x 180) outside the approved range for sphere

Table 13 summarizes the increase in astigmatic vector magnitude, or induced astigmatism for spherical treatments stratified by the attempted level of treatment. This table shows that spherical only treatment in eyes with low cylinder (<1D) at baseline appears to induce more astigmatism (which increases with the amount of attempted spherical correction). Tables 11 and 12 show the impact of the amount of preoperative cylinder on the key efficacy outcomes. These tables demonstrate that astigmatic treatment appears to result in better effectiveness outcomes.

There was a strong tendency for overcorrection of cylinder, with a significant number of eyes with large axis shifts and residual astigmatism. The overcorrection of astigmatism averaged 0.22D and affected UCVA 20/20 outcome. Spherical corrections induced greater amounts of astigmatism than present at baseline

Table 13
Increase in Astigmatic Vector Magnitude (SIRC – IRC)
at the Point of Stability (6 months) Stratified by Attempted Spherical Correction

Statistics	Attempted Spherical Correction						
	0.51 to 1.00 D	1.01 to 1.50 D	1.51 to 2.00 D	2.01 to 3.50 D	2.51 to 3.00 D	3.01 to 4.50 D	3.51 to 4.00 D
N	8	35	34	36	31	17	17
MEAN	0.34	0.47	0.48	0.51	0.57	0.62	0.71
MEDIAN	0.26	0.50	0.46	0.50	0.41	0.50	0.57
STD	0.13	0.30	0.36	0.36	0.49	0.56	0.48
MIN	0.23	0.00	0.00	0.00	0.00	0.00	0.00
MAX	0.50	1.25	1.50	1.69	1.85	2.25	1.83

IRC = square root of (preop*preop + itt*itt - 2*preop*itt*cos).
SIRC = square root of (preop*preop + postop*postop - 2*preop*postop*cos.)
Where preop = preop cylinder, postop = postop cylinder, itt = intended postop cylinder, & cos = cosine of the axis difference between preop & itt or preop & postop.
Since attempted cylindrical correction = 0, intended postop cylinder = preop cylinder.

Table 14 presents percent reduction of absolute cylinder and achieved vs. intended vector magnitude ratio (SIRC/IRC) at the point of stability, stratified by diopter of preoperative cylinder. The vector magnitude ratio (SIRC/IRC) was 1.33 at 6 months, which was the point of refractive stability. Overcorrection of astigmatism was most pronounced when treating less than 1.00D cylinder as shown by the mean SIRC/IRC ratio of 1.49 in this group. Table 15 shows that the large axis shifts (greater than 30°) that result from overcorrections were most often associated with less than 1.00D of residual astigmatism. Overcorrections of this nature contributed to the low mean percent reduction (7.5 ± 87.5%) of absolute cylinder reported in Table 14.

Table 14
Cylinder Correction Effectiveness at the Point of Stability (6 months) Stratified By Preoperative Cylinder - Astigmatic Hyperopia Eyes With Complete Preoperative and Postoperative Refraction

Preoperative Cylinder	Percent Reduction of Absolute Cylinder (Not Vector)*			Achieved vs Intended Vector Magnitude Ratio (SIRC/IRC)†		
	N	Mean (SD)	Median (Range)	N	Mean (SD)	Median (Range)
0.25 to 0.99 D	60	7.50 (87.46)	16.67 (-300.0 to 100.00)	60	1.49 (0.83)	1.20 (0.12 to 4.07)
1.00 to 1.74 D	41	51.26 (40.14)	50.00 (-100.0 to 100.00)	41	1.19 (0.47)	1.05 (0.31 to 2.99)
1.75 to 2.00 D	11	59.58 (39.92)	71.43 (-12.50 to 100.00)	11	1.06 (0.40)	0.99 (0.58 to 2.05)
Total	112	28.63 (72.91)	45.00 (-300.0 to 100.00)	112	1.33 (0.70)	1.04 (0.12 to 4.07)

* Data with a preoperative manifest cylinder = 0 were excluded from the 'Percent Reduction of Absolute Cylinder' calculations

† Data with an IRC = 0 were excluded from the 'SIRC/IRC' calculation.

Percent Reduction of Absolute Cylinder = Reduction of Absolute Cylinder ÷ Preop. Cylinder × 100. A negative value means an increase in astigmatism.
IRC = square root of (preop × preop + itt × itt - 2 × preop × itt × cos).
SIRC = square root of (preop × preop + postop × postop - 2 × preop × postop × cos.)
Where preop = preop cylinder, postop = postop cylinder, itt = intended postop cylinder, & cos = cosine of the axis difference between preop & itt or preop & postop.

Table 15
Report of the Residual Astigmatic Error at 6 Months
Stratified by Preoperative Diopter of Absolute Cylinder
Eyes Treated for Astigmatic Hyperopia

Preoperative Diopter of Absolute Cylinder	Residual Manifest Cylinder Magnitude	Absolute Shift in Manifest Axis					
		£ 5° n/N (%)	> 5° to £ 10° n/N (%)	> 10° to £ 15° n/N (%)	> 15° to £ 30° n/N (%)	> 30° n/N (%)	Total n/N (%)
Preoperative Manifest Cylinder 0.25 to 0.99 D	0.00 to <0.50 D	15/60 (25.0%)	1/60 (1.7%)	0/60 (0.0%)	4/60 (6.7%)	4/60 (6.7%)	24/60 (40.0%)
Not reported = 0	0.50 to <1.00 D	3/60 (5.0%)	1/60 (1.7%)	0/60 (0.0%)	4/60 (6.7%)	17/60 (28.3%)	25/60 (41.7%)
# of CRFs with non-missing value = 60	1.00 to <2.00 D	0/60 (0.0%)	1/60 (1.7%)	0/60 (0.0%)	0/60 (0.0%)	10/60 (16.7%)	11/60 (18.3%)
Total # of CRFs received = 60	2.00 to <3.00 D	0/60 (0.0%)	0/60 (0.0%)	0/60 (0.0%)	0/60 (0.0%)	0/60 (0.0%)	0/60 (0.0%)
	Total	18/60 (30.0%)	3/60 (5.0%)	0/60 (0.0%)	8/60 (13.3%)	31/60 (51.7%)	60/60 (100.0%)
Preoperative Manifest Cylinder 1.00 to 1.74 D	0.00 to <0.50 D	10/41 (24.4%)	0/41 (0.0%)	0/41 (0.0%)	0/41 (0.0%)	1/41 (2.4%)	11/41 (26.8%)
Not reported = 0	0.50 to <1.00 D	1/41 (2.4%)	4/41 (9.8%)	0/41 (0.0%)	1/41 (2.4%)	17/41 (41.5%)	23/41 (56.1%)
# of CRFs with non-missing value = 41	1.00 to <2.00 D	0/41 (0.0%)	1/41 (2.4%)	0/41 (0.0%)	0/41 (0.0%)	5/41 (12.2%)	6/41 (14.6%)
Total # of CRFs received = 41	2.00 to <3.00 D	0/41 (0.0%)	0/41 (0.0%)	0/41 (0.0%)	0/41 (0.0%)	1/41 (2.4%)	1/41 (2.4%)
	Total	11/41 (26.8%)	5/41 (12.2%)	0/41 (0.0%)	1/41 (2.4%)	24/41 (58.5%)	41/41 (100.0%)
Preoperative Manifest Cylinder 1.75 to 2.00 D	0.00 to <0.50 D	3/11 (27.3%)	0/11 (0.0%)	0/11 (0.0%)	1/11 (9.1%)	0/11 (0.0%)	4/11 (36.4%)
Not reported = 0	0.50 to <1.00 D	1/11 (9.1%)	0/11 (0.0%)	1/11 (9.1%)	0/11 (0.0%)	2/11 (18.2%)	4/11 (36.4%)
# of CRFs with non-missing value = 11	1.00 t o <2.00 D	0/11 (0.0%)	0/11 (0.0%)	0/11 (0.0%)	1/11 (9.1%)	0/11 (0.0%)	1/11 (9.1%)
Total # of CRFs received = 11	2.00 to <3.00 D	0/11 (0.0%)	0/11 (0.0%)	0/11 (0.0%)	0/11 (0.0%)	2/11 (18.2%)	2/11 (18.2%)
	Total	4/11 (36.4%)	0/11 (0.0%)	1/11 (9.1%)	2/11 (18.2%)	4/11 (36.4%)	11/11 (100.0%)

Axis shift = 0 for eyes with a postoperative cylinder = 0.
N = # of CRFs with non-missing value.

d. Safety Outcomes

The key safety variables for all treated eyes are presented in Table 16. Key safety outcomes stratified by each 0.50 diopter of preoperative MRSE for all treated eyes, eyes treated for spherical hyperopia and eyes treated for hyperopic astigmatism are presented in Tables 17, 18 and 19 respectively.

Note from Tables 18 and 19 that most reports of Key Safety findings occurred in eyes treated for spherical hyperopia only and only 2 occurred in eyes treated for hyperopic astigmatism. Six out of the 8 eyes with ≥ 2 lines of BSCVA loss at 6 months had returned to within 1 line of the preoperative BSCVA at the last available visit. The 2 eyes with a sustained 2-line loss had BSCVA of 20/20 and 20/25.

Table 20 provides a listing of all adverse events reported during the study at each visit period along with the overall cumulative adverse event rate.

Table 21 presents a summary of all complications reported for all treated eyes during the course of the study. The most commonly reported complication was debris in the interface, reported at least once for 15.1% of eyes. Debris continued to be reported for 9 eyes (3.1%) at the 6 month visit.

Patient symptoms were graded according to severity as either none, mild, moderate, marked, or severe, grade 0 to grade 4 respectively. Any symptom for which there is a one-grade increase from baseline is considered "worse", while an increase of 2 or more grades is considered "significantly worse". Table 22 presents the rate at which increased symptoms were reported at the 6-month and 12-month visits.

Table 16
Summary of Key Safety Variables
All Treated Eyes

Key Safety Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	[3] 12 Months n/N (%)
Loss of ≥ 2 lines BSCVA	27/328 (8.2%)	16/341 (4.7%)	8/290 (2.8%)	9/220 (4.1%)	8/172 (4.7%)
Loss of > 2 lines BSCVA	5/328 (1.5%)	5/341 (1.5%)	2/290 (0.7%)	1/220 (0.5%)	0/172 (0.0%)
BSCVA worse than 20/40	2/333 (0.6%)	2/341 (0.6%)	0/290 (0.0%)	1/221 (0.5%)	0/177 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	14/310 (4.5%)	8/319 (2.5%)	3/268 (1.1%)	3/204 (1.5%)	4/168 (2.4%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/333 (0.0%)	0/341 (0.0%)	0/290 (0.0%)	0/221 (0.0%)	0/177 (0.0%)
Increased manifest refractive astigmatism > 2.0 D*	1/184 (0.5%)	2/196 (1.0%)	1/178 (0.6%)	2/119 (1.7%)	0/130 (0.0%)
Refractive astigmatism treatment error > 2.0 D†	2/143 (1.4%)	1/147 (0.7%)	2/112 (1.8%)	0/103 (0.0%)	0/44 (0.0%)

N = Number of CRFs received with non-missing values at each visit.
* For eyes treated for spherical hyperopia only.
† For eyes treated for astigmatic hyperopia.

Table 17
Summary of Key Safety Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE*
All Treated Eyes

Key Safety Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BSCVA	0/14 (0.0%)	0/70 (0.0%)	4/71 (5.6%)	4/51 (7.8%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	8/290 (2.8%)
Loss of > 2 lines BSCVA	0/14 (0.0%)	0/70 (0.0%)	2/71 (2.8%)	0/51 (0.0%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	2/290 (0.7%)
BSCVA worse than 20/40	0/14 (0.0%)	0/70 (0.0%)	0/71 (0.0%)	0/51 (0.0%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/290 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/14 (0.0%)	0/68 (0.0%)	2/69 (2.9%)	1/48 (2.1%)	0/38 (0.0%)	0/15 (0.0%)	0/13 (0.0%)	0/3 (0.0%)	NA	3/268 (1.1%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/14 (0.0%)	0/70 (0.0%)	0/71 (0.0%)	0/51 (0.0%)	0/44 (0.0%)	0/18 (0.0%)	0/17 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/290 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	0/13 (0.0%)	0/44 (0.0%)	0/43 (0.0%)	0/32 (0.0%)	0/27 (0.0%)	1/9 (11.1%)	0/10 (0.0%)	NA	NA	1/178 (0.6%)
Refractive astigmatism treatment error > 2.0 D†	0/1 (0.0%)	0/26 (0.0%)	1/28 (3.6%)	1/19 (5.3%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	2/112 (1.8%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

§ For eyes treated for spherical hyperopia only.

† For eyes treated for astigmatic hyperopia.

Table 18
Summary of Key Safety Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE*
Eyes Treated for Spherical Hyperopia Only

Key Safety Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BSCVA	0/13 (0.0%)	0/44 (0.0%)	4/43 (9.3%)	4/32 (12.5%)	0/27 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	NA	NA	8/178 (4.5%)
Loss of > 2 lines BSCVA	0/13 (0.0%)	0/44 (0.0%)	2/43 (4.7%)	0/32 (0.0%)	0/27 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	NA	NA	2/178 (1.1%)
BSCVA worse than 20/40	0/13 (0.0%)	0/44 (0.0%)	0/43 (0.0%)	0/32 (0.0%)	0/27 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	NA	NA	0/178 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/13 (0.0%)	0/42 (0.0%)	2/42 (4.8%)	1/29 (3.4%)	0/23 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	NA	NA	3/164 (1.8%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/13 (0.0%)	0/44 (0.0%)	0/43 (0.0%)	0/32 (0.0%)	0/27 (0.0%)	0/9 (0.0%)	0/10 (0.0%)	NA	NA	0/178 (0.0%)
Increased manifest refractive astigmatism > 2.0 D	0/13 (0.0%)	0/44 (0.0%)	0/43 (0.0%)	0/32 (0.0%)	0/27 (0.0%)	1/9 (11.1%)	0/10 (0.0%)	NA	NA	1/178 (0.6%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

Table 19
Summary of Key Safety Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE*
Eyes Treated for Astigmatic Hyperopia

Key Effectiveness Variables	0.51 to 1.00 D n/N (%)	1.01 to 1.50 D n/N (%)	1.51 to 2.00 D n/N (%)	2.01 to 2.50 D n/N (%)	2.51 to 3.00 D n/N (%)	3.01 to 3.50 D n/N (%)	3.51 to 4.00 D n/N (%)	4.01 to 4.50 D n/N (%)	4.51 to 5.00 D n/N (%)	Total n/N (%)
Loss of ≥ 2 lines BSCVA	0/1 (0.0%)	0/26 (0.0%)	0/28 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/112 (0.0%)
Loss of > 2 lines BSCVA	0/1 (0.0%)	0/26 (0.0%)	0/28 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/112 (0.0%)
BSCVA worse than 20/40	0/1 (0.0%)	0/26 (0.0%)	0/28 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/112 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/1 (0.0%)	0/26 (0.0%)	0/27 (0.0%)	0/19 (0.0%)	0/15 (0.0%)	0/8 (0.0%)	0/5 (0.0%)	0/3 (0.0%)	NA	0/104 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/1 (0.0%)	0/26 (0.0%)	0/28 (0.0%)	0/19 (0.0%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	0/112 (0.0%)
Increased manifest refractive astigmatism > 2.0 D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Refractive astigmatism treatment error > 2.0 D†	0/1 (0.0%)	0/26 (0.0%)	1/28 (3.6%)	1/19 (5.3%)	0/17 (0.0%)	0/9 (0.0%)	0/7 (0.0%)	0/4 (0.0%)	0/1 (0.0%)	2/112 (1.8%)

N = Number of CRFs received with non-missing values at each visit.

* MRSE = Manifest Spherical Equivalent.

† For eyes treated for astigmatic hyperopia.

Table 20
Adverse Events Summary — All Treated Eyes

All Reported Adverse Events	1 Day n/N (%)	7 Day n/N (%)	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	[3] 12 Months n/N (%)	Cumulative n/N (%)
Angioplasty	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	2/178 (1.1%)	2/358 (0.6%)
Anterior membrane dystrophy	1/355 (0.3%)	1/339 (0.3%)	2/333 (0.6%)	4/343 (1.2%)	3/290 (1.0%)	3/222 (1.4%)	1/178 (0.6%)	4/358 (1.1%)
Corneal edema (flap) at > 1 month	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	1/178 (0.6%)	2/358 (0.6%)
Debris in interface	1/355 (0.3%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Decrease in BSCVA of > 2 lines not due to irregular astigmatism	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	2/290 (0.7%)	1/222 (0.5%)	0/178 (0.0%)	3/358 (0.8%)
Edema	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Epithelial ingrowth	0/355 (0.0%)	1/339 (0.3%)	2/333 (0.6%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Folds in flap	2/355 (0.6%)	1/339 (0.3%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Heart attack	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Lamellar keratitis	6/355 (1.7%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	6/358 (1.7%)
Mini-stroke	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	2/178 (1.1%)	2/358 (0.6%)
Procedure aborted	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Secondary surgical intervention other than excimer laser treatment	3/355 (0.8%)	2/339 (0.6%)	3/333 (0.9%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	7/358 (2.0%)
Not reported*	0	0	0	0	0	0	0	0
Total†	355	339	333	343	290	222	178	358

1 PROCEDURE ABORTED was reported at day of surgery. 1 LAMELLAR KERATITIS was reported at an interim visit between 1 day to 7 day postop.
1 ANTERIOR MEMBRANE DYSTROPHY was reported at an interim visit between 7 days to 1 month postop.
2 ANTERIOR MEMBRANE DYSTROPHY, & 1 HEART ATTACK were reported at an interim visit between 1 to 3 months postop.
N = Number of CRFs received with non-missing values at each visit.
* Number of CRFs received with missing values at each visit.
† Number of CRFs received at each visit.

Table 21
Complications Summary — All Treated Eyes

All Reported Complications	1 Day n/N (%)	7 Day n/N (%)	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	[3] 12 Months n/N (%)	Cumulative n/N (%)
Allergies	0/355 (0.0%)	1/339 (0.3%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Bells palsy	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	1/178 (0.6%)	1/358 (0.3%)
Blepharitis	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	2/343 (0.6%)	4/290 (1.4%)	4/222 (1.8%)	3/178 (1.7%)	7/358 (2.0%)
Blurry vision	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Bowmans wrinkle	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	1/290 (0.3%)	1/222 (0.5%)	1/178 (0.6%)	1/358 (0.3%)
Chalazion	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	1/358 (0.3%)
Conjunctival injection	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Conjunctivitis	0/355 (0.0%)	1/339 (0.3%)	2/333 (0.6%)	2/343 (0.6%)	4/290 (1.4%)	2/222 (0.9%)	4/178 (2.2%)	8/358 (2.2%)
Corneal abrasion	3/355 (0.8%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Corneal edema at ≤ 1 month	0/355 (0.0%)	20/339 (5.9%)	4/333 (1.2%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	24/358 (6.7%)
Debris in interface	29/355 (8.2%)	26/339 (7.7%)	26/333 (7.8%)	18/343 (5.2%)	9/290 (3.1%)	9/222 (4.1%)	8/178 (4.5%)	54/358 (15.1%)
Double vision	0/355 (0.0%)	0/339 (0.0%)	2/333 (0.6%)	0/343 (0.0%)	1/290 (0.3%)	0/222 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Edema	0/355 (0.0%)	1/339 (0.3%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	3/358 (0.8%)
Epiretinal membrane	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	1/178 (0.6%)	1/358 (0.3%)
Epithelial defect	6/355 (1.7%)	2/339 (0.6%)	2/333 (0.6%)	1/343 (0.3%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	8/358 (2.2%)
Epithelial ingrowth	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	3/343 (0.9%)	2/290 (0.7%)	1/222 (0.5%)	1/178 (0.6%)	5/358 (1.4%)
Epithelium in the interface	1/355 (0.3%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA	1/355 (0.3%)	1/339 (0.3%)	1/333 (0.3%)	1/343 (0.3%)	4/290 (1.4%)	1/222 (0.5%)	0/178 (0.0%)	5/358 (1.4%)
Erosion	1/355 (0.3%)	1/339 (0.3%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Folds in flap	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	2/343 (0.6%)	0/290 (0.0%)	0/222 (0.0%)	2/178 (1.1%)	3/358 (0.8%)
Ghost images	0/355 (0.0%)	0/339 (0.0%)	2/333 (0.6%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Guttata	2/355 (0.6%)	0/339 (0.0%)	2/333 (0.6%)	0/343 (0.0%)	1/290 (0.3%)	1/222 (0.5%)	0/178 (0.0%)	5/358 (1.4%)
Interface disruption	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	1/343 (0.3%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Itching	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	2/290 (0.7%)	0/222 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Keratitis	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	1/290 (0.3%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Meibomitis	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	2/290 (0.7%)	2/222 (0.9%)	0/178 (0.0%)	2/358 (0.6%)
Opacity, crystalline lens	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	5/290 (1.7%)	2/222 (0.9%)	5/178 (2.8%)	10/358 (2.8%)
Pain > 7 days	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	1/290 (0.3%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Papillae	0/355 (0.0%)	0/339 (0.0%)	3/333 (0.9%)	2/343 (0.6%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	4/358 (1.1%)
Partial flap	1/355 (0.3%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Not reported*	0	0	0	0	0	0	0	0
Total†	355	339	333	343	290	222	178	358

Table 21
Complications Summary — All Treated Eyes *(Continued)*

All Reported Complications	1 Day n/N (%)	7 Day n/N (%)	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	[3] 12 Months n/N (%)	Cumulative n/N (%)
Peripheral corneal epithelial defect (on the flap)	6/355 (1.7%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	1/290 (0.3%)	0/222 (0.0%)	0/178 (0.0%)	8/358 (2.2%)
Posterior vitreous detachment	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	1/343 (0.3%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Pterygium	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	1/358 (0.3%)
Punctal stenosis	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	2/222 (0.9%)	0/178 (0.0%)	2/358 (0.6%)
Redness	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	1/358 (0.3%)
Sebaceous cyst	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	1/358 (0.3%)
Subconjunctival hemorrhage	1/355 (0.3%)	1/339 (0.3%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Subepithelial opacity	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	1/290 (0.3%)	0/222 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Trichiasis	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	1/290 (0.3%)	1/222 (0.5%)	0/178 (0.0%)	2/358 (0.6%)
Vitreal traction	0/355 (0.0%)	0/339 (0.0%)	1/333 (0.3%)	0/343 (0.0%)	0/290 (0.0%)	0/222 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Vitreous detachment	0/355 (0.0%)	0/339 (0.0%)	0/333 (0.0%)	0/343 (0.0%)	0/290 (0.0%)	1/222 (0.5%)	0/178 (0.0%)	1/358 (0.3%)
Not reported*	0	0	0	0	0	0	0	0
Total†	355	339	333	343	290	222	178	358

2 DEBRIS IN INTERFACE, 1 EDEMA, & 1 PERIPHERAL CORNEAL EPITHELIAL DEFECT (ON THE FLAP) were reported at an interim visit between 7 days to 1 month postop.
1 BLEPHARITIS, 1 EPITHELIAL INGROWTH, & 1 VITREAL TRACTION were reported at an interim visit between 1 to 3 months postop.
1 DEBRIS IN INTERFACE, & 1 EPITHELIAL INGROWTH were reported at an interim visit between 3 to 6 months postop. 1 DEBRIS IN INTERFACE was reported at an interim visit between 6 to 9 months postop.
N = Number of CRFs received with non-missing values at each visit.
* Number of CRFs received with missing values at each visit.
† Number of CRFs received at each visit.

Table 22
Patient Symptom Increases from Preoperative
All Treated Eyes

Patient Symptom	6 Months			12 Months		
	N*	Worse % (n)	Significantly Worse % (n)	N*	Worse % (n)	Significantly Worse % (n)
Light Sensitivity	264	18.6 % (49)	7.2 % (19)	167	12.0 % (20)	3.6 % (6)
Headaches	265	4.2 % (11)	0.8 % (2)	167	4.2 % (7)	1.2 % (2)
Pain	263	4.9 % (13)	0.8 % (2)	166	0.6 % (1)	1.8 % (3)
Redness	264	11.4 % (30)	4.5 % (12)	166	17.5 % (29)	1.8 % (3)
Dryness	266	32.7 % (87)	11.3 % (30)	166	7.2 % (12)	1.2 % (2)
Excessive Tearing	266	4.5 % (12)	1.1 % (3)	167	4.8 % (8)	0.6 % (1)
Burning	264	12.1 % (32)	1.5 % (4)	166	10.8 % (18)	1.2 % (2)
Gritty Feeling	265	15.5 % (41)	5.3 % (14)	167	12.0 % (20)	2.4 % (4)
Glare	265	24.2 % (64)	4.5 % (12)	167	18.6 % (31)	1.2 % (2)
Halos	265	13.6 % (36)	7.5 % (20)	167	10.8 % (18)	3.0 % (5)
Blurry Vision	263	20.2 % (53)	10.3 % (27)	166	20.5 % (34)	6.0 % (10)
Double Vision	264	9.8 % (26)	4.9 % (13)	166	11.4 % (19)	1.8 % (3)
Ghost Images	265	14.0 % (37)	4.2 % (11)	167	10.8 % (18)	0.6 % (1)
Fluctuation of Vision	265	32.5 % (86)	9.8 % (26)	167	29.9 % (50)	6.6 % (11)
Variations of Vision in Bright Light	264	17.4 % (46)	6.1 % (16)	167	13.2 % (22)	5.4 % (9)
Variations of Vision in Normal Light	265	20.8 % (55)	5.7 % (15)	167	19.2 % (32)	4.8 % (8)
Variations of Vision in Dim Light	265	22.3 % (59)	14.3 % (38)	167	20.4 % (34)	11.4 % (19)
Difficulties with Night Driving	265	12.1 % (32)	6.4 % (17)	167	16.2 % (27)	1.2 % (2)

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

e. Patient Symptoms

The rate of symptoms reported as none, mild, and moderate to severe preoperatively and at 6 months are reported in Table 23. A statistical comparison of the rates of clinically significant symptoms (moderate to severe) at the preoperative versus the 6 month visit demonstrated that 6 months after treatment patients had significantly lower occurrences of headaches (3.0% vs. 14.3%, $p<0.0001$), excessive tearing (2.6% vs. 7.5%, $p<.00029$) and difficulties with night driving (11.3% vs. 20.8%, $p<0.003$). The occurrence rate for the symptoms dryness (22.6% vs. 10.5%, $p<0.0001$), gritty feeling (6.8% vs 2.6%), fluctuation of vision (14.7% vs. 5.7%, p-value = 0.0005), and variations of vision in dim light (18.1% vs. 27.9%, $p<0.0032$) were higher at the 6 month visit than at the preoperative visit.

Changes in patient symptoms from preoperative to 1 month, 6 months and ≥ 12 months are presented in Tables 24 through 26. The proportion of eyes that rated each symptom better at 6 months than at baseline versus the proportion of eyes that rated each symptom worse at 6 months than at baseline were compared statistically. This analysis showed that the proportion of eyes that improved was significantly greater than the proportion of eyes that got worse for the symptoms headaches ($p<0.0001$), excessive tearing ($p<0.0001$), and difficulties with night driving ($p<0.0001$). The analysis also demonstrated that the proportion of eyes with symptoms rated as worse was significantly greater than the proportion of eyes that had the symptom rated better for dryness ($p<0.0001$), gritty feeling ($p<.0024$), double vision ($p<0.0135$), ghost images ($p<0.0005$), fluctuations of vision ($p<0.0001$), variations of vision in normal light ($p<0.0001$) and variations of vision in dim light ($p<0.0002$).

Treatment of higher amounts of hyperopia resulted in a lower rate of accuracy in the refractive outcome (see Section IX.F.2.c). An analysis of the impact of treatment accuracy on symptoms showed that the rate of "worse" and "significantly worse" symptoms increased as the magnitude of the treatment inaccuracy increased as seen in Table 27. The effect reached statistical significance ($p<0.05$) for headaches and for variation of vision in bright and dim light.

Induced astigmatism was associated with spherical treatments and the efficacy of spherical treatments was reduced relative to astigmatic treatments for eyes with low amounts of astigmatism (see Section IX.F.2.c). The symptom data for spherical versus astigmatic treatments, shown in Table 28, do not follow these same trends.

Table 23
Patient Symptoms at Preop & 6 Months
All Treated Eyes

Patient Symptoms	None % (n/N)		Mild % (n/N)		Moderate to Severe % (n/N)	
	Preop.	6 Months	Preop.	6 Months	Preop.	6 Months
Light sensitivity	47.7% (167/350)	44.2% (121/274)	29.1% (102/350)	36.1% (99/274)	23.1% (81/350)	19.7% (54/274)
Headaches	68.6% (240/350)	84.7% (232/274)	19.7% (69/350)	12.4% (34/274)	11.7% (41/350)	2.9% (8/274)
Pain	89.4% (313/350)	92.0% (252/274)	8.3% (29/350)	6.9% (19/274)	2.3% (8/350)	1.1% (3/274)
Redness	75.4% (264/350)	71.9% (197/274)	18.6% (65/350)	20.4% (56/274)	6.0% (21/350)	7.7% (21/274)
Dryness	60.6% (212/350)	34.3% (94/274)	29.4% (103/350)	43.8% (120/274)	10.0% (35/350)	21.9% (60/274)
Tearing	76.3% (267/350)	88.3% (242/274)	16.3% (57/350)	9.1% (25/274)	7.4% (26/350)	2.6% (7/274)
Burning	77.1% (270/350)	77.0% (211/274)	19.4% (68/350)	20.8% (57/274)	3.4% (12/350)	2.2% (6/274)
Gritty feeling	77.4% (271/350)	67.9% (186/274)	19.7% (69/350)	25.5% (70/274)	2.9% (10/350)	6.6% (18/274)
Glare	59.1% (207/350)	49.6% (136/274)	28.9% (101/350)	37.6% (103/274)	12.0% (42/350)	12.8% (35/274)
Halos	82.0% (287/350)	73.7% (202/274)	11.1% (39/350)	16.4% (45/274)	6.9% (24/350)	9.9% (27/274)
Blurred vision	57.1% (200/350)	43.8% (120/274)	21.4% (75/350)	37.6% (103/274)	21.4% (75/350)	18.6% (51/274)
Double vision	91.7% (321/350)	82.5% (226/274)	5.1% (18/350)	12.0% (33/274)	3.1% (11/350)	5.5% (15/274)
Ghost images	92.3% (323/350)	78.8% (216/274)	4.9% (17/350)	16.8% (46/274)	2.9% (10/350)	4.4% (12/274)
Fluctuations of vision	70.0% (245/350)	38.3% (105/274)	24.3% (85/350)	47.1% (129/274)	5.7% (20/350)	14.6% (40/274)
Variation of vision in bright light	58.3% (204/350)	57.7% (158/274)	30.0% (105/350)	32.5% (89/274)	11.7% (41/350)	9.9% (27/274)
Variation of vision in normal light	78.9% (276/350)	63.5% (174/274)	16.0% (56/350)	29.2% (80/274)	5.1% (18/350)	7.3% (20/274)
Variation of vision in dim light	51.4% (180/350)	35.8% (98/274)	30.3% (106/350)	36.5% (100/274)	18.3% (64/350)	27.7% (76/274)
Night driving vision	43.4% (152/350)	59.5% (163/274)	38.0% (133/350)	29.6% (81/274)	18.6% (65/350)	10.9% (30/274)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

At 6 months, the symptoms graded as moderate or worse that were reported at an incidence level of more than 1% higher than the baseline incidence level were redness, dryness, gritty feeling, halos, double vision, ghost images, fluctuations of vision, variation of vision in normal light, and variation of vision in dim light.

15 'other' symptoms were reported preoperative and 8 'other' symptoms were reported at 6 Months

Table 24
Patient Symptom Changes from Preoperative to 1 Month
All Treated Eyes

Patient Symptom	N*	Significantly Better % (n)	Better % (n)	No Change % (n)	Worse % (n)	Significantly Worse % (n)
Light Sensitivity	304	4.6 % (14)	16.1 % (49)	43.1 % (131)	27.0 % (82)	9.2 % (28)
Headaches	305	4.3 % (13)	18.0 % (55)	66.9 % (204)	8.5 % (26)	2.3 % (7)
Pain	303	1.0 % (3)	5.6 % (17)	83.2 % (252)	9.9 % (30)	0.3 % (1)
Redness	304	2.3 % (7)	10.9 % (33)	64.1 % (195)	18.8 % (57)	3.9 % (12)
Dryness	304	0.7 % (2)	6.6 % (20)	38.5 % (117)	39.1 % (119)	15.1 % (46)
Excessive Tearing	305	3.6 % (11)	15.1 % (46)	76.4 % (233)	4.6 % (14)	0.3 % (1)
Burning	303	1.3 % (4)	12.2 % (37)	71.0 % (215)	13.2 % (40)	2.3 % (7)
Gritty Feeling	304	0.7 % (2)	8.2 % (25)	67.4 % (205)	22.7 % (69)	1.0 % (3)
Glare	304	3.3 % (10)	11.2 % (34)	50.0 % (152)	25.7 % (78)	9.9 % (30)
Halos	304	2.6 % (8)	7.2 % (22)	58.6 % (178)	21.4 % (65)	10.2 % (31)
Blurry Vision	301	10.3 % (31)	11.0 % (33)	36.9 % (111)	26.2 % (79)	15.6 % (47)
Double Vision	303	1.7 % (5)	4.3 % (13)	75.6 % (229)	12.2 % (37)	6.3 % (19)
Ghost Images	303	1.3 % (4)	2.3 % (7)	74.9 % (227)	15.8 % (48)	5.6 % (17)
Fluctuation of Vision	304	0.3 % (1)	4.3 % (13)	39.8 % (121)	36.5 % (111)	19.1 % (58)
Variations of Vision in Bright Light	303	3.3 % (10)	14.2 % (43)	49.5 % (150)	24.1 % (73)	8.9 % (27)
Variations of Vision in Normal Light	301	1.7 % (5)	7.0 % (21)	62.1 % (187)	21.6 % (65)	7.6 % (23)
Variations of Vision in Dim Light	304	6.9 % (21)	11.2 % (34)	42.1 % (128)	27.0 % (82)	12.8 % (39)
Difficulties with Night Driving	297	9.4 % (28)	21.5 % (64)	44.8 % (133)	13.5 % (40)	10.8 % (32)

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

Table 25
Patient Symptom Changes from Preoperative to 6 Month
All Treated Eyes

Patient Symptom	N*	Significantly Better % (n)	Better % (n)	No Change % (n)	Worse % (n)	Significantly Worse % (n)
Light Sensitivity	264	8.0 % (21)	21.2 % (56)	45.1 % (119)	18.6 % (49)	7.2 % (19)
Headaches	265	7.9 % (21)	21.1 % (56)	66.0 % (175)	4.2 % (11)	0.8 % (2)
Pain	263	1.5 % (4)	7.6 % (20)	85.2 % (224)	4.9 % (13)	0.8 % (2)
Redness	264	3.4 % (9)	10.2 % (27)	70.5 % (186)	11.4 % (30)	4.5 % (12)
Dryness	266	2.3 % (6)	7.5 % (20)	46.2 % (123)	32.7 % (87)	11.3 % (30)
Excessive Tearing	266	3.8 % (10)	14.3 % (38)	76.3 % (203)	4.5 % (12)	1.1 % (3)
Burning	264	1.9 % (5)	12.5 % (33)	72.0 % (190)	12.1 % (32)	1.5 % (4)
Gritty Feeling	265	1.5 % (4)	9.8 % (26)	67.9 % (180)	15.5 % (41)	5.3 % (14)
Glare	265	5.3 % (14)	18.9 % (50)	47.2 % (125)	24.2 % (64)	4.5 % (12)
Halos	265	4.9 % (13)	10.6 % (28)	63.4 % (168)	13.6 % (36)	7.5 % (20)
Blurry Vision	263	10.3 % (27)	16.3 % (43)	43.0 % (113)	20.2 % (53)	10.3 % (27)
Double Vision	264	2.3 % (6)	4.9 % (13)	78.0 % (206)	9.8 % (26)	4.9 % (13)
Ghost Images	265	1.9 % (5)	4.5 % (12)	75.5 % (200)	14.0 % (37)	4.2 % (11)
Fluctuation of Vision	265	1.9 % (5)	7.5 % (20)	48.3 % (128)	32.5 % (86)	9.8 % (26)
Variations of Vision in Bright Light	264	6.4 % (17)	19.7 % (52)	50.4 % (133)	17.4 % (46)	6.1 % (16)
Variations of Vision in Normal Light	265	1.5 % (4)	10.6 % (28)	61.5 % (163)	20.8 % (55)	5.7 % (15)
Variations of Vision in Dim Light	265	6.0 % (16)	14.3 % (38)	43.0 % (114)	22.3 % (59)	14.3 % (38)
Difficulties with Night Driving	265	14.3 % (38)	24.5 % (65)	42.6 % (113)	12.1 % (32)	6.4 % (17)

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

Table 26
Patient Symptom Changes from Preoperative to ³ 12 Months
All Treated Eyes

Patient Symptom	N*	Significantly Better % (n)	Better % (n)	No Change % (n)	Worse % (n)	Significantly Worse % (n)
Light Sensitivity	167	19.8 % (33)	21.6 % (36)	43.1 % (72)	12.0 % (20)	3.6 % (6)
Headaches	167	19.2 % (32)	20.4 % (34)	55.1 % (92)	4.2 % (7)	1.2 % (2)
Pain	166	11.4 % (19)	7.2 % (12)	78.9 % (131)	0.6 % (1)	1.8 % (3)
Redness	166	13.9 % (23)	16.3 % (27)	50.6 % (84)	17.5 % (29)	1.8 % (3)
Dryness	166	19.3 % (32)	21.1 % (35)	51.2 % (85)	7.2 % (12)	1.2 % (2)
Excessive Tearing	167	15.0 % (25)	13.2 % (22)	66.5 % (111)	4.8 % (8)	0.6 % (1)
Burning	166	13.3 % (22)	11.4 % (19)	63.3 % (105)	10.8 % (18)	1.2 % (2)
Gritty Feeling	167	12.0 % (20)	8.4 % (14)	65.3 % (109)	12.0 % (20)	2.4 % (4)
Glare	167	16.8 % (28)	18.6 % (31)	44.9 % (75)	18.6 % (31)	1.2 % (2)
Halos	167	13.2 % (22)	10.8 % (18)	62.3 % (104)	10.8 % (18)	3.0 % (5)
Blurry Vision	166	20.5 % (34)	16.9 % (28)	36.1 % (60)	20.5 % (34)	6.0 % (10)
Double Vision	166	12.7 % (21)	6.6 % (11)	67.5 % (112)	11.4 % (19)	1.8 % (3)
Ghost Images	167	12.0 % (20)	4.2 % (7)	72.5 % (121)	10.8 % (18)	0.6 % (1)
Fluctuation of Vision	167	11.4 % (19)	7.2 % (12)	44.9 % (75)	29.9 % (50)	6.6 % (11)
Variations of Vision in Bright Light	167	15.0 % (25)	22.2 % (37)	44.3 % (74)	13.2 % (22)	5.4 % (9)
Variations of Vision in Normal Light	167	13.8 % (23)	7.8 % (13)	54.5 % (91)	19.2 % (32)	4.8 % (8)
Variations of Vision in Dim Light	167	20.4 % (34)	10.8 % (18)	37.1 % (62)	20.4 % (34)	11.4 % (19)
Difficulties with Night Driving	167	19.8 % (33)	25.1 % (42)	37.7 % (63)	16.2 % (27)	1.2 % (2)

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

Table 27
Impact of Treatment Accuracy
On Patient Symptom Changes from Preoperative to 6 Months

Patient Symptom	Level of Outcome Accuracy											
	Postop |MRSE| ≤ 0.50D				Postop |MRSE| 0.51 to 1.00D				Postop |MRSE| > 1.00D			
	N*	Unchanged or Better (%)	Worse (%)	Significantly Worse (%)	N*	Unchanged or Better (%)	Worse (%)	Significantly Worse (%)	N*	Unchanged or Better (%)	Worse (%)	Significantly Worse (%)
Light Sensitivity	141	74.5	20.6	5.0	47	76.6	14.9	8.5	21	71.4	19.0	9.5
Headaches	142	97.9	2.1	0.0	47	89.4	8.5	2.1	21	81.0	14.3	4.8
Pain	142	94.4	4.9	0.7	46	95.7	4.3	0.0	20	100.0	0.0	0.0
Redness	143	82.5	13.3	4.2	45	86.7	8.9	4.4	21	90.5	9.5	0.0
Dryness	143	56.6	35.7	7.7	47	57.4	31.9	10.6	21	42.9	38.1	19.0
Excessive Tearing	143	93.7	6.3	0.0	47	95.7	2.1	2.1	21	90.5	0.0	9.5
Burning	142	83.8	14.8	1.4	47	93.6	6.4	0.0	21	85.7	14.3	0.0
Gritty Feeling	142	83.1	12.7	4.2	47	74.5	19.1	6.4	21	76.2	9.5	14.3
Glare	142	71.8	24.6	3.5	47	76.6	19.1	4.3	21	57.1	38.1	4.8
Halos	142	77.5	15.5	7.0	47	87.2	8.5	4.3	21	66.7	19.0	14.3
Blurry Vision	142	72.5	16.9	10.6	45	62.2	31.1	6.7	21	61.9	19.0	19.0
Double Vision	142	83.1	11.3	5.6	46	91.3	2.2	6.5	21	81.0	19.0	0.0
Ghost Images	142	82.4	13.4	4.2	47	80.9	12.8	6.4	21	76.2	23.8	0.0
Fluctuation of Vision	142	61.3	28.9	9.9	47	57.4	36.2	6.4	21	42.9	52.4	4.8
Variations of Vision in Bright Light	141	78.7	16.3	5.0	47	74.5	17.0	8.5	21	57.1	28.6	14.3
Variations of Vision in Normal Light	142	74.6	21.8	3.5	47	76.6	21.3	2.1	21	71.4	14.3	14.3
Variations of Vision in Dim Light	142	70.4	21.1	8.5	47	59.6	25.5	14.9	21	33.3	33.3	33.3
Difficulties with Night Driving	142	83.8	11.3	4.9	47	83.0	12.8	4.3	21	66.7	19.0	14.3

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

Table 28
Impact of Treatment Type (Astigmatic vs. Spherical)
On Patient Symptom Changes from Preoperative to 6 Months

Patient Symptom	Astigmatic Treatments				Spherical Treatments			
	N*	Unchanged or Better (%)	Worse (%)	Significantly Worse (%)	N*	Unchanged or Better (%)	Worse (%)	Significantly Worse (%)
Light Sensitivity	110	66.3	25.5	8.2	154	79.9	13.6	6.5
Headaches	110	97.3	2.7	0.0	155	93.5	5.2	1.3
Pain	109	92.7	6.4	0.9	154	95.5	3.9	0.6
Redness	109	83.5	11.9	4.6	155	84.5	11.0	4.5
Dryness	110	47.2	37.3	15.5	156	62.2	29.5	8.3
Excessive Tearing	110	95.5	4.5	0.0	156	93.6	4.5	1.9
Burning	108	86.1	13.0	0.9	156	86.6	11.5	1.9
Gritty Feeling	109	66.9	23.9	9.2	156	87.8	9.6	2.6
Glare	109	66.9	23.9	9.2	156	74.3	24.4	1.3
Halos	109	77.1	15.6	7.3	156	80.1	12.2	7.7
Blurry Vision	108	64.8	22.2	13.0	155	72.9	18.7	8.4
Double Vision	109	89.0	6.4	4.6	155	82.5	12.3	5.2
Ghost Images	109	80.8	12.8	6.4	156	82.7	14.7	2.6
Fluctuation of Vision	109	54.1	34.9	11.0	156	60.2	30.8	9.0
Variations of Vision in Bright Light	109	74.3	15.6	10.1	155	78.1	18.7	3.2
Variations of Vision in Normal Light	109	67.0	25.7	7.3	156	78.2	17.3	4.5
Variations of Vision in Dim Light	109	53.2	27.5	19.3	156	70.5	18.6	10.9
Difficulties with Night Driving	109	76.2	16.5	7.3	156	85.2	9.0	5.8

* Number of CRFs received with non-missing values at both the preoperative visit and the indicated follow-up visit.

f. Retreatment

Eighteen (18) eyes were discontinued following their 6 month visits due to retreatment with other than the TECHNOLAS 217A laser. The retreatments ranged from low hyperopia (due to undercorrection) to low myopia (due to overcorrection). In the absence of data from the clinical trial, no recommendations can be made regarding the safety and effectiveness of LASIK retreatment, however, caution should be taken to assure refractive stability before performing additional procedures.

g. Factors Associated with Outcomes

The primary effectiveness outcomes (UCVA 20/40 or better, MRSE deviation from attempted correction within ± 0.50 D and ±1.00 D) were analysed by baseline characteristics (surgical eye, age, gender, preoperative MRSE, and preoperative MRCYL), and study site. These analyses show the following:

1) For UCVA of 20/40 or better at 3 and 6 months postoperative, there are no significant differences between the primary (first) eye and the fellow eye results.
2) The success rates are consistent among the different age groups with the exception of the 30 to <40 age group whose success rate of MRSE deviation from attempted correction with ±1.00 D was lower at 6 months.
3) The success rates are consistent between males and females.
4) The success rates are consistent between sites with one exception of the primary effectiveness variables. At 3 months, one site had a relatively lower success rate of MRSE deviation from attempted correction within ±0.50D for treated primary eyes compared to rates at other sites.
5) The success rates of UCVA 20/40 or better are consistent among the different preoperative spherical equivalent groups. For the success rates of MRSE deviation from attempted correction within ±0.50D and ±1.00D, there are significant differences which suggest the effectiveness of the treatment diminishes at the high end of the treatment range. Accuracy within ±0.50D decreases from 83% to 47% in the spherical treatment group at the extremes of the attempted corrections.
6) The success rates are consistent among the different preoperative manifest cylinder groups with the exception of the 6-month outcome of UCVA 20/40 or better, eyes with a preoperative manifest cylinder of 2.00D to 2.99D. This group had a relatively lower success rate than the other groups.
7) Accuracy of refractive outcomes and the proportion of eyes that achieve UCVA 20/20 decrease with increasing preoperative manifest refractive cylinder and with MRSE.

h. Patient Satisfaction

Responses provided by the study subjects at 3 and 6 months to three questions regarding their experiences with the laser surgery are provided in Table 29. These three questions related to: 1) the perceived overall quality of vision following surgery; 2) the subject's willingness to have the surgery again if he/she could make the choice over; and 3) the subject's overall satisfaction with the results of the surgical procedure.

Over 98% of patients (by eye) indicated that there was improvement in the quality of vision after excimer laser. Less than 3% of patients indicated that they were dissatisfied with the results of their excimer laser treatment.

Table 29
Self-Evaluation at 3 and 6 Months
Overall Quality of Vision, Choose Again, & Satisfaction
All Treated Eyes

Slef-Evaluation Questions	Response	Overall % (n/N)	Spherical Hyperopia % (n/N)	Astigmatic Hyperopia % (n/N)
3 Months				
Overall Quality of Vision after Excimer Laser	No Improvement	1.2% (4/331)	1.1% (2/184)	1.4% (2/147)
	Slight Improvement	3.6% (12/331)	3.3% (6/184)	4.1% (6/147)
	Moderate Improvement	9.4% (31/331)	10.3% (19/184)	8.2% (12/147)
	Marked Improvement	32.3% (107/331)	28.8% (53/184)	36.7% (54/147)
	Extreme Improvement	53.5% (177/331)	56.5% (104/184)	49.7% (73/147)
	Not reported*	6	6	0
	Total†	337	190	147
Choose Excimer Again?	No	2.1% (7/332)	1.6% (3/187)	2.8% (4/145)
	Unsure	6.6% (22/332)	6.4% (12/187)	6.9% (10/145)
	Yes	91.3% (303/332)	92.0% (172/187)	90.3% (131/145)
	Not reported*	5	3	2
	Total†	337	190	147
How Satisfied with the Excimer Laser Results?	Very Satisfied	70.8% (233/329)	71.7% (132/184)	69.7% (101/145)
	Moderately Satisfied	21.6% (71/329)	22.3% (41/184)	20.7% (30/145)
	Neutral	5.5% (18/329)	4.9% (9/184)	6.2% (9/145)
	Dissatisfied	2.1% (7/329)	1.1% (2/184)	3.4% (5/145)
	Very Dissatisfied	0.0% (0/329)	0.0% (0/184)	0.0% (0/145)
	Not reported*	8	6	2
	Total†	337	190	147
6 Months				
Overall Quality of Vision after Excimer Laser	No Improvement	1.1% (3/269)	0.6% (1/157)	1.8% (2/112)
	Slight Improvement	4.5% (12/269)	3.2% (5/157)	6.3% (7/112)
	Moderate Improvement	10.0% (27/269)	10.2% (16/157)	9.8% (11/112)
	Marked Improvement	34.2% (92/269)	33.1% (52/157)	35.7% (40/112)
	Extreme Improvement	50.2% (135/269)	52.9% (83/157)	46.4% (52/112)
	Not reported*	5	5	0
	Total†	274	162	112
Choose Excimer Again?	No	1.9% (5/263)	0.6% (1/154)	3.7% (4/109)
	Unsure	8.7% (23/263)	7.8% (12/154)	10.1% (11/109)
	Yes	89.4% (235/263)	91.6% (141/154)	86.2% (94/109)
	Not reported*	11	8	3
	Total†	274	162	112
How Satisfied with the Excimer Laser Results?	Very Satisfied	71.7% (190/265)	76.8% (119/155)	64.5% (71/110)
	Moderately Satisfied	20.8% (55/265)	18.7% (29/155)	23.6% (26/110)
	Neutral	4.9% (13/265)	3.2% (5/155)	7.3% (8/110)
	Dissatisfied	2.3% (6/265)	1.3% (2/155)	3.6% (4/110)
	Very Dissatisfied	0.4% (1/265)	0.0% (0/155)	0.9% (1/110)
	Not reported*	9	7	2
	Total†	274	162	112

N = Number of CRFs received with non-missing values at each visit.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.

i. Device Failures and Replacements

There were a total of 4 cases out of 358 procedures with problems during surgery. Of these, 3 were epithelial defects and one was due to an aborted LASIK procedure secondary to a loss of suction before the microkeratome pass.

X. CONCLUSIONS DRAWN FROM THE STUDIES

The data in this application provides reasonable assurance that the device is safe and effective when used in accordance with the directions for use.

XI. 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 Device Panel, and FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CDRH DECISION

CDRH issued an approval order on February 25, 2003. The applicant's manufacturing facility was inspected on February 11-14, 2002 and was found to be in compliance with the medical device Quality System Regulation.

XIII. APPROVAL SPECIFICATIONS

Directions for Use: See Device Labeling.

Hazards to health from use of the device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Post-approval requirements and restrictions: See Approval Order