BAUSCH & LOMB, INC.
TECHNOLAS®217A EXCIMER LASER SYSTEM

LASER IN SITU KERATOMILEUSIS (LASIK) PROFESSIONAL USE INFORMATION

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

This document provides information concerning the intended clinical use of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the Bausch & Lomb TECHNOLAS 217A Excimer Laser System *User Guide.*

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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SECTION 1

SAFETY CONSIDERATIONS

Gas Handling

The high-pressure gas cylinders should only be handled by service technicians professionally trained by Bausch & Lomb TECHNOLAS. Please refer to the Bausch & Lomb TECHNOLAS 217A Excimer Laser System User Guide, Section 2, SAFETY CONSIDERATIONS.

Skin and Eye Exposure

The Bausch & Lomb TECHNOLAS 217A Excimer Laser System contains a Class IV laser with an output at 193nm which is potentially hazardous to the skin and the surface layers of the cornea. For this reason, specific controls are required which prevent accidental exposure of laser energy to the eye and skin from both direct and reflected laser beams. In addition, precautions must be taken in the surgical area to prevent the hazards of fire and electrical injury. Please refer to the Bausch & Lomb TECHNOLAS 217A Excimer Laser System User Guide, Section 2, SAFETY CONSIDERATIONS.

SECTION 2

DEVICE DESCRIPTION

The specifications for the Bausch & Lomb TECHNOLAS 217A Excimer Laser System are provided below.

Laser Type:	Argon Fluoride
Laser Wavelength:	193 nanometers
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

Features and Components of the Excimer 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 Bausch & Lomb 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 Bausch & Lomb 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.

SECTION 3

INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

3.1. INDICATIONS FOR USE

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

- 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 <-3.00 D;
- 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; and,
- in patients who are 21 years of age or older.

3.2. 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).

3.3. WARNINGS

- The decision to perform LASIK surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status should be approached cautiously. The safety and effectiveness of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System has not been established in patients with these conditions.

- LASIK is not recommended in patients with a known history of *Herpes simplex* or *Herpes zoster*.

- LASIK is not recommended in patients whose preoperative corneal thickness would leave less than 250 microns of remaining non-ablated cornea following the laser treatment.

3.4. PRECAUTIONS

The safety and effectiveness of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System have NOT been established:

- In patients with ocular disease, corneal abnormality, and previous corneal surgery or trauma to the intended ablation zone

- In patients with corneal neovascularization within 1.0 mm of the ablation zone

- In patients whose preoperative corneal thickness resulted in the laser ablation approaching closer than 250 microns to the corneal endothelium

- In patients under 21 years of age

- In patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery

- In patients who are taking sumatripin (Imitrex) for migraine headaches

- In patients with a history of glaucoma

- In patients with a history of keloid formation

- For treatment of myopic astigmatism equal to or greater than -12.00 D MRSE

- Over the longer term (more than 6 months after surgery)

- For retreatment of myopic astigmatism

Patients 50 years of age and older may be likely to experience a reduction in predictability of outcomes (as compared to younger patients).

LASIK flap diameter that is minimally larger (0.5 mm) than the optical zone size may result in decreased success rate.

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

3.5. ADVERSE EVENTS AND COMPLICATIONS

Table 1 presents all the cumulative key safety, adverse events, and complications for all treated eyes reported in the study.

Table 1
Cumulative Key Safety, Adverse Events, And Complications
All Treated Eyes

Key Safety, Adverse Events, & Complications	n/N (%)
Key Safety Events	
Loss of ≥ 2 lines BSCVA at 3 months or later	14/308 (4.5%)
Loss of > 2 lines BSCVA at 3 months or later	2/308 (0.6%)
BSCVA worse than 20/40 at 3 months or later	2/308 (0.6%)
BSCVA worse than 20/25 at 3 months or later if 20/20 or better preoperatively	9/283 (3.2%)
Haze ≥ trace with loss of BSCVA > 2 lines at 3 months or later	0/308 (0.0%)
Increased manifest refractive astigmatism > 2.0 D at 3 months or later	0/80 (0.0%)
All Adverse Event Reports Other than Above at Any Postoperative Visits	
Any corneal epithelial defect involving the keratectomy	1/308 (0.3%)
Corneal edema (flap) at > 1 month	1/308 (0.3%)
Folds in flap	2/308 (0.6%)
Lamellar keratitis	6/308 (1.9%)
Late onset of haze with loss of 2 lines or more BSCVA	2/308 (0.6%)
Procedure aborted	1/308 (0.3%)
Secondary surgical intervention other than excimer laser treatment	3/308 (1.0%)
Striae in flap	1/308 (0.3%)
Vitreous detachment	1/308 (0.3%)
All Complications at Any Postoperative Visits	
Abrasion	2/308 (0.6%)
Anterior basement membrane change	2/308 (0.6%)
Conjunctivitis	5/308 (1.6%)
Corneal abrasion	3/308 (1.0%)
Corneal edema at/before 1 month	13/308 (4.2%)
Debris in interface	50/308 (16.2%)
Epithelial defect	1/308 (0.3%)
Epithelial irregularity	1/308 (0.3%)
Epithelial vacuoles	1/308 (0.3%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA	2/308 (0.6%)
Folds in flap	23/308 (7.5%)
Lamellar keratitis	1/308 (0.3%)
Peripheral corneal epithelial defect (across the flap junction)	1/308 (0.3%)
Peripheral corneal epithelial defect (on the flap)	2/308 (0.6%)
Striae in flap	6/308 (1.9%)
Subconjunctival hemorrhage	8/308 (2.6%)
Vitreous detachment	2/308 (0.6%)

At each scheduled postoperative visit, patients were asked to complete a questionnaire that allowed them to report any findings they had regarding their vision or ocular comfort following the surgery. The percentage of subjects that rated each condition as worse than before surgery are provided in Table 2.

Table 2
Patient Findings Change from Baseline at 3 & 6 Months ≥ 1% Worse
All Treated Eyes
(Sorted by Worse % at 6 Months)

Patient Findings	3 Months n/N (%) Worse	6 Months n/N (%) Worse
Halos	120/267 (44.9)	96/224 (42.9)
Blurred vision	110/267 (41.2)	85/224 (37.9)
Variation of vision in dim light	107/267 (40.1)	83/224 (37.1)
Fluctuations of vision	124/267 (46.4)	82/224 (36.6)
Night driving vision	99/267 (37.1)	82/224 (36.6)
Glare	100/267 (37.5)	67/224 (29.9)
Variation of vision in normal light	72/267 (27.0)	62/224 (27.7)
Dryness	84/267 (31.5)	48/224 (21.4)
Ghost images	56/267 (21.0)	42/224 (18.8)
Variation of vision in bright light	50/267 (18.7)	36/224 (16.1)
Gritty feeling	33/267 (12.4)	27/224 (12.1)
Light sensitivity	46/267 (17.2)	24/224 (10.7)
Burning	38/267 (14.2)	22/224 (9.8)
Double vision	22/267 (8.2)	19/224 (8.5)
Headaches	21/267 (7.9)	16/224 (7.1)
Tearing	13/267 (4.9)	15/224 (6.7)
Pain	17/267 (6.4)	12/224 (5.4)
Redness	23/267 (8.6)	12/224 (5.4)

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

Table 2.A presents all patient symptoms graded at 6 months as moderate or worse. It can be seen that those symptoms reported at 6 months postoperative fall predominantly into the mild category, which are not considered to be clinically significant.

Table 2 A.
Patient Symptoms at Preop & 6 Months
All Treated Eyes

Patient Symptoms	None n/N (%)		Mild N/N (%)		≥ Moderate n/N (%)	
	Preop.	6 Months	Preop.	6 Months	Preop.	6 Months
Light sensitivity	99/293 (33.8%)	116/234 (49.6%)	106/293 (36.2%)	99/234 (42.3%)	88/293 (30.0%)	19/234 (8.1%)
Headaches	168/293 (57.3%)	184/234 (78.6%)	95/293 (32.4%)	34/234 (14.5%)	30/293 (10.2%)	16/234 (6.8%)
Pain	271/293 (92.5%)	216/234 (92.3%)	20/293 (6.8%)	15/234 (6.4%)	2/293 (0.7%)	3/234 (1.3%)
Redness	174/293 (59.4%)	176/234 (75.2%)	100/293 (34.1%)	52/234 (22.2%)	19/293 (6.5%)	6/234 (2.6%)
Dryness	125/293 (42.7%)	101/234 (43.2%)	120/293 (41.0%)	105/234 (44.9%)	48/293 (16.4%)	28/234 (12.0%)
Tearing	264/293 (90.1%)	217/234 (92.7%)	27/293 (9.2%)	15/234 (6.4%)	2/293 (0.7%)	2/234 (0.9%)
Burning	233/293 (79.5%)	192/234 (82.1%)	48/293 (16.4%)	41/234 (17.5%)	12/293 (4.1%)	1/234 (0.4%)
Gritty feeling	250/293 (85.3%)	196/234 (83.8%)	33/293 (11.3%)	33/234 (14.1%)	10/293 (3.4%)	5/234 (2.1%)
Glare	166/293 (56.7%)	118/234 (50.4%)	81/293 (27.6%)	90/234 (38.5%)	46/293 (15.7%)	26/234 (11.1%)
Halos	175/293 (59.7%)	86/234 (36.8%)	82/293 (28.0%)	106/234 (45.3%)	36/293 (12.3%)	42/234 (17.9%)
Blurred vision	175/293 (59.7%)	105/234 (44.9%)	63/293 (21.5%)	85/234 (36.3%)	55/293 (18.8%)	44/234 (18.8%)
Double vision	281/293 (95.9%)	211/234 (90.2%)	6/293 (2.0%)	12/234 (5.1%)	6/293 (2.0%)	11/234 (4.7%)
Ghost images	256/293 (87.4%)	183/234 (78.2%)	31/293 (10.6%)	38/234 (16.2%)	6/293 (2.0%)	13/234 (5.6%)
Fluctuations of vision	212/293 (72.4%)	115/234 (49.1%)	61/293 (20.8%)	95/234 (40.6%)	20/293 (6.8%)	24/234 (10.3%)
Variation of vision in bright light	196/293 (66.9%)	169/234 (72.2%)	68/293 (23.2%)	52/234 (22.2%)	29/293 (9.9%)	13/234 (5.6%)
Variation of vision in normal light	247/293 (84.3%)	159/234 (67.9%)	38/293 (13.0%)	65/234 (27.8%)	8/293 (2.7%)	10/234 (4.3%)
Variation of vision in dim light	148/293 (50.5%)	86/234 (36.8%)	101/293 (34.5%)	89/234 (38.0%)	44/293 (15.0%)	59/234 (25.2%)
Night driving vision	107/293 (36.5%)	62/234 (26.5%)	111/293 (37.9%)	105/234 (44.9%)	75/293 (25.6%)	67/234 (28.6%)
Astigmatism	293/293 (100.0%)	232/234 (99.1%)	0/293 (0.0%)	2/234 (0.9%)	0/293 (0.0%)	0/234 (0.0%)
Discharge	292/293 (99.7%)	234/234 (100.0%)	0/293 (0.0%)	0/234 (0.0%)	1/293 (0.3%)	0/234 (0.0%)
Edema	293/293 (100.0%)	234/234 (100.0%)	0/293 (0.0%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Eye strain	293/293 (100.0%)	233/234 (99.6%)	0/293 (0.0%)	1/234 (0.4%)	0/293 (0.0%)	0/234 (0.0%)
Floaters	285/293 (97.3%)	234/234 (100.0%)	6/293 (2.0%)	0/234 (0.0%)	2/293 (0.7%)	0/234 (0.0%)
Haze	293/293 (100.0%)	234/234 (100.0%)	0/293 (0.0%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Infection	291/293 (99.3%)	234/234 (100.0%)	2/293 (0.7%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Itching	289/293 (98.6%)	234/234 (100.0%)	4/293 (1.4%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Light flash	293/293 (100.0%)	234/234 (100.0%)	0/293 (0.0%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Myopic regression	293/293 (100.0%)	234/234 (100.0%)	0/293 (0.0%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Starburst	292/293 (99.7%)	234/234 (100.0%)	1/293 (0.3%)	0/234 (0.0%)	0/293 (0.0%)	0/234 (0.0%)
Twitch	293/293 (100.0%)	233/234 (99.6%)	0/293 (0.0%)	1/234 (0.4%)	0/293 (0.0%)	0/234 (0.0%)

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 halos, double vision, ghost images, fluctuations of vision, variation of vision in normal light, variation of vision in dim light, and night driving vision.

SECTION 4

CLINICAL RESULTS

4.1. STUDY OBJECTIVES

A prospective, non-randomized, multicenter clinical study of 308 eyes was conducted to evaluate the safety and effectiveness of the Bausch & Lomb TECHNOLAS 217A Excimer Laser System.

4.2. DATA ANALYSIS AND RESULTS

4.2.1. DEMOGRAPHICS AND BASELINE PARAMETERS

Demographic characteristics of the study population are presented in Table 3. The baseline refraction parameters for the study population are presented in Table 4.

Table 3
Demographics
All Treated Eyes

Demographics	Treated for Spherical Myopia Only		Treated for Astigmatic Myopia		All Treated Eyes	
	Number	Percentage	Number	Percentage	Number	Percentage
NUMBER OF EYES & SUBJECTS	80 Eyes of 65 Enrolled Subjects		228 Eyes of 152 Enrolled Subjects		308 Eyes of 188 Enrolled Subjects	
GENDER						
Male	27	33.8%	89	39.0%	116	37.7%
Female	53	66.3%	139	61.0%	192	62.3%
RACE						
White	75	93.8%	216	94.7%	291	94.5%
Black	2	2.5%	2	0.9%	4	1.3%
Asian	3	3.8%	5	2.2%	8	2.6%
Other	0	0.0%	5	2.2%	5	1.6%
SURGICAL EYE						
Right	38	47.5%	110	48.2%	148	48.1%
Left	42	52.5%	118	51.8%	160	51.9%
AGE (in years)						
Mean	37.3 (9.7)		38.6 (8.9)		38.2 (9.1)	
Minimum, Maximum	19.5, 56.8		20.2, 60.6		19.5, 60.6	

Table 4
Preoperative Refraction Parameters
Stratified by Sphere and Cylinder Components
All Treated Eyes

Manifest Sphere Mean (SD): 8.65 (1.17) Range: 7.25 to 12.25	Manifest Cylinder Mean (SD): 0.92 (0.77), Range: 0.00* to 3.50				Total
	0.00 to 0.99 D n/N (%)	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	n/N (%)
7.01 to 7.99 D	59/308 (19.2)	25/308 (8.1)	9/308 (2.9)	1/308 (0.3)	94/308 (30.5)
8.00 to 8.99 D	60/308 (19.5)	30/308 (9.7)	12/308 (3.9)	1/308 (0.3)	103/308 (33.4)
9.00 to 9.99 D	34/308 (11.0)	22/308 (7.1)	7/308 (2.3)	3/308 (1.0)	66/308 (21.4)
10.00 to 10.99 D	11/308 (3.6)	6/308 (1.9)	4/308 (1.3)	0/308 (0.0)	21/308 (6.8)
11.00 to 11.99 D	7/308 (2.3)	8/308 (2.6)	3/308 (1.0)	2/308 (0.6)	20/308 (6.5)
≥ 12.00 D	4/308 (1.3)	0/308 (0.0)	0/308 (0.0)	0/308 (0.0)	4/308 (1.3)
Total	175/308 (56.8)	91/308 (29.5)	35/308 (11.4)	7/308 (2.3)	308/308 (100.0)

N = Total number of eyes treated for astigmatic myopia.
1 eye (-8.50-2.50x165) was reported with an aborted procedure.
* Eyes with a preoperative manifest cylinder = 0 were treated based on their preoperatve cycloplegic cylinder.

4.2.2 SAFETY AND EFFECTIVENESS RESULTS

Table 5 presents the summary of the key safety and effectiveness variables for the 308 treated eyes at all available postoperative visits.

Table 5
Summary of Key Safety and Effectiveness Variables
All Treated Eyes

Key Safety & Effectiveness Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Effectiveness Variables			
UCVA 20/20 or better†	145/290 (50.0%)	138/288 (47.9%)	138/259 (53.3%)
UCVA 20/40 or better†	261/290 (90.0%)	260/288 (90.3%)	234/259 (90.3%)
MRSE‡, from Emmetropia, ± 0.50 D†	182/290 (62.8%)	176/288 (61.1%)	159/259 (61.4%)
MRSE‡, from Emmetropia, ± 1.00 D†	245/290 (84.5%)	223/288 (77.4%)	211/259 (81.5%)
MRSE‡, from Emmetropia, ± 2.00 D†	283/290 (97.6%)	277/288 (96.2%)	249/259 (96.1%)
Safety Variables			
Loss of ≥ 2 lines BSCVA	20/292 (6.8%)	9/292 (3.1%)	4/263 (1.5%)
Loss of > 2 lines BSCVA	2/292 (0.7%)	1/292 (0.3%)	0/263 (0.0%)
BSCVA worse than 20/40	1/294 (0.3%)	1/292 (0.3%)	1/263 (0.4%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	13/272 (4.8%)	7/272 (2.6%)	2/240 (0.8%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/294 (0.0%)	0/292 (0.0%)	0/262 (0.0%)
Increased manifest refractive astigmatism > 2.0 D¶	0/75 (0.0%)	0/73 (0.0%)	0/65 (0.0%)

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

† For all eyes minus those treated for monovision.

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

¶ For eyes treated for spherical myopia only.

4.2.3. SAFETY AND EFFECTIVENESS RESULTS AT THE POINT OF STABILITY

Table 6 presents the results for key safety and effectiveness for all treated eyes at the point of refractive stability (6 months) stratified by the preoperative myopia.

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

Key Safety & Effectiveness Variables	7.00 to 7.99 D n/N (%)	8.00 to 8.99 D n/N (%)	9.00 to 9.99 D n/N (%)	10.00 to 10.99 D n/N (%)	11.00 to 11.99 D n/N (%)	≥ 12.00 D n/N (%)
Effectiveness Variables						
UCVA 20/20 or better†	24/44 (54.5%)	51/94 (54.3%)	40/68 (58.8%)	12/26 (46.2%)	6/18 (33.3%)	5/9 (55.6%)
UCVA 20/40 or better†	40/44 (90.9%)	87/94 (92.6%)	62/68 (91.2%)	22/26 (84.6%)	15/18 (83.3%)	8/9 (88.9%)
MRSE*, from Emmetropia, ± 0.50 D†	29/44 (65.9%)	53/94 (56.4%)	47/68 (69.1%)	18/26 (69.2%)	7/18 (38.9%)	5/9 (55.6%)
MRSE*, from Emmetropia, ± 1.00 D†	38/44 (86.4%)	79/94 (84.0%)	58/68 (85.3%)	20/26 (76.9%)	8/18 (44.4%)	8/9 (88.9%)
MRSE*, from Emmetropia, ± 2.00 D†	43/44 (97.7%)	93/94 (98.9%)	64/68 (94.1%)	24/26 (92.3%)	16/18 (88.9%)	9/9 (100.0%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	1/44 (2.3%)	0/94 (0.0%)	2/68 (2.9%)	1/29 (3.4%)	0/18 (0.0%)	0/10 (0.0%)
Loss of > 2 lines BSCVA	0/44 (0.0%)	0/94 (0.0%)	0/68 (0.0%)	0/29 (0.0%)	0/18 (0.0%)	0/10 (0.0%)
BSCVA worse than 20/40	0/44 (0.0%)	0/94 (0.0%)	0/68 (0.0%)	0/29 (0.0%)	1/18 (5.6%)	0/10 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/43 (0.0%)	0/87 (0.0%)	1/64 (1.6%)	1/23 (4.3%)	0/16 (0.0%)	0/7 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/43 (0.0%)	0/94 (0.0%)	0/68 (0.0%)	0/29 (0.0%)	0/18 (0.0%)	0/10 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	0/19 (0.0%)	0/18 (0.0%)	0/19 (0.0%)	0/6 (0.0%)	0/1 (0.0%)	0/2 (0.0%)

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

* MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

§ For eyes treated for spherical myopia only.

4.2.4. STABILITY OF THE MANIFEST REFRACTION

Results for stability of the manifest refraction as determined by the manifest spherical equivalent refraction are presented for those eyes that had data at all scheduled follow-up visits during the study (the "consistent cohort"). Stability is defined as a change in the spherical equivalent manifest refraction of 1.00 diopter or less between successive visits at least 3 months apart for 95% of the treated eyes. Table 7 presents the results for all treated eyes.

Table 7
Stability of Manifest Refraction Spherical Equivalent (MRSE)
All Eyes Treated
Consistent Cohort (N = 248 Eyes)

Change in Refraction	Between 1 and 3 Months	Between 3 and 6 Months
Change of **MRSE** by ≤ 1.00 D		
n/N (%)	226/248 (91.1%)	236/248 (95.2%)
95% CI for %	(87.4%, 94.9%)	(91.9%, 98.4%)
Change of **MRSE** (Paired-Differences) in Diopters		
Mean	-0.193	-0.037
SD	0.619	0.485
95% CI for Mean	(-0.287, -0.098)	(-0.110, 0.036)

The 95% confidence interval was adjusted for the correlation between eyes.
This analysis used all eyes examined at 1, 3, and 6 months (consistent cohort).

For both treatment groups combined (spherical myopia only and astigmatic myopia), the refraction was demonstrated to be stable by 6 months postoperative based upon 95.2% of all treated eyes remaining within 1.00 D of the previous visit's refraction.

One investigational site evidenced generally lower success rates than for the other investigational sites in the study. These decreased outcomes may be related to the use of smaller corneal flap diameters and larger treatment zone sizes chosen by the investigator at this site compared to those used at the other sites.

4.2.5. CYLINDER CORRECTION/VECTOR ANALYSIS

Table 8 presents the summary of vector magnitude analysis for those eyes treated for astigmatic myopia.

Table 8
Vector Magnitude Analysis Summary at 3 And 6 Months
Eyes Treated for Astigmatic Myopia
With Complete Preoperative and Postoperative Refraction

Statistics	Preoperative	Postoperative	IRC	SIRC	SIRC/IRC*
3 Months (1 eye was reported with an IRC = 0.)					
N	219	219	219	219	218
Mean	-1.18	-0.45	1.17	1.38	1.24
Median	-1.00	-0.25	1.00	1.09	1.00
Standard Deviation	0.69	0.60	0.68	0.94	0.72
Minimum	-3.50	-6.00	0.00	0.00	0.00
Maximum	0.00	0.00	3.50	6.88	6.88
6 Months (1 eye was reported with an IRC = 0.)					
N	198	198	198	198	197
Mean	-1.18	-0.48	1.16	1.39	1.28
Median	-1.00	-0.50	1.00	1.23	1.00
Standard Deviation	0.68	0.65	0.67	0.94	0.77
Minimum	-3.50	-7.00	0.00	0.00	0.00
Maximum	0.00	0.00	3.50	7.75	7.75

* Data with an IRC = 0 were excluded from the 'SIRC/IRC' column.
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.

4.2.6. PATIENT SUBJECTIVE EVALUATIONS

Presented in Table 9 are the results for the patient subjective assessments of their overall quality of vision after the surgery, whether or not they would choose to have the surgery again if given the choice, and their overall satisfaction with the surgery.