BAUSCH & LOMB TECHNOLAS®217A EXCIMER LASER SYSTEM

LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) PROFESSIONAL USE INFORMATION

FOR THE REDUCTION OR ELIMINATION OF LOW-TO-MODERATE NATURALLY OCCURRING HYPEROPIA UP TO +4.00 DIOPTERS MRSE, WITH SPHERE BETWEEN +1.00 TO +4.00 DIOPTERS WITH OR WITHOUT REFRACTIVE ASTIGMATISM UP TO +2.00 DIOPTERS AT THE SPECTACLE PLANE

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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GENERAL WARNINGS

Restricted Device: Federal (U.S.) law restricts these devices to sale by or on the order of, a physician.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions.

Ventilation & Air-borne Contaminants
The treatment room must be adequately ventilated to provide air circulation. However, air contamination can cause attenuation of the ultraviolet laser radiation in the optical path, reducing the available power at the treatment site. It is recommended that a three stage 99.8% HEPA filtration system be used. Steps must be taken to keep the ambient air free of vapors from solvents or cleaning fluids, including floor wax and the adhesives used in new floor and wall coverings. Dust generating work and smoking are prohibited in the laser room.. Use of air sterilization devices must be avoided. Disinfecting of the patient must not be carried out with volatile, organic hydrocarbons (alcohol). Storage of explosive or flammable substances in the treatment room is prohibited. Please refer to the Bausch & Lomb TECHNOLAS® 217A Excimer Laser System User Guide, Section 4, Site Requirements and Installation.

Electromagnetic Compatibility
Radio interference or electromagnetic radiation can influence the function of the laser and/or other devices in the vicinity. The operator must remove possible interference sources. Persons wearing pacemakers should not be present in the treatment room when the laser is in operation. The use of mobile phones in the direct vicinity of the Bausch & Lomb TECHNOLAS 217A Excimer laser is not allowed as a negative influence cannot be ruled out. Please refer to the Bausch & Lomb TECHNOLAS 217A Excimer Laser System User Guide, Section 2, 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 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 1.75mm for hyperopic astigmatism. 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 3.14A.

A. Laser System

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.

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.

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 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 diopters (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.

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 for patients whose preoperative corneal thickness would leave less than 250 microns of remaining stromal bed following the laser treatment.

- Poorer uncorrected distance visual acuity outcomes may be anticipated with correction of higher refractive errors.

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 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 hyperopic astigmatism greater than +4.00 D of sphere or >+2.00 D of cylinder

- Over the long term (i.e. more than 12 months after surgery)

- For retreatment of hyperopic astigmatism

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.

Pupil size should be evaluated under mesopic conditions, and patients with large mesopic pupils should be advised of the potential for negative effects on optical visual symptoms after surgery such as glare, halos, and difficulty with night driving.

The optical zone should be (a) at least as large as the scotopic pupil and (b) small enough to leave at least 250 microns of residual stromal thickness. Prospective patients who can not satisfy both of these criteria should be disqualified for treatment.

Preoperative evaluation for dry eye should be performed. Patients should be advised of potential for worsening of symptoms associated with dry eye syndrome post-LASIK surgery.

LASIK is not recommended in patients with latent hyperopia to the degree that the patient cannot accept the full cycloplegic refraction and the cycloplegic refraction differs from the manifest refraction by 0.75 D or more.

Treatment of hyperopic astigmatism using a minus cylinder ablation profile will remove more tissue than the same corneal refractive modification using a plus cylinder profile.

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. 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.

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

Key Safety, Adverse Events, & Complications	3 Months n/N (%)	6 Months n/N (%)	≥12 Months n/N (%)	Cumulative* n/N (%)
Key Safety Events				
Loss of ≥ 2 lines BSCVA†	16/341 (4.7%)	8/290 (2.8%)	8/172 (4.7%)	18/358 (5.0%)
Loss of > 2 lines BSCVA†	5/341 (1.5%)	2/290 (0.7%)	0/172 (0.0%)	3/358 (0.8%)
BSCVA worse than 20/40†	2/341 (0.6%)	0/290 (0.0%)	0/177 (0.0%)	1/358 (0.3%)
BSCVA worse than 20/25 if 20/20 or better preoperatively†	8/319 (2.5%)	3/268 (1.1%)	4/168 (2.4%)	7/333 (2.1%)
Haze ≥ trace with loss of BSCVA > 2 lines†	0/341 (0.0%)	0/290 (0.0%)	0/177 (0.0%)	0/358 (0.0%)
Increased manifest refractive astigmatism > 2.0 D‡	2/196 (1.0%)	1/178 (0.6%)	0/130 (0.0%)	3/211 (1.4%)
Refractive astigmatism treatment error > 2.0 D§	1/147 (0.7%)	2/112 (1.8%)	0/44 (0.0%)	2/147 (1.4%)
All Adverse Event Reports Other than Above at Any Postoperative Visits				
Angioplasty	0/343 (0.0%)	0/290 (0.0%)	2/178 (1.1%)	2/358 (0.6%)
Anterior membrane dystrophy	4/343 (1.2%)	3/290 (1.0%)	1/178 (0.6%)	4/358 (1.1%)
Corneal edema (flap) at > 1 month	0/343 (0.0%)	0/290 (0.0%)	1/178 (0.6%)	2/358 (0.6%)
Debris in interface	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Decrease in BSCVA of > 2 lines not due to irregular astigmatism	0/343 (0.0%)	2/290 (0.7%)	0/178 (0.0%)	3/358 (0.8%)
Edema	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Epithelial ingrowth	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Folds in flap	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Heart attack	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Lamellar keratitis	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	6/358 (1.7%)
Mini-stroke	0/343 (0.0%)	0/290 (0.0%)	2/178 (1.1%)	2/358 (0.6%)
Procedure aborted	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Secondary surgical intervention other than excimer laser treatment	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	7/358 (2.0%)
All Complications at Any Postoperative Visits				
Allergies	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Bells palsy	0/343 (0.0%)	0/290 (0.0%)	1/178 (0.6%)	1/358 (0.3%)
Blepharitis	2/343 (0.6%)	4/290 (1.4%)	3/178 (1.7%)	7/358 (2.0%)
Blurry vision	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Bowmans wrinkle	0/343 (0.0%)	1/290 (0.3%)	1/178 (0.6%)	1/358 (0.3%)
Chalazion	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Conjunctival injection	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Conjunctivitis	2/343 (0.6%)	4/290 (1.4%)	4/178 (2.2%)	8/358 (2.2%)
Corneal abrasion	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Corneal edema at/before 1 month	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	24/358 (6.7%)
Debris in interface	18/343 (5.2%)	9/290 (3.1%)	8/178 (4.5%)	54/358 (15.1%)

N = # of eyes returned for the corresponding visit and with non-missing measurements.

* For cumulative Key Safety Events, the time frame is defined as at 6 months or later.

† For cumulative Key Safety Events, if an eye did not have visits ≥ 6 months or did have visits ≥ 6 months but missing BSCVA, the last non-missing BSCVA was carried forward.

‡ For eyes treated for spherical myopia only.

§ For eyes treated for astigmatic hyperopia.

Table 1 *(Continued)*
Key Safety, Adverse Events, And Complications
All Treated Eyes

Key Safety, Adverse Events, & Complications	3 Months n/N (%)	6 Months n/N (%)	≥12 Months n/N (%)	Cumulative* n/N (%)
All Complications at Any Postoperative Visits				
Double vision	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	3/358 (0.8%)
Edema	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	3/358 (0.8%)
Epiretinal membrane	0/343 (0.0%)	0/290 (0.0%)	1/178 (0.6%)	1/358 (0.3%)
Epithelial defect	1/343 (0.3%)	0/290 (0.0%)	0/178 (0.0%)	8/358 (2.2%)
Epithelial ingrowth	3/343 (0.9%)	2/290 (0.7%)	1/178 (0.6%)	5/358 (1.4%)
Epithelium in the interface	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA	1/343 (0.3%)	4/290 (1.4%)	0/178 (0.0%)	5/358 (1.4%)
Erosion	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Folds in flap	2/343 (0.6%)	0/290 (0.0%)	2/178 (1.1%)	3/358 (0.8%)
Ghost images	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Guttata	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	5/358 (1.4%)
Interface disruption	1/343 (0.3%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Itching	0/343 (0.0%)	2/290 (0.7%)	0/178 (0.0%)	2/358 (0.6%)
Keratitis	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	1/358 (0.3%)
Meibomitis	0/343 (0.0%)	2/290 (0.7%)	0/178 (0.0%)	2/358 (0.6%)
Opacity, crystalline lens	0/343 (0.0%)	5/290 (1.7%)	5/178 (2.8%)	10/358 (2.8%)
Pain > 7 days	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	1/358 (0.3%)
Papillae	2/343 (0.6%)	0/290 (0.0%)	0/178 (0.0%)	4/358 (1.1%)
Partial flap	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Peripheral corneal epithelial defect (on the flap)	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	8/358 (2.2%)
Posterior vitreous detachment	1/343 (0.3%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Pterygium	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Punctal stenosis	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Redness	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Sebaceous cyst	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)
Subconjunctival hemorrhage	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Subepithelial opacity	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	1/358 (0.3%)
Trichiasis	0/343 (0.0%)	1/290 (0.3%)	0/178 (0.0%)	2/358 (0.6%)
Vitreal traction	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	2/358 (0.6%)
Vitreous detachment	0/343 (0.0%)	0/290 (0.0%)	0/178 (0.0%)	1/358 (0.3%)

N = # of eyes returned for the corresponding visit and with non-missing measurements.
* For cumulative Key Safety Events, the time frame is defined as at 6 months or later.
† For cumulative Key Safety Events, if an eye did not have visits ≥ 6 months or did have visits ≥ 6 months but missing BSCVA, its last non-missing BSCVA was carried forward.
‡ For eyes treated for spherical myopia only.
§ For eyes treated for astigmatic hyperopia.

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
Increased Patient Symptoms from Preoperative at 3, 6, 9 and ≥ 12 Months
All Treated Eyes
(Sorted by Worse % at 6 Months)

Patient Symptom	3 Months			6 Months			9 Months			≥ 12 Months		
	N*	Worse % (n)	Significantly Worse % (n)	N*	Worse % (n)	Significantly Worse % (n)	N*	Worse % (n)	Significantly Worse % (n)	N*	Worse % (n)	Significantly Worse % (n)
Dryness	328	28.7 % (94)	14.6 % (48)	266	32.7 % (87)	11.3 % (30)	200	30.5 % (61)	10.5 % (21)	166	7.2 % (12)	1.2 % (2)
Fluctuation of Vision	328	36.3 % (119)	11.3 % (37)	265	32.5 % (86)	9.8 % (26)	198	31.8 % (63)	8.6 % (17)	167	29.9 % (50)	6.6 % (11)
Variations of Vision in Dim Light	325	24.6 % (80)	10.2 % (33)	265	22.3 % (59)	14.3 % (38)	197	21.3 % (42)	12.7 % (25)	167	20.4 % (34)	11.4 % (19)
Blurry Vision	324	21.0 % (68)	9.6 % (31)	263	20.2 % (53)	10.3 % (27)	198	22.2 % (44)	5.1 % (10)	166	20.5 % (34)	6.0 % (10)
Glare	328	23.2 % (76)	5.5 % (18)	265	24.2 % (64)	4.5 % (12)	198	21.7 % (43)	1.5 % (3)	167	18.6 % (31)	1.2 % (2)
Variations of Vision in Normal Light	328	23.5 % (77)	5.2 % (17)	265	20.8 % (55)	5.7 % (15)	198	19.7 % (39)	5.6 % (11)	167	19.2 % (32)	4.8 % (8)
Light Sensitivity	329	19.8 % (65)	10.0 % (33)	264	18.6 % (49)	7.2 % (19)	200	15.5 % (31)	6.0 % (12)	167	12.0 % (20)	3.6 % (6)
Variations of Vision in Bright Light	327	19.6 % (64)	10.7 % (35)	264	17.4 % (46)	6.1 % (16)	198	15.2 % (30)	5.1 % (10)	167	13.2 % (22)	5.4 % (9)
Halos	326	16.6 % (54)	5.8 % (19)	265	13.6 % (36)	7.5 % (20)	198	12.6 % (25)	4.5 % (9)	167	10.8 % (18)	3.0 % (5)
Gritty Feeling	328	14.9 % (49)	4.3 % (14)	265	15.5 % (41)	5.3 % (14)	197	12.7 % (25)	1.5 % (3)	167	12.0 % (20)	2.4 % (4)
Difficulties with Night Driving	327	14.4 % (47)	4.0 % (13)	265	12.1 % (32)	6.4 % (17)	198	17.2 % (34)	2.5 % (5)	167	16.2 % (27)	1.2 % (2)
Ghost Images	326	14.4 % (47)	3.4 % (11)	265	14.0 % (37)	4.2 % (11)	198	10.6 % (21)	2.0 % (4)	167	10.8 % (18)	0.6 % (1)
Redness	327	15.0 % (49)	3.4 % (11)	264	11.4 % (30)	4.5 % (12)	199	11.6 % (23)	2.5 % (5)	166	17.5 % (29)	1.8 % (3)
Double Vision	327	9.8 % (32)	4.9 % (16)	264	9.8 % (26)	4.9 % (13)	198	9.1 % (18)	3.0 % (6)	166	11.4 % (19)	1.8 % (3)
Burning	327	10.4 % (34)	3.7 % (12)	264	12.1 % (32)	1.5 % (4)	197	11.2 % (22)	2.0 % (4)	166	10.8 % (18)	1.2 % (2)
Pain	327	6.7 % (22)	0.9 % (3)	263	4.9 % (13)	0.8 % (2)	198	3.5 % (7)	0.5 % (1)	166	0.6 % (1)	1.8 % (3)
Excessive Tearing	328	3.0 % (10)	0.0 % (0)	266	4.5 % (12)	1.1 % (3)	200	3.0 % (6)	2.0 % (4)	167	4.8 % (8)	0.6 % (1)
Headaches	328	6.1 % (20)	1.5 % (5)	265	4.2 % (11)	0.8 % (2)	200	2.5 % (5)	0.5 % (1)	167	4.2 % (7)	1.2 % (2)

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

SECTION 4

CLINICAL RESULTS

4.1. STUDY OBJECTIVES

A prospective, non-randomized, multicenter clinical study of 358 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 AND ACCOUNTABILITY

Demographic characteristics of the study population are presented in Table 3. The baseline refraction parameters for the study population are presented in Table 4. Accountability for all treated eyes across the study visit schedule is presented in Table 5.

Table 3
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	

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

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	
	0.25-0.99 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 all treated eyes.
1 eye (3.500.75x15) was reported with an aborted procedure.
79 eyes were treated for monovision.

Table 5
Accountability — All Treated Eyes

Status		1 Month	3 Months	6 Months	9 Months	≥ 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.

4.2.2 SAFETY AND EFFECTIVENESS RESULTS

Table 6 presents the summary of the key safety and effectiveness variables for the treated eyes at all available postoperative visits.

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Table 6
Summary of Key Safety and Effectiveness Variables
All Treated Eyes

Key Safety & Effectiveness Variables	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	≥ 12 Months n/N (%)
Effectiveness Variables				
UCVA 20/20 or better†	159/265 (60.0%)	143/233 (61.4%)	100/168 (59.5%)	83/141 (58.9%)
UCVA 20/40 or better†	255/265 (96.2%)	221/233 (94.8%)	161/168 (95.8%)	134/141 (95.0%)
MRSE‡, Attempted vs. Achieved, ± 0.50 D	222/343 (64.7%)	174/290 (60.0%)	142/222 (64.0%)	109/177 (61.6%)
MRSE‡, Attempted vs. Achieved, ± 1.00 D	314/343 (91.5%)	251/290 (86.6%)	191/222 (86.0%)	151/177 (85.3%)
MRSE‡, Attempted vs. Achieved, ± 2.00 D	340/343 (99.1%)	287/290 (99.0%)	220/222 (99.1%)	175/177 (98.9%)
MRSE‡, from Emmetropia, ± 0.50 D†	193/265 (72.8%)	155/233 (66.5%)	120/168 (71.4%)	95/141 (67.4%)
MRSE‡, from Emmetropia, ± 1.00 D†	246/265 (92.8%)	209/233 (89.7%)	147/168 (87.5%)	120/141 (85.1%)
MRSE‡, from Emmetropia, ± 2.00 D†	263/265 (99.2%)	232/233 (99.6%)	167/168 (99.4%)	140/141 (99.3%)
Safety Variables				
Loss of ≥ 2 lines BSCVA	16/341 (4.7%)	8/290 (2.8%)	9/220 (4.1%)	8/172 (4.7%)
Loss of > 2 lines BSCVA	5/341 (1.5%)	2/290 (0.7%)	1/220 (0.5%)	0/172 (0.0%)
BSCVA worse than 20/40	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	8/319 (2.5%)	3/268 (1.1%)	3/204 (1.5%)	4/168 (2.4%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/341 (0.0%)	0/290 (0.0%)	0/221 (0.0%)	0/177 (0.0%)
Increased manifest refractive astigmatism > 2.0 D¶	2/196 (1.0%)	1/178 (0.6%)	2/119 (1.7%)	0/130 (0.0%)
Refractive astigmatism treatment error > 2.0 D§	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.

• 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.

¶ For eyes treated for spherical hyperopia only.

§ For eyes treated for astigmatic hyperopia.

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

4.2.3. SAFETY AND EFFECTIVENESS RESULTS AT THE POINT OF STABILITY

Tables 7 through 9 present the results for key safety and effectiveness for all treated eyes, eyes treated for spherical hyperopia only, and eyes treated for astigmatic hyperopia at the point of refractive stability (6 months) stratified by the preoperative 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 10. Accuracy within 0.50D of intended refractive outcome fell below the target rate of 50% for treatment of MRSE greater than +3.00D. Table 11 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 decreased with increasing preoperative manifest refractive cylinder as shown in Tables 12 and 13. 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.

Most reports of Key Safety findings at 6 months 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 7
Summary of Key Safety and Effectiveness Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE
All Treated Eyes

Key Safety & 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 (%)
Effectiveness Variables										
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%)
Safety Variables										
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 all eyes minus those treated for monovision

§ For eyes treated for spherical hyperopia only.

¶ For eyes treated for astigmatic hyperopia.

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

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

Key Safety & 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 (%)
Effectiveness Variables										
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%)
Safety Variables										
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.

† For all eyes minus those treated for monovision

§ For eyes treated for spherical hyperopia only.

Table 9
Summary of Key Safety and Effectiveness Variables at 6 Months (Stable Point)
Stratified By Preoperative MRSE
Eyes Treated for Astigmatic Hyperopia

Key Safety & 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 (%)
Effectiveness Variables										
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%)
Safety Variables										
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 all eyes minus those treated for monovision

§ For eyes treated for spherical hyperopia only.

¶ For eyes treated for astigmatic hyperopia.

Table 10
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. Higest Preoperative MRSE = 4.875D.

Table 11
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 (%)	≥ 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 12
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 13
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

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4.2.4. STABILITY OF THE MANIFEST REFRACTION

Table 14 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 14
Stability of Manifest Refraction Spherical Equivalent (MRSE)
6-Month Consistent Cohort

Change in Refraction	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and ≥12 Months
Change of MRSE by ≤ 1.00 D				
n/N (%)	258/267 (96.6%)	262/269 (97.4%)	205/210 (97.6%)	111/112 (99.1%)
95% CI for %	(94.5%, 98.8%)	(95.3%, 99.5%)	(95.2%, 99.9%)	(96.1%, 99.9%)
Change of MRSE (Paired-Differences) in Diopters				
Mean	0.127	0.081	-0.015	0.041
SD	0.483	0.408	0.388	0.352
95% CI for Mean	(0.065, 0.189)	(0.032, 0.130)	(-0.074, 0.044)	(-0.031, 0.113)

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

4.2.5. CYLINDER CORRECTION/VECTOR ANALYSIS

Table 15 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). The treatment created astigmatism in most farsighted patients who had no astigmatism before. The amount of induced astigmatism tended to be larger in patients who were more farsighted before surgery. Table 12 shows 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.

Table 15
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 16 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 17 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 16.

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. Astigmatism treatments tended to be too strong, leaving most patients with some astigmatism at a very different axis than before the treatment. Of eyes with axis shifts greater than 30°, 16% had at least 1 diopter of astigmatism 6 months after surgery and 3 % had at least 2 diopters. Such overcorrections of astigmatism can cause visual distortions that are disturbing to the patient. Of all eyes treated for astigmatism, 18% had more astigmatism 6 months after surgery than they had before surgery.

Table 16
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 17
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 to <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.

4.2.6. PATIENT SYMPTOMS AND SUBJECTIVE EVALUATIONS

The rate of symptoms reported as none, mild, and moderate to severe preoperatively and at the point of stability (6 months) are reported in Table 18.

Table 18
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

Changes in patient symptoms from preoperative to 1 month, 6 months and ≥12 months are presented in Tables 19 through 21.

Table 19
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 20
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 21
Patient Symptom Changes from Preoperative to ≥ 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.

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 22. The effect reached statistical significance ($p<0.05$) for headaches and for variation of vision in bright and dim light. As reported in Section 4.2.3, there is an increased rate of treatment outcome inaccuracies as the attempted treatment increases.

It was reported in Section 4.2.5, Table 15, that induced astigmatism was associated with spherical treatments. Table 12 in Section 4.2.3 shows that the efficacy of spherical treatments was reduced relative to astigmatic treatments for eyes with low amounts of astigmatism. The symptom data for the spherical versus astigmatic treatments, shown in Table 23, do not follow these same trends.

Table 22
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 23
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.

Presented in Table 24 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. Table 25 separates these results for the spherical and astigmatic treatments at the 3 and 6 month visits.

Table 26 gives details about 14 eyes of 9 patients that reported using spectacles or contact lenses for distance vision tasks at the 6-month visit. Three of the patients received a monovision correction and therefore the use of spectacles for certain distance tasks is not unexpected. Seven out of these nine patients indicated that they would have the surgery again if they had the opportunity to make the decision over.

Table 24
Self-Evaluation
Overall Quality of Vision, Choose Again, & Satisfaction
All Treated Eyes

Self-Evaluation Questions	Response	3 Months % (n/N)	6 Months % (n/N)	9 Months % (n/N)	≥ 12 Months % (n/N)
Overall Quality of Vision after Excimer Laser	No Improvement	1.2% (4/331)	1.1% (3/269)	0.5% (1/208)	0.6% (1/165)
	Slight Improvement	3.6% (12/331)	4.5% (12/269)	4.8% (10/208)	4.2% (7/165)
	Moderate Improvement	9.4% (31/331)	10.0% (27/269)	7.2% (15/208)	11.5% (19/165)
	Marked Improvement	32.3% (107/331)	34.2% (92/269)	30.8% (64/208)	24.8% (41/165)
	Extreme Improvement	53.5% (177/331)	50.2% (135/269)	56.7% (118/208)	58.8% (97/165)
	Not reported*	6	5	1	0
	Total†	337	274	209	165
Choose Excimer Laser Again?	No	2.1% (7/332)	1.9% (5/263)	0.0% (0/205)	0.0% (0/161)
	Unsure	6.6% (22/332)	8.7% (23/263)	(7.3%) (15/205)	7.5% (12/161)
	Yes	91.3% (303/332)	89.4% (235/263)	92.7% (190/205)	92.5% (149/161)
	Not reported*	5	11	4	4
	Total†	337	274	209	165
How Satisfied with the Excimer Laser Results?	Very Satisfied	70.8% (233/329)	71.7% (190/265)	72.7% (152/209)	71.5% (118/165)
	Moderately Satisfied	21.6% (71/329)	20.8% (55/265)	22.0% (46/209)	22.4% (37/165)
	Neutral	5.5% (18/329)	4.9% (13/265)	1.4% (3/209)	4.2% (7/165)
	Dissatisfied	2.1% (7/329)	2.3% (6/265)	3.8% (8/209)	1.8% (3/165)
	Very Dissatisfied	0.0% (0/329)	0.4% (1/265)	0.0% (0/209)	0.0% (0/165)
	Not reported*	8	9	0	0
	Total†	337	274	209	165

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.
24/333 (7.2%) at the 1 Months visit, 6/343 (1.7%) at the 3 Months visit, 16/290 (5.5%) at the 6 Months visit, 13/222 (5.9%) at the 9 Months visit, and 13/178 (7.3%) at the 12 Months visit were not reported with the Self-Evaluation CRFs.

Table 25
Self-Evaluation at 3 and 6 Months
Overall Quality of Vision, Choose Again, & Satisfaction
All Treated Eyes

Self-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.