## I. GENERAL INFORMATION

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| **Device Generic Name:** | Excimer Laser |
| **Device Trade Name:** | Bausch & Lomb TECHNOLAS®217A Excimer Laser System |
| **Applicant's Name and Address:** | Bausch & Lomb, Inc.<br>180 E. Via Verde Drive<br>San Dimas, California 91773 USA<br>(909) 971-5100 |
| **Date(s) of Panel Recommendation:** | None |
| **PMA Number:** | P990027/S2 |
| **Date of Good Manufacturing Practice Inspection:** | February 11-14, 2002 |
| **Date of Notice of Approval to Applicant:** | May 17, 2002 |

The Bausch & Lomb TECHNOLAS®217A Excimer Laser System was approved on February 23, 2000 under PMA P990027/S2 for the indication of photorefractive keratectomy for the reduction or elimination of myopia ranging from -1.00 D to -7.00 D spherical myopia with or without ≤ -3.00 D astigmatism. The sponsor submitted the current supplement to further expand the indication statement. The updated clinical data to support this expanded indication are provided in this summary. The pre-clinical test results were presented in the original PMA application. For more information on the data that supported the approved indication, the summary of safety and effectiveness data (SSED) for P990027/S2 should be referenced. Written requests for copies of the SSED can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Maryland 20857. The summary can also be found on the FDA CDRH Internet Home Page located at http://www.fda.gov/cdrh/pmapage.html

## II. INDICATIONS FOR USE

The Bausch & Lomb TECHNOLAS 217A Excimer Laser System is indicated for 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.

## III. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

### A. Contraindications

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

### B. Warning and Precautions

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

## IV. DEVICE DESCRIPTION

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

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

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

**TECHNOLAS®217A Excimer Laser Specifications**

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

## V. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative methods of correcting nearsightedness (myopia) include: glasses, contact lenses, photorefractive keratectomy (PRK), incisional refractive keratotomy (RK), and lamellar refractive keratotomy.

## VI. MARKETING HISTORY

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

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

## VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

Please refer to Tables 10 and 11 for a summary of adverse events observed in this clinical trial.

## VIII. SUMMARY OF PRECLINICAL STUDIES

Please refer to the SSED of the original PMA P990027

## IX. SUMMARY OF CLINICAL STUDIES

### A. Objectives

The objective of the study was to demonstrate the safety and effectiveness of the Bausch & Lomb TECHNOLAS®217A Excimer Laser System for the correction of moderate to high myopia from >-7.00 to -10.99 diopters with astigmatism less than 3.00 diopters (in minus cylinder form) or MRSE ≤ -12.00 D when used as part of the LASIK surgical procedure.

### B. Study Design

The core study for this submission was a prospective, open-label, non-randomized, multi-center clinical evaluation conducted at eight clinical sites. The study protocol originally allowed for the enrollment of eyes with myopia from -1.00 to -12.00 diopters. However, during the conduct of this study, the Bausch & Lomb TECHNOLAS 217A Excimer Laser System was approved for the treatment of up to -7.00 diopters of myopia and less than 3.00 diopters of astigmatism based on the results of a separate investigational study. Therefore, for the purposes of determining safety and effectiveness for treatment of moderate to high myopia (greater than -7 diopters), a sub-group of eyes from this study with myopia greater than -7.00 diopters was used to support safety and effectiveness.

### C Inclusion and Exclusion Criteria

In order to be enrolled in the study, patients needed to meet these conditions: have the required amount of myopia and astigmatism; have a stable refraction for the past year; discontinue use of contact lenses prior to surgery; have normal, healthy eyes with visual acuity correctable to at least 20/40; be at least 21 years of age; be willing and able to return for scheduled follow-up examinations; and provide written informed consent.

Patients not meeting the above inclusion criteria were excluded from the study. In addition, subjects who exhibited any of the following conditions were excluded: history of anterior segment pathology, including cataracts; residual, recurrent, active ocular or uncontrolled eyelid disease, or any corneal abnormality (specifically, recurrent corneal erosion, severe basement membrane disease); ophthalmoscopic signs of progressive or unstable myopia or keratoconus; required ablation is deeper than 250 microns from the corneal endothelium; unstable corneal mires on central keratotomy readings; blind in the fellow eye; previous ocular surgery; history of herpes zoster or herpes simplex keratitis, diabetes, autoimmune disease, connective tissue disease, or clinically significant atopic syndrome; taking chronic systemic corticosteroid or other immunosuppressive therapy; immunocompromised; pregnant, lactating, or of child-bearing potential and not practicing a medically approved form of birth control; sensitivity to planned evaluation medications; simultaneous participation in any other ophthalmic drug or device clinical trial.

## D Study Plan, Patient Assessments and Efficacy Criteria

All subjects were expected to return for follow-up examinations at 1 day, 1 wk, 1 month, 3 months and 6 months postoperatively.

Subjects were permitted to have second eyes (fellow eyes) treated on the same day as the first eye surgery. In addition, subjects were eligible for retreatment no sooner than 3 months after the original surgery and only if refraction was stable after treatment. To qualify for retreatment, eyes must have had residual myopia $\geq$0.50D and/or residual astigmatism $\geq$0.50D and/or uncorrected visual acuity worse than 20/40.

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

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

## E. Study Period, Investigational Sites, and Demographics Data

### 1. Study Period and Investigational Sites

Subjects were treated between April 1999 to April 2000. The database for this PMA supplement reflected data collected through March 15, 2001. A total of 308 eyes were treated at eight sites.

### 2. Demographics

The demographics of this study are typical for a contemporary refractive surgery trial performed in the U.S. The cohort consists primarily of Caucasians.

## Table 1: 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 | |

## F. Data Analysis and Results

### 1. Preoperative characteristics

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

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

| Manifest Sphere Mean (SD): 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.

5 of 5 eyes that were treated for mono-vision had an astigmatic myopia treatment.

* Eyes with a preoperative manifiest cylinder = 0 were treated based on their preoperatve cycloplegic cylinder.

## 2. Post-operative Characteristics and Results

### a. Accountability

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

**Table 3: Accountability - All Treated Eyes**

| Status | | 1 Month | 3 Months | 6 Months |
|---|---|---|---|---|
| Available for Analysis | n/N (%) | 294/308 (95.5%) | 292/308 (94.8%) | 263/308 (85.4%) |
| Discontinued* | n/N (%) | 1/308 (0.3%) | 1/308 (0.3%) | 8/308 (2.6%) |
| Active (Not yet eligible for the interval) | n/N (%) | 0/308 (0.0%) | 0/308 (0.0%) | 21/308 (6.8%) |
| Lost to Follow-up† | n/N (%) | 0/308 (0.0%) | 2/308 (0.6%) | 16/308 (5.2%) |
| Missed Visit‡ | n/N (%) | 13/308 (4.2%) | 13/308 (4.2%) | 0/308 (0.0%) |
| % Accountability = Available for Analysis ÷ (Enrolled – Discontinued - Not yet eligible) | | 294/307 (95.8%) | 292/307 (95.1%) | 263/279 (94.3%) |

N = Total eyes enrolled

* Discontinued = Exited due to Technolas laser retreatment (7 eyes) or non-Technolas laser retreatment (0 eye) or aborted procedure (1 eye) or death (0 eye).

† Loss to follow-up: Eyes not examined at the 6 month visit, and not considered active or discontinued. 16 cases of lost-to-follow-up were 170-9013-A0, 170-9013-B0, 170-9025-A0, 170-9026-B0, 316-9030-A0, 316-9030-B0, 351-9012-A0, 407-9060-A0, 407-9060-B0, 407-9085-A0, 407-9085-B0, 409-9009-A0, 409-9026-A0, 409-9026-B0, 420-9048-A0, and 420-9048-B0.

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

**b. Stability of outcome**

Table 4 presents the results for the stability of the manifest refraction spherical equivalent for the consistent cohort (all treated eyes examined at 1, 3, and 6 months). Table 4 demonstrates that over 95% of the overall cohort were within ±1.00 D by 6 months. The mean of the differences was 0.037 D between 3 and 6 months with a standard deviation of 0.485.

**Table 4**
**Stability of Manifest Refraction Sphere (MRSE)**
**Consistent Cohort (N=248)**

| Change in Spherical Refraction | Between 1 and 3 Months | | | Between 3 and 6 Months | | |
|---|---|---|---|---|---|---|
| | Full Cohort | Treated For Sphere Only | Treated For Sphere & Cylinder | Full Cohort | Treated For Sphere Only | Treated For Sphere & Cylinder |
| Change of **MRSE** by ≤ 1.00 D | | | | | | |
| n/N (%) | 226/248 (91.1%) | 54/59 (91.5%) | 172/189 (91.0%) | 236/248 (95.2%) | 54/59 (91.5%) | 182/189 (96.3%) |
| 95% CI for % | (87.4%, 94.9%) | (83.3%, 99.7%) | (87.1%, 95.0%) | (91.9%, 98.4%) | (83.7%, 99.3%) | (93.3%, 99.3%) |
| Change of **MRSE** (Paired-Differences) in Diopters | | | | | | |
| Mean | -0.193 | -0.129 | -0.212 | -0.037 | -0.042 | -0.035 |
| SD | 0.619 | 0.696 | 0.595 | 0.485 | 0.511 | 0.477 |
| 95% CI for Mean | (-0.287, -0.098) | (-0.336, 0.078) | (-0.312, -0.113) | (-0.110, 0.036) | (-0.200, 0.115) | (-0.111, 0.041) |

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

**c. Effectiveness Outcomes**

Table 5 presents the key effectiveness variables outcomes for all treated eyes at 1, 3 and 6 months. Key efficacy outcomes stratified by each diopter of preoperative MRSE for all treated eyes are presented in Table 6.

**Table 5**
**Summary of Key Effectiveness Variables**
**All Treated Eyes**

| Key Safety & Effectiveness Variables | 1 Month | | 3 Months | | 6 Months | |
|---|---|---|---|---|---|---|
| | n/N (%) | 95%* CI | n/N (%) | 95%* CI | n/N (%) | 95%* CI |
| UCVA 20/20 or better† | 145/290 (50.0%) | (43.5, 56.5) | 138/288 (47.9%) | (41.3, 54.5) | 138/259 (53.3%) | (46.0, 60.5) |
| UCVA 20/40 or better† | 261/290 (90.0%) | (86.3, 93.7) | 260/288 (90.3%) | (86.1, 94.4) | 234/259 (90.3%) | (86.4, 94.3) |
| MRSE‡, Attempted vs. Achieved, ± 0.50 D | 177/294 (60.2%) | (54.1, 66.3) | 174/292 (59.6%) | (53.1, 66.1) | 161/263 (61.2%) | (54.7, 67.7) |
| MRSE‡, Attempted vs. Achieved, ± 1.00 D | 245/294 (83.3%) | (78.5, 88.1) | 232/292 (79.5%) | (74.2, 84.7) | 216/263 (82.1%) | (76.9, 87.4) |
| MRSE‡, Attempted vs. Achieved, ± 2.00 D | 287/294 (97.6%) | (95.7, 99.6) | 282/292 (96.6%) | (94.1, 99.0) | 253/263 (96.2%) | (93.7, 98.7) |
| MRSE‡, from Emmetropia, ± 0.50 D† | 182/290 (62.8%) | (56.9, 68.6) | 176/288 (61.1%) | (54.6, 67.6) | 159/259 (61.4%) | (54.8, 68.0) |
| MRSE‡, from Emmetropia, ± 1.00 D† | 245/290 (84.5%) | (79.8, 89.2) | 223/288 (77.4%) | (72.0, 82.9) | 211/259 (81.5%) | (75.9, 87.0) |
| MRSE‡, from Emmetropia, ± 2.00 D† | 283/290 (97.6%) | (95.6, 99.6) | 277/288 (96.2%) | (93.6, 98.7) | 249/259 (96.1%) | (93.6, 98.7) |
| Vector Deviation, ≤ 0.5 D§ | 157/219 (71.7%) | (65.4, 78.0) | 140/219 (63.9%) | (56.8, 71.0) | 126/198 (63.6%) | (56.2, 71.1) |
| Vector Deviation, ≤ 1.0 D§ | 183/219 (83.6%) | (78.3, 88.9) | 176/219 (80.4%) | (74.7, 86.0) | 155/198 (78.3%) | (71.8, 84.7) |

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 astigmatic myopia.

**Table 6**
**Summary of Key Effectiveness Variables at 6 Months**
**Stratified By Preoperative MRSE***
**All Treated Eyes**

| Key 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 n/N (%) | Total n/N (%) |
|---|---|---|---|---|---|---|---|
| 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%) | 138/259 (53.3%) |
| 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%) | 234/259 (90.3%) |
| MRSE, Attempted vs. Achieved, ± 0.50 D | 30/44 (68.2%) | 52/94 (55.3%) | 45/68 (66.2%) | 19/29 (65.5%) | 9/18 (50.0%) | 6/10 (60.0%) | 161/263 (61.2%) |
| MRSE, Attempted vs. Achieved, ± 1.00 D | 38/44 (86.4%) | 79/94 (84.0%) | 57/68 (83.8%) | 24/29 (82.8%) | 10/18 (55.6%) | 8/10 (80.0%) | 216/263 (82.1%) |
| MRSE, Attempted vs. Achieved, ± 2.00 D | 43/44 (97.7%) | 93/94 (98.9%) | 64/68 (94.1%) | 27/29 (93.1%) | 16/18 (88.9%) | 10/10 (100.0%) | 253/263 (96.2%) |
| 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%) | 159/259 (61.4%) |
| 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%) | 211/259 (81.5%) |
| 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%) | 249/259 (96.1%) |
| Vector Deviation, ≤ 0.5 D‡ | 16/25 (64.0%) | 49/76 (64.5%) | 32/49 (65.3%) | 14/23 (60.9%) | 11/17 (64.7%) | 4/8 (50.0%) | 126/198 (63.6%) |
| Vector Deviation, ≤ 1.0 D‡ | 18/25 (72.0%) | 57/76 (75.0%) | 41/49 (83.7%) | 19/23 (82.6%) | 14/17 (82.4%) | 6/8 (75.0%) | 155/198 (78.3%) |

N = Number of CRFs received with non-missing values at each visit.
* MRSE = Manifest Spherical Equivalent.
† For all eyes minus those treated for monovision
‡ For eyes treated for astigmatic myopia.

When analyzed by treatment group, for the astigmatic myopia group (n= 224) in the 11.00 to 11.99 D stratum, 52.9% of eyes (versus recommended 60%) achieved MRSE within ±1.00 D. For the spherical myopia group (n=80), there were only 3 eyes with MRSE ≥ 11.00 D, which was insufficient to support a determination of efficacy.

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.

i. Correction of Cylindrical Component

The sponsor utilized the Sanders and Annello method for calculating vector change. This method was described in the PMA Supplement.

Table 7 presents stratification by diopter of preoperative cylinder percent reduction of absolute cylinder and achieved vs. intended vector magnitude ratio (SIRC/IRC). The Intended Refractive Correction ("IRC") had a mean of 1.16 with a median of 1.00 (range 0.00 to 3.50). The Surgically Induced Refractive Correction ("SIRC") had a mean of 1.39 with a median of 1.23 (range 0.00 to 7.75). The vector magnitude ratio (SIRC/IRC) was 1.28 at 6 months.

**Table 7: Cylinder Correction Effectiveness Stratified By Preoperative Cylinder - Astigmatic Myopia 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) |
| **1 Month (1 eye was reported with an IRC = 0, and 4 eyes had a preop cylinder = 0.)** | | | | | | |
| < 1.00 D | 87 | 56.51 (64.42) | 100.00 (-150.0 to 100.00) | 90 | 1.21 (0.70) | 1.00 (0.00 to 4.36) |
| 1.00 to 1.99 D | 88 | 60.13 (92.14) | 80.00 (-725.0 to 100.00) | 88 | 1.18 (0.78) | 1.00 (0.28 to 7.59) |
| 2.00 to 2.99 D | 33 | 79.65 (20.27) | 77.78 (37.50 to 100.00) | 33 | 1.13 (0.19) | 1.00 (0.77 to 1.57) |
| 3.00 to 3.99 D | 7 | 95.92 (10.80) | 100.00 (71.43 to 100.00) | 7 | 1.00 (0.10) | 1.00 (0.80 to 1.09) |
| Total | 215 | 62.83 (72.68) | 83.33 (-725.0 to 100.00) | 218 | 1.18 (0.67) | 1.00 (0.00 to 7.59) |
| **3 Months (1 eye was reported with an IRC = 0, and 4 eyes had a preop cylinder = 0.)** | | | | | | |
| < 1.00 D | 89 | 43.26 (71.89) | 100.00 (-166.7 to 100.00) | 92 | 1.29 (0.83) | 1.00 (0.00 to 4.96) |
| 1.00 to 1.99 D | 87 | 56.50 (73.89) | 71.43 (-500.0 to 100.00) | 87 | 1.23 (0.74) | 1.00 (0.51 to 6.88) |
| 2.00 to 2.99 D | 33 | 76.97 (18.26) | 75.00 (25.00 to 100.00) | 33 | 1.14 (0.19) | 1.13 (0.72 to 1.74) |
| 3.00 to 3.99 D | 6 | 80.95 (18.99) | 82.14 (50.00 to 100.00) | 6 | 1.13 (0.24) | 1.10 (0.85 to 1.56) |
| Total | 215 | 54.84 (67.30) | 75.00 (-500.0 to 100.00) | 218 | 1.24 (0.72) | 1.00 (0.00 to 6.88) |
| **6 Months (1 eye was reported with an IRC = 0, and 2 eyes had a preop cylinder = 0.)** | | | | | | |
| < 1.00 D | 80 | 29.37 (74.59) | 33.33 (-200.0 to 100.00) | 81 | 1.39 (0.85) | 1.00 (0.00 to 4.90) |
| 1.00 to 1.99 D | 83 | 57.55 (83.01) | 66.67 (-600.0 to 100.00) | 83 | 1.23 (0.82) | 1.00 (0.52 to 7.75) |
| 2.00 to 2.99 D | 27 | 75.28 (22.09) | 75.00 (25.00 to 100.00) | 27 | 1.12 (0.23) | 1.15 (0.54 to 1.72) |
| 3.00 to 3.99 D | 6 | 82.74 (17.08) | 83.33 (58.33 to 100.00) | 6 | 1.14 (0.19) | 1.09 (0.94 to 1.47) |
| Total | 196 | 49.26 (74.46) | 66.67 (-600.0 to 100.00) | 197 | 1.28 (0.77) | 1.00 (0.00 to 7.75) |

* 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.

There were an insufficient number of eyes treated for cylinder of 3.00D and above to adequately demonstrate the effectiveness or safety of the procedure.

## d. Safety Outcomes

The key safety variables for all treated eyes at 3 and 6 months are presented in Tables 8 and 9, with all the adverse events reported in table 10.

**Table 8: Key Safety Variables at 3 And 6 Months**
**All Treated Eyes**

| Key Safety Events | All Eyes n/N (%) | |
|---|---|---|
| | 3 Months | 6 Months |
| Loss of ≥ 2 lines BSCVA | 9/292 (3.1%) | 4/263 (1.5%) |
| Loss of > 2 lines BSCVA | 1/292 (0.3%) | 0/263 (0.0%) |
| BSCVA worse than 20/40 | 1/292 (0.3%) | 1/263 (0.4%) |
| BSCVA worse than 20/25 if 20/20 or better preoperatively | 7/272 (2.6%) | 2/240 (0.8%) |
| Haze ≥ trace with loss of BSCVA > 2 lines | 0/292 (0.0%) | 0/262 (0.0%) |
| Increased manifest refractive astigmatism > 2.0 D* | 0/73 (0.0%) | 0/65 (0.0%) |

N = Number of CRFs received with non-missing values at each visit.
For eyes treated with spherical myopia only.

**Table 9**
**Key Safety Variables at 6 Months Stratified by Preoperative MRSE**
**All Treated Eyes**

| Key Safety 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 n/N (%) |
|---|---|---|---|---|---|---|
| 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.

* For eyes treated for spherical myopia only.

Table 10 provides a listing of all adverse events reported during the study at each visit period along with the overall cumulative adverse event rate. The cumulative adverse event rate for all reported events was quite low, with only one category (lamellar keratitis) exceeding 1.0% on a cumulative basis.

**Table 10: Adverse Events Summary - All Treated Eyes**

| All Reported Adverse Events | 1 Day n/N (%) | 7 Day n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months n/N (%) | Cumulative n/N (%) |
|---|---|---|---|---|---|---|
| Any corneal epithelial defect involving the keratectomy | 0/304 (0.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) | 1/308 (0.3%) |
| Corneal edema (flap) at > 1 month | 0/304 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 0/292 (0.0%) | 0/263 (0.0%) | 1/308 (0.3%) |
| Folds in flap | 1/304 (0.3%) | 0/282 (0.0%) | 1/294 (0.3%) | 0/292 (0.0%) | 0/263 (0.0%) | 2/308 (0.6%) |
| Lamellar keratitis | 5/304 (1.6%) | 2/282 (0.7%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) | 6/308 (1.9%) |
| Late onset of haze with loss of 2 lines or more BSCVA | 0/304 (0.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 2/263 (0.8%) | 2/308 (0.6%) |
| Secondary surgical intervention other than excimer laser treatment | 1/304 (0.3%) | 1/282 (0.4%) | 1/294 (0.3%) | 0/292 (0.0%) | 0/263 (0.0%) | 3/308 (1.0%) |
| Striae in flap | 0/304 (0.0%) | 1/282 (0.4%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) | 1/308 (0.3%) |
| Vitreous detachment | 0/304 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 0/292 (0.0%) | 0/263 (0.0%) | 1/308 (0.3%) |
| Not reported* | 0 | 0 | 0 | 0 | 0 | 0 |
| Total† | 304 | 282 | 294 | 292 | 263 | 308 |

1 ANY CORNEAL EPITHELIAL DEFECT INVOLVING THE KERATECTOMY, & 1 PROCEDURE ABORTED were reported at surgery day.1 LAMELLAR KERATITIS was reported at an interim visit between 1 day to 7 days postop.
1 LAMELLAR KERATITIS was reported at an interim visit between 7 days to 1 month postop.
N = Number of CRFs received with non-missing values at each visit.
The maximal cumulative adverse event rate is 1.9%.
* Number of CRFs received with missing values at each visit.
† Number of CRFs received at each visit.

Table 11 presents a summary of all complications reported for all treated eyes during the course of the study.

**Table 11: Complications Summary - All Treated Eyes**

| All Reported Complications | 1 Day n/N (%) | 7 Days n/N (%) | 1 Month n/N (%) | 3 Months n/N (%) | 6 Months n/N (%) |
|---|---|---|---|---|---|
| Abrasion | 2/303 (0.7%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Anterior basement membrane change | 0/303 (0.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 2/263 (0.8%) |
| Conjunctivitis | 0/303 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 3/292 (1.0%) | 1/263 (0.4%) |
| Corneal abrasion | 3/303 (1.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Corneal edema at ≤ 1 month | 0/303 (0.0%) | 10/282 (3.5%) | 6/294 (2.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Debris in interface | 35/303 (11.6%) | 24/282 (8.5%) | 18/294 (6.1%) | 11/292 (3.8%) | 8/263 (3.0%) |
| Epithelial defect | 1/303 (0.3%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Epithelial irregularity | 0/303 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Epithelial vacuoles | 1/303 (0.3%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Epithelium in the interface with loss ≤ 2 lines of BSCVA | 0/303 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 2/292 (0.7%) | 1/263 (0.4%) |
| Folds in flap | 1/303 (0.3%) | 0/282 (0.0%) | 14/294 (4.8%) | 14/292 (4.8%) | 11/263 (4.2%) |
| Lamellar keratitis | 0/303 (0.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 1/292 (0.3%) | 0/263 (0.0%) |
| Peripheral corneal epithelial defect (across the flap junction) | 1/303 (0.3%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Peripheral corneal epithelial defect (on the flap) | 2/303 (0.7%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Striae in flap | 0/303 (0.0%) | 0/282 (0.0%) | 1/294 (0.3%) | 4/292 (1.4%) | 1/263 (0.4%) |
| Subconjunctival hemorrhage | 4/303 (1.3%) | 6/282 (2.1%) | 0/294 (0.0%) | 0/292 (0.0%) | 0/263 (0.0%) |
| Vitreous detachment | 0/303 (0.0%) | 0/282 (0.0%) | 0/294 (0.0%) | 0/292 (0.0%) | 2/263 (0.8%) |
| Not reported* | 1 | 0 | 0 | 0 | 0 |
| Total† | 304 | 282 | 294 | 292 | 263 |

2 DEBRIS IN INTERFACE, & 1 FOLDS IN FLAP were reported at an interim visit between 1 day to 7 days postop. 1 DEBRIS IN INTERFACE was reported at an interim visit between 1 to 3 months postop.

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

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

† Number of CRFs received at each visit.

Table 12 presents the changes in patient symptoms from baseline for all treated eyes at 3 and 6 months postoperative. Those categories in which there was a clinically significant greater percentage (≥ 5% difference) of eyes reporting that symptoms were worse rather than better at 6 months include glare, halos, blurred vision, double vision, ghost images, fluctuation of vision, variation of vision in normal light, variation of vision in dim light, and night driving vision.

## Table 12: Patient Symptoms Change from Baseline - All Treated Eyes

| Patient Symptoms | 3 Months n/N (%) | | | 6 Months n/N (%) | | |
|---|---|---|---|---|---|---|
| | Better | No Change | Worse | Better | No Change | Worse |
| Light sensitivity | 111/267 (41.6) | 110/267 (41.2) | 46/267 (17.2) | 95/224 (42.4) | 105/224 (46.9) | 24/224 (10.7) |
| Headaches | 79/267 (29.6) | 167/267 (62.5) | 21/267 (7.9) | 63/224 (28.1) | 145/224 (64.7) | 16/224 (7.1) |
| Pain | 14/267 (5.2) | 236/267 (88.4) | 17/267 (6.4) | 14/224 (6.3) | 198/224 (88.4) | 12/224 (5.4) |
| Redness | 54/267 (20.2) | 190/267 (71.2) | 23/267 (8.6) | 48/224 (21.4) | 164/224 (73.2) | 12/224 (5.4) |
| Dryness | 48/267 (18.0) | 135/267 (50.6) | 84/267 (31.5) | 64/224 (28.6) | 112/224 (50.0) | 48/224 (21.4) |
| Tearing | 22/267 (8.2) | 232/267 (86.9) | 13/267 (4.9) | 18/224 (8.0) | 191/224 (85.3) | 15/224 (6.7) |
| Burning | 35/267 (13.1) | 194/267 (72.7) | 38/267 (14.2) | 37/224 (16.5) | 165/224 (73.7) | 22/224 (9.8) |
| Gritty feeling | 24/267 (9.0) | 210/267 (78.7) | 33/267 (12.4) | 20/224 (8.9) | 177/224 (79.0) | 27/224 (12.1) |
| Glare | 48/267 (18.0) | 119/267 (44.6) | 100/267 (37.5) | 55/224 (24.6) | 102/224 (45.5) | 67/224 (29.9) |
| Halos | 35/267 (13.1) | 112/267 (41.9) | 120/267 (44.9) | 35/224 (15.6) | 93/224 (41.5) | 96/224 (42.9) |
| Blurred vision | 58/267 (21.7) | 99/267 (37.1) | 110/267 (41.2) | 51/224 (22.8) | 88/224 (39.3) | 85/224 (37.9) |
| Double vision | 2/267 (0.7) | 243/267 (91.0) | 22/267 (8.2) | 3/224 (1.3) | 202/224 (90.2) | 19/224 (8.5) |
| Ghost images | 15/267 (5.6) | 196/267 (73.4) | 56/267 (21.0) | 16/224 (7.1) | 166/224 (74.1) | 42/224 (18.8) |
| Fluctuations of vision | 33/267 (12.4) | 110/267 (41.2) | 124/267 (46.4) | 27/224 (12.1) | 115/224 (51.3) | 82/224 (36.6) |
| Variation of vision in bright light | 60/267 (22.5) | 157/267 (58.8) | 50/267 (18.7) | 46/224 (20.5) | 142/224 (63.4) | 36/224 (16.1) |
| Variation of vision in normal light | 22/267 (8.2) | 173/267 (64.8) | 72/267 (27.0) | 21/224 (9.4) | 141/224 (62.9) | 62/224 (27.7) |
| Variation of vision in dim light | 34/267 (12.7) | 126/267 (47.2) | 107/267 (40.1) | 31/224 (13.8) | 110/224 (49.1) | 83/224 (37.1) |
| Night driving vision | 55/267 (20.6) | 113/267 (42.3) | 99/267 (37.1) | 47/224 (21.0) | 95/224 (42.4) | 82/224 (36.6) |
| Astigmatism | 0/267 (0.0) | 267/267 (100.0) | 0/267 (0.0) | 0/224 (0.0) | 222/224 (99.1) | 2/224 (0.9) |
| Discharge | 1/267 (0.4) | 266/267 (99.6) | 0/267 (0.0) | 1/224 (0.4) | 223/224 (99.6) | 0/224 (0.0) |
| Edema | 0/267 (0.0) | 265/267 (99.3) | 2/267 (0.7) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Eye strain | 0/267 (0.0) | 266/267 (99.6) | 1/267 (0.4) | 0/224 (0.0) | 223/224 (99.6) | 1/224 (0.4) |
| Floaters | 8/267 (3.0) | 259/267 (97.0) | 0/267 (0.0) | 8/224 (3.6) | 216/224 (96.4) | 0/224 (0.0) |
| Haze | 0/267 (0.0) | 267/267 (100.0) | 0/267 (0.0) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Infection | 2/267 (0.7) | 265/267 (99.3) | 0/267 (0.0) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Itching | 4/267 (1.5) | 263/267 (98.5) | 0/267 (0.0) | 4/224 (1.8) | 220/224 (98.2) | 0/224 (0.0) |
| Light flash | 0/267 (0.0) | 266/267 (99.6) | 1/267 (0.4) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Myopic regression | 0/267 (0.0) | 266/267 (99.6) | 1/267 (0.4) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Starburst | 1/267 (0.4) | 264/267 (98.9) | 2/267 (0.7) | 0/224 (0.0) | 224/224 (100.0) | 0/224 (0.0) |
| Twitch | 0/267 (0.0) | 266/267 (99.6) | 1/267 (0.4) | 0/224 (0.0) | 223/224 (99.6) | 1/224 (0.4) |

N = Number of Self-evaluation Forms received with non-missing values at each visit.
12 3-Month postop evaluation CRFs did not have the respective preop evaluation CRFs.
10 6-Month postop evaluation CRFs did not have the respective preop evaluation CRFs.
4 preop. Evaluation CRFs did not have any postop evaluation CRFs.

Table 12.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 12.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.

**e. Retreatment**

Eight (8) eyes underwent LASIK retreatment during the study. (Seven of these eyes were discontinued prior to their 6-month visit and 1 eye after the 6-month visit due to low myopia LASIK retreatment with the Technolas laser.) The small number of retreatments is insufficient to yield clinically useful information

**f. Factors Associated with Outcomes**

Gender, preoperative refraction, age, primary vs. fellow eye, and study site were evaluated as statistically significant predictors of the UCVA and refractive outcome for the LASIK procedure. These analyses show the following:

1) For UCVA of 20/40 or better at 3 and 6 months postoperative, the primary (first) eye treated for any patient is associated with a lower success rate.

2) There are no statistically significant predictors for deviation from attempted spherical correction within ±1.00 D at 3 and 6 months. However, for deviation within ±0.50 D of attempted correction at 3 and 6 months, age, study site and preoperative sphere are predictors. An older subject is associated with a lower success rate. Also, a larger preoperative sphere is associated with a lower success rate. Lastly, one particular investigational site had a relatively lower success rate than the other investigational sites for this parameter.

3) For manifest cylinder vector deviation ≤ 1.00 D at 3 and 6 months postoperative, preoperative cylinder amount and gender were significant predictors. A higher preoperative cylinder is associated with a higher success rate, and male gender is also associated with a higher success rate. For manifest vector deviation ≤0.50 D at 3 and 6 months, one particular study site (the same one as in item 2) above) was associated with a relatively lower success rate for this parameter.

**g. Patient Satisfaction**

Responses provided by the study subjects at 6 months to three questions regarding their experiences with the laser surgery are provided in Table 13. These three questions related to: 1) the perceived overall quality of vision following surgery; 2) the subject's willingness to have the surgery again if he/she could make the choice over; and 3) the subject's overall satisfaction with the results of the surgical procedure.

The overall quality of vision was rated highly, with 95.2% of patients (by eye) indicating that there was an extreme or marked improvement, while only 1.3% indicated that there was only slight or no improvement; 92.1% would elect to have the surgery again; 74.8% reported being very satisfied, and 19.6% were moderately satisfied, while 1.7% were dissatisfied and 0.9% were very dissatisfied.

**Table 13: Self-Evaluation at 6 Months**
**Overall Quality of Vision, Choose Again, & Satisfaction - All Treated Eyes**

| Slef-Evaluation Questions | Response | Overall n/N (%) | Spherical Myopia n/N (%) | Astigmatic Myopia n/N (%) |
|---|---|---|---|---|
| Overall Quality of Vision After Excimer Laser | No Improvement | 0/232 (0.0%) | 0/56 (0.0%) | 0/176 (0.0%) |
| | Slight Improvement | 3/232 (1.3%) | 1/56 (1.8%) | 2/176 (1.1%) |
| | Moderate Improvement | 8/232 (3.4%) | 0/56 (0.0%) | 8/176 (4.5%) |
| | Marked Improvement | 46/232 (19.8%) | 13/56 (23.2%) | 33/176 (18.8%) |
| | Extreme Improvement | 175/232 (75.4%) | 42/56 (75.0%) | 133/176 (75.6%) |
| | Not reported* | 2 | 0 | 2 |
| | Total† | 234 | 56 | 178 |
| Choose Excimer Again? | No | 9/228 (3.9%) | 5/56 (8.9%) | 4/172 (2.3%) |
| | Unsure | 9/228 (3.9%) | 1/56 (1.8%) | 8/172 (4.7%) |
| | Yes | 210/228 (92.1%) | 50/56 (89.3%) | 160/172 (93.0%) |
| | Not reported* | 6 | 0 | 6 |
| | Total† | 234 | 56 | 178 |
| How Satisfied with the Excimer Laser Results? | Very Satisfied | 172/230 (74.8%) | 40/56 (71.4%) | 132/174 (75.9%) |
| | Moderately Satisfied | 45/230 (19.6%) | 13/56 (23.2%) | 32/174 (18.4%) |
| | Neutral | 7/230 (3.0%) | 1/56 (1.8%) | 6/174 (3.4%) |
| | Dissatisfied | 4/230 (1.7%) | 2/56 (3.6%) | 2/174 (1.1%) |
| | Very Dissatisfied | 2/230 (0.9%) | 0/56 (0.0%) | 2/174 (1.1%) |
| | Not reported* | 4 | 0 | 4 |
| | Total† | 234 | 56 | 178 |

### h. Device Failures and Replacements

There were three device failures/malfunctions and there were no device replacements during the course of the study. The three failures were related to poor corneal flap creation with the microkeratome. One LASIK procedure was aborted (no excimer laser treatment), and the other two LASIK procedures were completed as planned.

## X. CONCLUSIONS DRAWN FROM THE STUDIES

The preclinical studies completed for this device did not raise any new safety or effectiveness concerns. Clinical studies demonstrated that safety and effectiveness parameters fell within acceptable FDA criteria providing reasonable assurance that the device is safe and effective when used in accordance with the directions for use.

## XI. PANEL RECOMMENDATION

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

## XII. CDRH DECISION

CDRH issued an approval order on May 17, 2002. The applicant's manufacturing facility was inspected on February 11-14, 2002 and was found to be in compliance with the medical device Quality System Regulation.

## XIII. APPROVAL SPECIFICATIONS

Directions for Use: See Device Labeling.

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

Post-approval requirements and restrictions: See Approval Order