LABELING

BAUSCH & LOMB INCORPORATED TECHNOLAS 217z Zyoptix System for Personalized Vision Correction

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

- **For the reduction or elimination of myopia with sphere up to -7.00 D, cylinder up to -3.00 D and MRSE $\leq$ 7.50 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; and,**
- **in patients who are 21 years of age or older.**

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 217z Zyoptix System for Personalized Vision Correction. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the Bausch & Lomb TECHNOLAS 217z Excimer Laser System Operator's Manual.

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

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SECTION 1
GENERAL WARNINGS

"WARNING:" - Identifies conditions or practices that could result in damage to equipment or other property, personal injury or loss of life.

"NOTE:" - Identifies conditions or practices warranting special attention.

WARNING: Specific training from Bausch & Lomb or an authorized representative of Bausch & Lomb is required before anyone is qualified to operate the Zyoptix™ Excimer Laser System. Read and understand this manual and the Zyoptix Excimer Laser System Operator's Manual prior to operating the system.

Refer to the Zyoptix Excimer Laser System *Operator's Manual* for additional warnings regarding use of the Zyoptix Excimer Laser System.

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 Contaminent
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 217z 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 217z Excimer laser is not allowed as a negative influence cannot be ruled out. Please refer to the Bausch & Lomb TECHNOLAS 217z 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. Please refer to the Bausch & Lomb TECHNOLAS 217z Excimer Laser System (Zyoptix System) Operator's Manual, Section 2, Safety Considerations.

Skin and Eye Exposure

The Bausch & Lomb TECHNOLAS 217z Excimer Laser (Zyoptix 217z) contains a Class IV laser with an output at 193nm that 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 217z Excimer Laser System Operator's Manual, Section 2, Safety Considerations.

SECTION 2

DEVICE DESCRIPTION

2.1 WAVEFRONT ABERROMETER (Zywave)

The first step in performing Zyoptix® LASIK surgery is to perform a Wavefront examination on the patient using a Wavefront Detector (Zywave) compatible with the Zyoptix® Excimer Laser System. The only compatible Wavefront detector is the Bausch & Lomb ™ Zywave® Wavefront System. Essential features of Zywave are as follows:

PATIENT FIXATION AND FOGGING

The Zywave includes a fixation optical subsystem that provides the patient with a fixation point. In addition, the fixation subsystem includes adjustable optics to compensate for the patient's inherent refractive error. The optics are used to "fog" the eye, first clarifying the fixation target and then it optically adjusts beyond the patient's far point to minimize accommodation.

WAVEFRONT MEASUREMENT

The Zywave Wavefront sensor measures the Wavefront profile of the eye with a high degree of accuracy and characterizes the profile using Zernike polynomials up to and including the 5th Order

DATA EXPORT

The Zywave sensor has the ability to export the Wavefront examination data as an electronic file to floppy disk for transfer to the Zyoptix® system. The electronic file is structured in a specific format and contains essential patient information, and the detailed aberration data. In addition, the electronic file is encrypted in a manner that prohibits any data alteration or tampering prior to import into the Zylink Custom Treatment Planning Software.

2.2 MICROKERATOME

A microkeratome is used to achieve a partial thickness cut of the cornea, which creates a "flap" as part of the LASIK procedure. The microkeratome is a precision instrument used in performing lamellar corneal resections. This instrument cuts a corneal disc of pre-selected thickness and diameter. The system generally consists of a head, plates, ring, handle, wrenches, shaft, motor, hand-piece, disposable blades, and power supply with footswitches and power cords. The system is completed with the applanation lens set, tonometer, corneal storage jar, optical zone marker, spatula, stop attachment, and digital thickness gauge.

Microkeratome Used in the Clinical Trial:

The microkeratome used in the clinical trial was the Hansatome® (manufactured by Bausch & Lomb).

2.3 LASER SYSTEM with ACTIVE TRACKER

The specifications for the Bausch & Lomb TECHNOLAS Zyoptix 217z Laser 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 treatment area):	120 mJ/cm^2
Range of Ablation Diameter:	2 mm hard aperture: 2.0 to 2.05 mm
	2 mm soft aperture: 2.0 to 2.05 mm
	1 mm soft aperture: 1.0 to 1.05 mm
Active Eye Tracker	
- Tracking frequency	120 Hz

- Bausch & Lomb recommends use of the largest possible optic zone size based on the patient's wavefront data, while ensuring residual stromal thickness of 250 microns. The recommended optic zone should be selected from between 6.0 mm and 7.0 mm with a blend zone being held constant at 0.875 mm. A warning flag will appear when an optic zone <6.0 mm is selected. A warning flag will also appear in the event that the optic zone selected would result in residual stromal thickness of less than 250 microns. The ablation (treatment) zone is the sum of the optical zone selected plus the blend zone. This blend zone is smaller than that used in Planoscan Conventional LASIK, and results in a central ablation depth approximately 25% less than is required by the Planoscan Conventional LASIK procedure for treatment of myopia with sphere up to -7.00 D, cylinder up to –3.00 D and MRSE $\leq$ 7.50 D at the spectacle plane.

It should be noted that the optic zone cannot be selected to be larger than the patient's pupil size during the Wavefront measurement. Dilation to ensure a large optic zone is available to the surgeon during treatment planning is recommended.

FEATURES AND COMPONENTS OF THE ZYOPTIX 217Z 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 Zyoptix 217z 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.
Zyoptix Aperture Treatment Card	The Zyoptix Aperture Treatment Card (Aperture Card) softens the treatment laser beam edges to the truncated Gaussian formed beam through two different aperture diameters (1 mm and 2 mm).
Robotic Arm	The mechanical robotic arm provides the physical movement of the Aperture Card into the correct position of the laser's optical path.
Active Eye Tracker	The active eye tracker attaches to the laser to ensure the centration of the treatment on the cornea compensating for patient eye movement during treatment.
Operating Elements	The operating elements of the Bausch & Lomb Zyoptix Laser 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.

2.4 TRACKING SYSTEM

The Zyoptix laser system includes a 120 Hz active eye-tracker. The eye tracking system enables the surgeon to select the treatment center of the ablation, and compensate for horizontal eye movements (x and Y directions) by the patient during surgery. The overall reaction time of the laser system to eye movement is 10.7 milliseconds, allowing the laser to

actively compensate for eye movements up to 24 mm per second. During treatment, if the eye-tracker detects movement greater than 24 mm per second during the treatment, the laser pulse will be paused momentarily until the rapid eye movements come back within the active range of the eye-tracker.

SECTION 3

INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

3.1. INDICATIONS FOR USE

The Bausch & Lomb TECHNOLAS 217z Zyoptix System for Personalized Vision Correction (Zyoptix System) is indicated for wavefront-guided laser in-situ keratomileusis (LASIK) treatments:

- for the reduction or elimination of myopia with sphere up to -7.00 D, cylinder up to –3.00 D and MRSE $\leq$ 7.50 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; and,
- in patients who are 21 years of age or older.

3.2. CONTRAINDICATIONS

LASIK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune, or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane[1]), or amiodarone hydrochloride (Cordarone[2]).

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 Zyoptix System has not been established in patients with these conditions.
- LASIK is not recommended in patients with a known history of *Herpes simplex* or *Herpes zoster*.
- LASIK is not recommended in patients who have:
  - insulin-dependent diabetes.
  - severe allergies.
  - significant dry eye that is unresponsive to treatment.

[1] Accutane is the registered trademark of Hoffman La Roche Inc.
[2] Cordarone is the registered trademark of Sanofi-Synthlabo

3.4. PRECAUTIONS

The safety and effectiveness of the Zyoptix System for LASIK 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 prior history of refractive surgery (for example, RK, PRK, LASIK).
- 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[3]) for migraine headaches.
- In patients with a history of glaucoma.
- For treatment of myopia greater than -7.00 D of sphere, astigmatism greater than -3.00 D, and MRSE greater than -7.50 D at the spectacle plane.
- In patients with a residual corneal thickness less than 250 microns at the completion of ablation (see the section on Operative Procedure).
- Over the long term (more than 6 months after surgery).
- For retreatment with Zyoptix LASIK.

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

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.

Bausch & Lomb recommends selection of the largest optical zone between 6.0 and 7.0 mm, while ensuring residual stromal thickness of at least 250 microns. The optic zone cannot be selected to be larger than the patient's pupil size during the wavefront measurement. Bausch & Lomb recommends dilation to ensure a large optic zone is available to the surgeon during treatment planning.

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

Lower proportions of eyes with uncorrected visual acuity of 20/32 or better and accuracy of MRSE within $\leq \pm$ 0.5 D of emmetropia may be anticipated following treatment of eyes with higher levels of preoperative MRSE (greater than or equal to –7.00 D MRSE).

[3] Imitrex is the trademark of Glaxo Group Ltd.

Significantly fewer eyes with smaller optical zone (less than 6.25 mm) achieved BCVA of 20/20 or better at 3 months and 20/16 or better at 6 months in the population of all treated eyes.

The physician's adjustment of defocus has not been studied, and its effects on the safety and effectiveness outcomes of this procedure are unknown. No adjustments were performed in the clinical trial. However, the permitted adjustment of the spherical term (defocus) is $\pm$ 0.75 diopters.

3.5. ADVERSE EVENTS AND COMPLICATIONS

Tables 1A and 1B present all the cumulative key safety, adverse events, and complications for all treated eyes reported in the study.

TABLE 1A

ADVERSE EVENTS SUMMARY
ALL TREATED EYES

	VISITS		
ALL REPORTED ADVERSE EVENTS	**1 MONTH**	**3 MONTHS**	**6 MONTHS**
Total Eyes Reported*	340	340	340
Not Reported**	0	0	0
Distribution of Scores	% (n)	% (n)	% (n)
Decrease in BSCVA of ≥ 2 lines not due to irregular astigmatism at ≥ 6 months	0.0% (0)	0.0% (0)	0.6% (2)
Epithelial defect	0.0% (0)	0.0% (0)	0.0% (0)
Keratome stopped	0.0% (0)	0.0% (0)	0.0% (0)
Lamellar keratitis	0.0% (0)	0.0% (0)	0.3% (1)
Secondary surgical intervention other than Excimer laser treatment	0.0% (0)	0.0% (0)	0.0% (0)

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

TABLE 1B

COMPLICATION SUMMARY
ALL TREATED EYES

	VISITS		
	1 MONTH	**3 MONTHS**	**6 MONTHS**
ALL REPORTED CONDITIONS	% (n)	% (n)	% (n)
Recurrent corneal erosion	0.0% (0)	0.0% (0)	0.3% (1)
Foreign body sensation	0.0% (0)	0.0% (0)	0.0% (0)
Pain	0.0% (0)	0.0% (0)	0.0% (0)
Size and shape of flap not as intended	0.0% (0)	0.0% (0)	0.0% (0)
Misplaced, misaligned, loose flap, or free cap with loss of ≤ 2 lines (≤ 10 letters) of BSCVA	0.0% (0)	0.3% (1)	0.0% (0)
Epithelium in the interface with loss of ≤ 2lines of BSCVA	0.3% (1)	0.0% (0)	0.0% (0)
Double vision	0.0% (0)	0.0% (0)	0.0% (0)
Ghost images	0.0% (0)	0.3% (1)	0.0% (0)
Peripheral corneal epithelial defect (on the flap)	0.0% (0)	0.0% (0)	0.0% (0)
Peripheral corneal epithelial defect (off the flap)	0.0% (0)	0.0% (0)	0.0% (0)
Peripheral corneal epithelial defect (across the junction)	0.0% (0)	0.0% (0)	0.0% (0)
Epithelial ingrowth	0.0% (0)	0.0% (0)	0.0% (0)
Other			
Allergy	0.3% (1)	0.3% (1)	0.0% (0)
Bowmans wrinkle	0.0% (0)	0.0% (0)	0.6% (2)
Chalazion	0.3% (1)	0.3% (1)	0.0% (0)
Conjunctivitis	0.3% (1)	0.3% (1)	0.6% (2)
Corneal abrasion	0.0% (0)	0.0% (0)	0.3% (1)
Debris in interface	5.3% (18)	2.4% (8)	1.2% (4)
Debris in interface & Browns wrinkle	0.0% (0)	0.0% (0)	0.6% (2)
Debris in interface & Episcleritis	0.3% (1)	0.0% (0)	0.0% (0)
Episcleritis	0.3% (1)	0.0% (0)	0.0% (0)
Inflammation, interface	0.3% (1)	0.0% (0)	0.0% (0)

SECTION 4

CLINICAL RESULTS

4.1. STUDY OBJECTIVES

A prospective, non-randomized, multicenter clinical study of 342 eyes was conducted to evaluate the safety and effectiveness of the Bausch & Lomb TECHNOLAS 217z Zyoptix System for Personalized Vision Correction

4.2. DATA ANALYSIS AND RESULTS

4.2.1. DEMOGRAPHIC AND BASELINE PARAMETERS

Demographic characteristics of the study population are presented in Table 2. Accountability for all treated eyes across the study visit schedule is presented in Table 3. The baseline attempted corrections for the study population are presented in Table 4.

TABLE 2

DEMOGRAPHICS – ALL TREATED EYES

		Total
Number of eyes*		342
Number of Enrolled Subjects		191
Age (yrs)	Mean	34.4
	SD	8.29
	Range	21-61
Gender	Male	46.1%
	Female	53.9%
Race	White	90.6%
	Black	1.1%
	Asian	5.2%
	Other	3.1%
Operative Eye	OD	49.7%
	OS	50.3%

*Two surgery aborted/not attempted eyes are included in the total number of eyes.

4.2.2 ACCOUNTABILITY

Accountability was excellent with no patients lost to follow-up, and no missed visits from 1 month forward. Two eyes were discontinued at the time of surgery due to intraoperative problems associated with the flap creation. No patients were retreated and no eyes were discontinued from the study due to visual symptoms.

TABLE 3

ACCOUNTABILITY
ALL TREATED EYES

	VISITS				
	DAY 1 % (n)	**DAY 7** % (n)	**1 MONTH** % (n)	**3 MONTHS** % (n)	**6 MONTHS** % (n)
Eyes Enrolled	342	342	342	342	342
Eyes Treated	340	340	340	340	340
Available for Efficacy Analysis†	100.0% (340)	99.4% (338)	100.0% (340)	100.0% (340)	100.0% (340)
Discontinued/Terminated*	0.6% (2)	0.6% (2)	0.6% (2)	0.6% (2)	0.6% (2)
Lost To Follow-Up	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Missed Visit**	0.0% (0)	0.6% (2)	0.0% (0)	0.0% (0)	0.0% (0)
Active (Not Yet Eligible For The Interval)	0.0%(0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

† The denominator for the percent is all eyes treated.
* One could not be treated due to a small flap and the patient was exited prior to the laser surgery. The other eye was also exited at time surgery due to creation of a flap that was too thin and epithelium on the cornea that was loose
** Missed visit: Eyes not examined at the scheduled visit, but were then seen at a subsequent visit

Preoperatively, the mean manifest sphere was -3.30 D and the mean cylinder was 0.68 D. The intended correction was the full manifest refraction spherical equivalent with the goal of achieving a plano refraction after the surgery.

TABLE 4

ATTEMPTED SPHERICAL (DEFOCUS) AND CYLINDRICAL (ASTIGMATISM) CORRECTION*
ALL TREATED EYES, N = 340

SPHERE	**CYLINDER** Mean = 0.71D; S.D. = 0.56D; Range = 0.02D – 3.12D					
Mean = 3.17D S.D. = 1.60D Range = 0.46D – 7.13D	**0.00-0.49D** % (n)	**0.50-0.99D** % (n)	**1.00-1.99D** % (n)	**2.00-2.99D** % (n)	**3.00-3.99D** % (n)	**Total** % (n)
0.00-0.99D	0.3% (1)	0.6% (2)	1.8% (6)	0.3% (1)	0.3% (1)	3.2% (11)
1.00-1.99D	11.5% (39)	7.6% (26)	4.7% (16)	2.1% (7)	0.0% (0)	25.9% (88)
2.00-2.99D	10.9% (37)	6.5% (22)	3.8% (13)	0.6% (2)	0.0% (0)	21.8% (74)
3.00-3.99D	7.4% (25)	7.9% (27)	3.2% (11)	0.6% (2)	0.0% (0)	19.1% (65)
4.00-4.99D	5.6% (19)	6.5% (22)	2.6% (9)	0.6% (2)	0.0% (0)	15.3% (52)
5.00-5.99D	4.4% (15)	2.9% (10)	0.3% (1)	0.3% (1)	0.0% (0)	7.9% (27)
6.00-6.99D	2.9% (10)	2.9% (10)	0.6% (2)	0.0% (0)	0.0% (0)	6.5% (22)
7.00-7.99D	0.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.3% (1)
Total	43.2% (147)	35.0% (119)	17.1% (58)	4.4% (15)	0.3% (1)	100.0% (340)

*Attempted correction was the complete refractive error generated using the Zywave device.

4.2.3. SAFETY AND EFFECTIVENESS RESULTS

The primary cohort consisted of 340 eyes including 117 eyes with less than -0.50D of astigmatism and 223 eyes with -0.50D to -3.5D of astigmatism based on manifest refraction.

4.2.3.1 Key Safety and Effectiveness Parameters by Treatment (All Eyes, Spherical Eyes, Spherocylindrical Eyes)

Tables 5A-C presents the summary of the key safety and effectiveness parameters for the 340 treated eyes, the 117 spherical eyes and the 223 spherocylindrical eyes, respectively, at all available postoperative visits.

Preoperatively none of the eyes had uncorrected visual acuity of 20/40 or better. Postoperative UCVA of 20/20 or better was reported in ≥ 90% of eyes from the point of stability (3 months) forward. Approximately 70% of eyes had UCVA of 20/16 or better.

TABLE 5A

SUMMARY OF KEY EFFICACY VARIABLES OVER TIME (N=340)

Efficacy Variables		1 Month	3 Months	6 Months
UCVA 20/16 or better	%	61.2%	69.4%	70.3%
	(n/N)	208/340	236/340	239/340
	CI	54.8, 67.6	63.4, 75.4	64.4, 76.2
UCVA 20/20 or better	%	85.6%	90.3%	91.5%
	(n/N)	291/340	307/340	311/340
	CI	81.3, 89.9	86.7, 93.9	88.0, 95.0
UCVA 20/25 or better	%	94.4%	95.0%	95.3%
	(n/N)	321/340	323/340	324/340
	CI	91.4, 97.4	92.0, 98.0	92.7, 97.9
UCVA 20/32 or better	%	98.2%	98.2%	98.5%
	(n/N)	334/340	334/340	335/340
	CI	96.6, 99.8	96.6, 99.8	97.3, 99.8
UCVA 20/40 or better	%	99.4%	99.1%	99.4%
	(n/N)	338/340	337/340	338/340
	CI	97.9, 99.9	97.8, 100	97.9, 99.9
MRSE $\leq \pm 0.50$D of intended	%	73.8%	77.6%	75.9%
	(n/N)	251/340	264/340	258/340
	CI	68.3, 79.3	72.4, 82.9	70.2, 81.6
MRSE$\leq \pm 1.00$D of intended	%	93.8%	93.8%	93.8%
	(n/N)	319/340	319/340	319/340
	CI	90.8, 96.8	91.1, 96.6	91.1, 96.6
Safety Variables		**1 Month**	**3 Months**	**6 Months**
Loss of >2 Lines BSCVA	%	0.6%	0.0%	0.0%
	(n/N)	2/340	0/340	0/340
	CI	0.1, 2.1	0.0, 1.1	0.0, 1.1
Loss of $\geq$ 2 Lines BSCVA	%	1.5%	1.2%	0.6%
	(n/N)	5/340	4/340	2/340
	CI	0.2, 2.7	0, 2.6	0, 2.1
BSCVA worse than 20/40	%	0.3%	0	0
	(n/N)	1/340	0/340	0/340
	CI	0.0, 1.6	0, 1.1	0. 1, 1.1
BSCVA worse than 20/25 if 20/20 or better preoperatively	%	0.6%	0.3%	0
	(n/N)	2/335	1/335	0/335
	CI	0.1, 2.1	0. 1.7	0, 1.1

BSCVA = Best spectacle corrected visual acuity
CI = 95% Confidence interval for percentage
MRSE = Manifest refraction spherical equivalent
UCVA = Uncorrected visual acuity

TABLE 5B

SUMMARY OF KEY EFFICACY VARIABLES OVER TIME SPHERICAL EYES (N=117)

Efficacy Variables		1 Month	3 Months	6 Months
UCVA 20/16 or better	%	65.8%	73.5%	74.4%
	(n/N)	77/117	86/117	87/117
	CI	55.8, 75.8	63.4, 82.7	65.3, 83.5
UCVA 20/20 or better	%	92.3%	90.6%	94.0%
	(n/N)	108/117	106/117	110/117
	CI	86.9, 97.7	84.8, 96.4	89.1, 98.9
UCVA 20/25 or better	%	97.4%	96.6%	95.7%
	(n/N)	114/117	113/117	112/117
	CI	92.7, 99.5	92.5, 100	91.3, 100
UCVA 20/32 or better	%	98.3%	98.3%	98.3%
	(n/N)	115/117	115/117	115/117
	CI	94.0, 99.8	94.0, 99.8	94.0, 99.8
UCVA 20/40 or better	% (n/N)	100.0%	100.0%	100.0%
	CI	117/117	117/117	117/117
		96.9, 100	96.9, 100	96.9, 100
MRSE ≤ ±0.50 D of intended	%	81.2%	84.6%	84.6%
	(n/N)	95/117	99/117	99/117
	CI	73.2, 89.2	77.4, 91.9	77.4, 91.9
MRSE ≤ ±1.00 D of intended	%	94.0%	94.9%	96.6%
	(n/N)	110/117	111/117	113/117
	CI	89.1, 98.9	89.2, 98.1	91.5, 99.1
Safety Variables		**1 Month**	**3 Months**	**6 Months**
Loss of >2 Lines BSCVA	%	0%	0%	0%
	(n/N)	0/117	0/117	0/117
	CI	0.0, 3.1	0.0, 3.1	0.0, 3.1
Loss of ≥ 2 Lines BSCVA	%	0.0%	0.9%	0.9%
	(n/N)	0/117	1/117	1/117
	CI	0.0, 3.1	0.0, 4.7	0.0, 4.7
BSCVA worse than 20/40	%	0%	0%	0%
	(n/N)	0/117	0/117	0/117
	CI	0.0, 3.1	0.0, 3.1	0.0, 3.1
Increase >2D cylinder magnitude	%	0.0%	0.0%	0.0%
	(n/N)	0	0	0
BSCVA worse than 20/25	%	0%	0%	0%
if 20/20 or better preoperatively	(n/N)	0/115	0/115	0/115
	CI	0.0, 3.2	0.0, 3.2	0.0, 3.2

BSCVA = Best spectacle corrected visual acuity
CI = 95% Confidence interval for percentage
MRSE = Manifest refraction spherical equivalent
UCVA = Uncorrected visual acuity

TABLE 5C

SUMMARY OF KEY EFFICACY VARIABLES OVER TIME SPHEROCYLINDRICAL EYES (N=223)

Efficacy Variables		1 Month	3 Months	6 Months
UCVA 20/16 or better	% (n/N)	58.7%	67.3%	68.2%
	CI	131/223	150/223	152/223
		50.9, 66.6	59.8, 74.7	60.9, 75.4
UCVA 20/20 or better	%	82.1%	90.1%	90.1%
	(n/N)	183/223	201/223	201/223
	CI	76.3, 87.9	85.6, 94.6	85.6, 94.6
UCVA 20/25 or better	%	92.8%	94.2%	95.1%
	(n/N)	207/223	210/223	212/223
	CI	88.6, 97.1	90.3, 98.1	92.0, 98.1
UCVA 20/32 or better	%	98.2%	98.3%	98.7%
	(n/N)	219/223	219/223	220/223
	CI	96.1, 100	96.1, 100	97.2, 100
UCVA 20/40 or better	%	99.1%	99.1%	99.1%
	(n/N)	221/223	220/223	221/223
	CI	96.8, 99.9	96.7, 100	96.8, 99.9
MRSE ≤ ±0.50 D of intended	%	70.0%	74.0%	71.3
	(n/N)	156/221	165/223	159/223
	CI	63.0, 77.0	67.5, 80.5	64.2, 78.4
MRSE ≤ ±1.00 D of intended	%	93.7%	93.3%	92.4%
	(n/N)	209/223	208/223	206/223
	CI	90.2, 97.3	89.8, 96.7	88.2, 96.5
Safety Variables		**1 Month**	**3 Months**	**6 Months**
Loss of >2 Lines BSCVA	%	0.9%	0.0%	0.0%
	(n/N)	2/223	0/223	0/223
	CI	0.1, 3.2	0.0, 1.6	0.0, 1.6
Loss of ≥ 2 Lines BSCVA	%	2.2%	1.3%	0.4%
	(n/N)	5/223	3/223	1/223
	CI	0.3, 4.2	0.0, 3.3	0.0, 2.5
BSCVA worse than 20/40	%	0.4%	0.0%	0.0%
	(n/N)	1/223	0/223	0/223
	CI	0.0, 2.5	0.0, 1.6	0.0, 1.6
BSCVA worse than 20/25 if 20/20 or better preoperatively	%	0.9%	0.5%	0.0%
	(n/N)	2/220	1/220	0/220
	CI	0.1, 3.2	0.0, 2.5	0.0, 1.7

BSCVA = Best spectacle corrected visual acuity
CI = 95% Confidence interval for percentage
MRSE = Manifest refraction spherical equivalent
UCVA = Uncorrected visual acuity

4.2.3.2 Key Effectiveness Parameters by Preoperative MRSE

Tables 6A and 6B present the results for key safety and effectiveness for all treated eyes at 3 months and at 6 months, respectively, stratified by preoperative MRSE.

Lower proportions of eyes with uncorrected visual acuity of 20/32 or better and accuracy of MRSE within ≤ ± 0.5 D of emmetropia may be anticipated following treatment of eyes with higher levels of preoperative MRSE (greater than or equal to –7.00 D MRSE).

TABLE 6A

SUMMARY OF KEY EFFICACY VARIABLES AT 3 MONTHS STRATIFIED BY PREOPERATIVE MANIFEST REFRACTIVE SPHERICAL EQUIVALENT ALL TREATED EYES

	PREOPERATIVE MANIFEST REFRACTIVE SPHERICAL EQUIVALENT						
KEY EFFICACY VARIABLES	**1.00–1.99 D** % (n)	**2.00–2.99 D** % (n)	**3.00–3.99 D** % (n)	**4.00–4.99 D** % (n)	**5.00–5.99 D** % (n)	**6.00–6.99 D** % (n)	**7.00-7.99D** % (n)
Total Eyes Reported*	41	86	82	57	39	27	8
UCVA 20/16 or Better	70.7 % (29)	77.9% (67)	67.1% (55)	59.6% (34)	64 1% (25)	81.5% (22)	50.0% (4)
UCVA 20/20 or Better	95.1 % (39)	91.9% (79)	91.5% (75)	87.7% (50)	84.6% (33)	92.6% (25)	75.0% (6)
UCVA 20/25 or Better	100.0 % (41)	97.7% (84)	96.3% (79)	93.0% (53)	89 7% (35)	92.6% (25)	75.0% (6)
UCVA 20/32 or Better	100.0 % (41)	100.0% (86)	98.8% (81)	100.0% (57)	97.4% (38)	92.6% (25)	75.0% (6)
UCVA 20/40 or Better	100.0 % (41)	100.0%(86)	98.8% (81)	100.0% (57)	100 0% (39)	92.6% (25)	100.0% (8)
MRSE ≤ ± 0.50 D	90.2 % (37)	84.9% (73)	76.8% (63)	71.9% (41)	74.4% (29)	74.1% (20)	12.5% (1)
MRSE ≤ ± 1.00 D	97.6 % (40)	96.5% (93)	92.7% (76)	94.7% (54)	92.3% (36)	85.2% (23)	87.5% (7)

* Number of CRFs received with non-missing values.

TABLE 6B

SUMMARY OF KEY EFFICACY VARIABLES AT 6 MONTHS STRATIFIED BY PREOPERATIVE MANIFEST REFRACTIVE SPHERICAL EQUIVALENT ALL TREATED EYES

	PREOPERATIVE MANIFEST REFRACTIVE SPHERICAL EQUIVALENT						
KEY EFFICACY VARIABLES	**1.00–1.99 D** % (n)	**2.00–2.99 D** % (n)	**3.00–3.99 D** % (n)	**4.00–4.99 D** % (n)	**5.00–5.99 D** % (n)	**6.00–6.99 D** % (n)	**7.00-7.99D** % (n)
Total Eyes Reported*	41	86	82	57	39	27	8
UCVA 20/16 or Better	73.2% (30)	77.9% (67)	70.7% (58)	66.7% (38)	61.5% (24)	66.7% (18)	50.0% (4)
UCVA 20/20 or Better	97.6% (40)	95.3% (82)	92.7% (76)	91.2% (52)	84.6% (33)	81.5% (22)	75.0% (6)
UCVA 20/25 or Better	100.0% (41)	97.7% (84)	95.1% (78)	96.5% (55)	89.7% (35)	92.6% (25)	75.0% (6)
UCVA 20/32 or Better	100.0% (41)	100.0% (86)	97.6% (80)	100.0% (57)	97.4% (38)	96.3% (26)	87.5% (7)
UCVA 20/40 or Better	100.0% (41)	100.0% (86)	98.8% (81)	100.0% (57)	100.0% (39)	96.3% (26)	100.0% (8)
MRSE ≤ ± 0.50 D	95.1% (39)	82.6% (71)	72.0% (59)	75.4% (43)	69.2% (27)	66.7% (18)	12.5% (1)
MRSE ≤ ± 1.00 D	100.0% (41)	97.7% (84)	92.7% (76)	96.5% (55)	89.7% (35)	81.5% (22)	75.0% (6)

* Number of CRFs received with non-missing values.

4.2.3.3 Influence of Optic Zone Size Selection on Key Effectiveness Parameters

In the Zyoptix clinical trial, the investigators had the opportunity to select the optic zone size to use, with an effort made to keep the size at 6.0 mm or larger. There were only 3 eyes in the study with an optical zone of less than 6.0mm, each of which occurred based on the medical judgment of the surgeon at the time of the treatment. All three eyes had an optic zone of 5.8 mm and had UCVA of 20/20 or better at the 6-month postoperative evaluation.

An evaluation of the clinical results as a function of the optic zone size indicates that the results favor use of the largest possible optic zone size, while ensuring residual stromal thickness of 250 microns. The optic zone can be selected between the 6.0 mm and 7.0 mm with a blend zone being held constant at 0.875 mm. The blend zone is smaller than that used in Planoscan Conventional LASIK, resulting in a central ablation depth that is approximately 25% less than the ablation depth required by the Planoscan Conventional LASIK procedure for the reduction or elimination of myopia with sphere up to -7.00 D, cylinder up to –3.00 D and MRSE $\leq$ 7.50 D at the spectacle plane;

The effectiveness results by optic zone size for all study eyes are found in Table 7 below. No statistically significant differences among the optic zone groups were found on the parameters of MRSE within 0.5 and 1.0 diopters of emmetropia, or on achievement of UCVA of 20/16 or better, and 20/25 or better. Significant differences, favoring larger optic zones were found on the parameters of UCVA 20/20 or better, 20/32 or better and 20/40 or better.

Extensive analyses were performed to evaluate the effect of both treatment (i.e., sphere only or spherocylindrical corrections) and of optical zone size on safety and efficacy outcomes following treatment with the Zyoptix System. At both 3 months and 6 months, in the cohort of all treated eyes and in spherocylindrical eyes, smaller optical zones (less than 6.25 mm) were associated with lower proportions of eyes with UCVA of 20/20, 20/25, 20/32 and 20/40. No statistically significant differences in UCVA were observed across the optical zones for sphere only eyes, however, at 6 months, the proportion of spherical eyes with MRSE within 0.50 D of emmetropia was significantly lower for eyes treated with smaller optical zone (less than 6.25 mm). Notwithstanding these differences, all efficacy targets established in FDA guidance for clinical trials of excimer lasers were achieved or exceeded for all three cohorts (all treated eyes, sphere only eyes, spherocylindrical eyes) and for all optical zone sizes.

With regard to stratification of key safety variables by optical zone, because of the small number of adverse events and complications in the study population, stratification of these data by optical zone would not provide any statistically meaningful information. For this reason, this analysis was limited to stratification of BCVA by treatment and by optical zone. Significantly fewer eyes with smaller optical zone (less than 6.25 mm) achieved BCVA of 20/20 or better at 3 months and 20/16 or better at 6 months in the population of all treated eyes. In spherocylindrical eyes, at 3 and 6 months, the proportion of eyes with BCVA of 20/16 or better was smaller for eyes with smaller optical zone (less than 6.25 mm). No differences were observed across the three optical zone groups for the sphere only eyes, and it should be noted that all eyes (100%) achieved

BCVA of 20/25 or better at 6 months, and nearly all eyes (95% or greater) achieved BCVA of 20/20 or better at 6 months.

Bausch & Lomb recommends selection of the largest optical zone between 6.0 and 7.0 mm, while ensuring residual stromal thickness of at least 250 microns. A warning flag will appear when an optic zone <6.0 mm is selected. Optic zone cannot be selected to be larger than the patient's pupil size during the wavefront measurement. Dilation to ensure that a large optic zone is available to the surgeon for treatment planning is recommended.

Please refer to Section 4.2.9.3 for information on the effect of optical zone on patients symptoms, and to Section 4.2.11.3 for information on change from baseline in wavefront aberrations as a function of optic zone.

TABLE 7

SUMMARY OF KEY EFFICACY VARIABLES AT 6 MONTHS STRATIFIED BY OPTICAL ZONE SIZE ALL TREATED EYES

	OPTICAL ZONE SIZE (mm)			
KEY EFFICACY	**5.75-6.24**	**6.25-6.74**	**6.75-7.24**	
VARIABLES	% (n)	% (n)	% (n)	**p-value**
Total Eyes Reported*	73	246	20	
UCVA 20/16 or Better	60.3% (44)	73.6% (181)	65.0% (13)	0.0802
UCVA 20/20 or Better	83.6% (61)	93.5% (230)	95.0% (19)	0.0249
UCVA 20/25 or Better	90.4% (66)	96.7% (238)	95.0% (19)	0.0798
UCVA 20/32 or Better	94.5%(69)	99.6% (245)	100.0% (20)	0.0054
UCVA 20/40 or Better	97.3% (71)	100.0% (246)	100.0% (20)	0.0237
MRSE ≤ ± 0.5 D	67.1% (49)	78.9% (194)	70.0% (14)	0.1004
MRSE ≤ ± 1.0 D	91.8% (67)	94.7% (233)	90.0% (18)	0.5152

* Number of CRFs received with non-missing values.

** p-value for comparison of optical zone strata (Cochran-Mantel-Haenszel test, stratified by primary and fellow eye designations).

4.2.4 MANIFEST REFRACTION OVER TIME

Table 8 provides the mean refraction spherical equivalent over time. The postoperative mean refraction for the population is consistent over the term of the study.

TABLE 8

MANIFEST REFRACTION SPHERICAL EQUIVALENT OVER TIME

Mean ± Standard Deviation	**Preop**	**1 Month**	**3 Months**	**6 Months**
All Eyes N=340	-3.66 ± 1.53	0.15 ± 0.54	0.15 ± 0.50	0.15 ± 0.51
Spherical Eyes N=117	-3.41 ± 1.60	0.06 ± 0.53	0.07 ± 0.47	0.02 ± 0.48
Spherocylindrical Eyes N =223*	-3.80 ± 1.48	0.20 ± 0.54	0.20 ± 0.51	0.22 ± 0.51

* Preop value based on N=340 for all eyes and N=-225 for spherocylindrical eyes

4.2.5 STABILITY OF THE MANIFEST REFRACTION

Results for stability of the manifest refraction as determined by the manifest spherical equivalent refraction are presented in Tables 9A to 9C for those eyes that had data at all scheduled follow-up visits during the study (the "consistent cohort").

TABLE 9A

STABILITY OF MANIFEST REFRACTION SPHERICAL EQUIVALENT FOR ALL TREATED EYES

Change in Spherical Equivalent Between	**1 and 3 Months**	**3 and 6 Months**
≤ 0.50 Diopter (%, n/N)	86.8% (295/340)	90.9%, (309/340)
≤ 1.00 Diopter (%, n/N)	96.2% (327/340)	98.5% (335/340)
Mean Difference ± Standard Deviation	0.00 ± 0.41	0.00 ± 0.35
95% Confidence Interval	-0.054, 0.054	-0.046, 0.046

TABLE 9B

STABILITY OF MANIFEST REFRACTION SPHERICAL EQUIVALENT FOR SPHERICAL TREATED EYES

Change in Spherical Equivalent Between	1 and 3 Months	3 and 6 Months
≤ 0.50 Diopter (%, n/N)	84.6% (99/117)	94.9% (11/117)
≤ 1.00 Diopter (%, n/N)	95.7% (112/117)	98.3% (115/117)
Mean Difference ± Standard Deviation	0.00 ± 0.44	-0.04 ± 0.32
95% Confidence Interval	-0.083, 0.085	-0.106, 0.023

TABLE 9C

STABILITY OF MANIFEST REFRACTION SPHERICAL EQUIVALENT FOR ASTIGMATIC TREATED EYES

Change in Spherical Equivalent Between	1 and 3 Months	3 and 6 Months
≤ 0.50 Diopter (%, n/N)	87.9% (196/223)	88.8% (198/223)
≤ 1.00 Diopter (%, n/N)	96.4% (215/223)	98.7% (220/223)
Mean Difference ± Standard Deviation	0.00 ± 0.39	0.02 ± 0.37
95% Confidence Interval	-0.060, 0.060	-0.035, 0.080

4.2.6. Cylinder Correction/Vector Analysis

Table 10 presents the results of the mean percent reduction of astigmatism for spherocylindrical eyes, stratified by preoperative cylinder and the correction ratio of achieved vector versus intended vector magnitude.

TABLE 10
CYLINDER CORRECTION EFFICACY AT 3 MONTHS
STRATIFIED BY PREOPERATIVE CYLINDER
SPHEROCYLINDRICAL EYES

Preoperative Cylinder	N	Mean Percent Reduction Of Absolute Cylinder (Non-Vector)	Correction Ratio Achieved VS. Intended Vector Magnitude Ratio (SIRC/IRC)
All	223	64.0% ± 43.0%	1.00 ± 0.40
0.50 to <1.00 D	134	58.8% ± 51.0%	1.03 ± 0.43
1.00 to < 2.00 D	69	70.1% ± 26.3%	0.98 ± 0.27
2.00 to < 3.00 D	18	78.0% ± 19.3%	1.00 ± 0.26
3.00 to < 4.00 D	2	76.9% ± 0.0%	0.89 ± 0.17

4.2.7. Correlation to Preoperative Best Corrected Visual Acuity

As shown in Table 11, best-corrected visual acuity was unchanged or improved in 90.9% of eyes at 1 months, in 93.0% of eyes at 3 months, and in 94.1% of eyes at 6 months. No eyes lost more than 2 lines, and two eyes lost 2 lines. One of these eyes was 20/12.5 preop and 20/20 at 6 months; the other was 20/16 preop and 20/25 at 6 months.

TABLE 11

CHANGE IN BEST SPECTACLE CORRECTED VISUAL ACUITY
FOR ALL EYES

	1 Month	3 Months	6 Months
	% (n/N)	% (n/N)	% (n/N)
	N=340	N=340	N=340
Decrease >2 Lines	0.6% (2)	0.0% (0)	0.0% (0)
Decrease 2 Lines	0.9% (3)	1.2 % (4)	0.6% (2)
Decrease 1 Line	7.6% (26)	5.9% (20)	5.3% (18)
No change	37.6% (128)	38.8% (132)	33.8% (115)
Increase 1 Line	36.2% (123)	35.6% (121)	41.5% (141)
Increase 2 Lines	15.3% (52)	17.3% (59)	17.3% (59)
Increase >2 Lines	1.8% (6)	1.2% (4)	1.5% (5)

Table 12 shows that at 3 months after surgery 77.3% of the patients and at 6 months after the surgery 78% of the patients saw as well ***without*** glasses after Zyoptix surgery as *with* glasses before surgery.

TABLE 11

VISUAL ACUITY *WITHOUT* GLASSES AFTER SURGERY COMPARED TO *WITH* GLASSES BEFORE SURGERY (N=340)

Time after Surgery	3 Months % (n)	6 Months % (n)
Percent of eyes with UCVA ≥2 lines better than preoperative BCVA	13.5% (46)	14.1% (48)
Percent of eyes with UCVA 1 line better than preoperative BCVA	25.6% (87)	27.9% (95)
Percent of eyes with UCVA equal to preoperative BCVA	38.2% (130)	36.2% (123)
Percent of eyes with UCVA 1 line worse than preoperative BCVA	15.3% (52)	14.7% (50)
Percent of eyes with UCVA ≥2 lines worse than preoperative BCVA	7.4% (25)	7.1% (24)

4.2.8. Change in Contrast Sensitivity After Surgery

A contrast sensitivity study was conducted to assess the effects of Zyoptix® myopic LASIK surgery to help determine how well patients see in conditions such as very dim light, rain, snow, and fog. The method used was Vision Sciences CST 1500 with FACT charts. Under mesopic lighting the conditions were controlled within the CST 1500 unit itself.

Table 13 shows the change in contrast sensitivity measured under photopic and mesopic lighting conditions after Zyoptix surgery compared to preoperative levels. Nearly all patients (97.9%) had no change or improvements in mesopic testing; 22.7% improved and only 2.1% were worse. Similarly, 96.5% of patients had no change or improvements in photopic testing; 24.4% improved and only 3.5% were worse.

TABLE 13
PROPORTION OF THE POPULATION WITH CHANGE OF >2 LEVELS (> 0.3 LOG) ON CSV-1500 AT 2 OR MORE SPATIAL FREQUENCIES FOR SPHERICAL MYOPIC EYES AT 6 MONTHS

	Photopic Conditions		
Change > 0.3 (log unit)	Decrease	No Change	Increase
% (n/N)	3.5%	72.1%	24.4%
	Mesopic Conditions		
Change > 0.3 (log unit)	Decrease	No Change	Increase
% (n/N)	2.1%	75.2%	22.7%

4.2.9. PATIENT SYMPTOMS AND SATISFACTION

4.2.9.1 Change in Clinically Significant Symptoms

The change from preoperative incidence of clinically significant symptoms (moderate, marked and severe) is found in Table 14A at the 3 and 6 month intervals. At 6 months significant differences in the incidence of clinically significant symptoms favoring improvement (reduced symptoms) occurred for the vision associated parameters of difficulties with night driving, variation of vision under bright light, and light sensitivity, and for the comfort associated parameters of headaches, pain, redness, and blurry vision. Significant differences in worsening symptoms were reported for the parameters of vision-associated parameters of double and fluctuating vision.

TABLE 14A

INCIDENCE OF CLINICALLY SIGNIFICANT* SYMPTOMS PREOPERATIVE AND POSTOPERATIVE

Patient Symptom	N**	Occurrence (%)+		P-value ++	N**	Occurrence (%)+		P-value ++
		Preop	3 Months			Preop	6 Months	
Light Sensitivity	340	18.5%	4.7%	<.0001	340	18.5%	2.6%	<.0001
Headache	340	9.7%	5.3%	0.0090	340	9.7%	4.1%	0.0004
Pain	340	2.4%	0.3%	0.0196	340	2.4%	0.0%	0.0047
Redness	340	3.5%	3.2%	0.8084	340	3.5%	1.5%	0.0896
Dryness	340	7.9%	16.5%	0.0003	340	7.9%	5.9%	0.2623
Excessive Tearing	340	2.4%	0.0%	0.0047	340	2.4%	0.6%	0.0578
Burning	340	2.1%	2.1%	1.0000	340	2.1%	0.6%	0.0956
Gritty Feeling	340	0.9%	1.5%	0.4795	340	0.9%	0.3%	0.3173
Glare	340	4.4%	5.0%	0.7150	340	4.4%	3.5%	0.5637
Halos	340	2.6%	5.0%	0.1025	340	2.6%	3.8%	0.3938
Blurring of Vision	340	11.5%	7.4%	0.0390	340	11.5%	7.1%	0.0287
Double Vision	340	0.3%	0.9%	0.3173	340	0.3%	2.4%	0.0196
Ghost Images	340	0.9%	1.5%	0.3173	339	0.9%	1.8%	0.1797
Fluctuation of Vision	336	0.9%	7.4%	<.0001	335	0.9%	5.4%	0.0011
Variation in Vision:								
In Bright Light	340	7.4%	0.6%	0.0025	339	7.4%	1.2%	<.0001
In Normal Light	340	1.5%	2.1%	0.5637	339	1.5%	2.9%	0.1967
In Dim Light	340	11.8%	6.5%	0.0162	339	11.5%	10.6%	0.6858
Night Driving Difficulty	340	18.5%	8.8%	<.0001	340	18.5%	7.1%	<.0001
Other+++	325	0.6%	2.2%	0.0956	324	0.6%	3.7%	0.0075

* Absent/Mild scores were considered clinically insignificant. Moderate/Marked/Severe scores were considered clinically significant.

** Number of eyes reporting scores at both visits. This number was used as the denominator for calculating percentages. Rates for eyes reporting data at both visits.

\+ Minor variations from sums are due to rounding.

++ McNemar's test comparing occurrence rates at preop and 3 months; and at preop and 6 months.

+++Other symptoms included difficulty reading, eye strain, itchiness, starburst, floaters, and headache.

4.2.9.2 Change in Symptoms from Baseline at 3 and 6 months

Patients were asked to rate the following symptoms at 3 and 6 months compared to before Zyoptix LASIK surgery for the correction of spherical myopia. As shown in Table 14B, patients rated symptoms as significantly better, better, no change, worse, or significantly worse than preoperative. At 6 months, significant differences favoring improvement (reduced symptoms) compared to worsening were reported for the parameters of light sensitivity, headaches, pain, redness, excessive tearing, burning, variation of vision under bright light and dim light, and difficulties with night driving. Significant differences in worsening symptoms were reported for the parameters of dryness, and fluctuating vision.

TABLE 14B. COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY

Symptom	Significantly Better	Better	No Change	Worse	Significantly Worse
3 Months (N=340)					
Light Sensitivity	8.2%	26.5%	54.4%	8.8%	2.1%
Headache	5.0%	19.4%	68.5%	5.3%	1.8%
Pain	2.4%	3.8%	92.1%	1.5%	0.3%
Redness	1.2%	17.4%	71.8%	7.9%	1.8%
Dryness	1.2%	11.8%	46.8%	30.6%	9.7%
Excessive Tearing	2.1%	8.8%	87.6%	1.5%	0.0%
Burning	0.3%	11.2%	75.6%	12.4%	0.6%
Gritty Feeling	0.6%	7.4%	81.5%	9.7%	0.9%
Glare	2.9%	12.9%	64.4%	16.5%	3.2%
Halos	1.5%	7.9%	69.1%	17.6%	3.8%
Blurring of Vision	7.9%	12.6%	60.3%	15.9%	3.2%
Double Vision	0.3%	1.2%	95.3%	2.4%	0.9%
Ghost Images**	0.3%	3.5%	91.8%	3.5%	0.9%
Fluctuation of Vision*	0.0%	7.4%	62.5%	24.1%	6.0%
Variation in Vision:					
In Bright Light	3.8%	17.9%	65.9%	10.9%	1.5%
In Normal Light	0.9%	8.2%	78.8%	10.6%	1.5%
In Dim Light	5.9%	18.2%	57.9%	15.6%	2.4%
Night Driving Difficulty	10.0%	24.4%	52.6%	12.1%	0.9%
6 Months (N=340)					
Light Sensitivity	9.4%	27.4%	55.6%	7.1%	0.6%
Headache	5.9%	19.4%	69.4%	4.1%	1.2%
Pain	2.4%	3.8%	91.8%	2.1%	0.0%
Redness	1.8%	21.5%	65.9%	9.7%	1.2%
Dryness	2.9%	16.8%	49.1%	28.8%	2.4%
Excessive Tearing	2.1%	10.0%	84.1%	3.2%	0.6%
Burning	1.2%	13.2%	77.6%	7.6%	0.3%
Gritty Feeling	0.6%	7.9%	85.3%	6.2%	0.0%
Glare	3.5%	17.4%	63.8%	12.1%	3.2%
Halos	1.8%	11.8%	72.1%	11.8%	2.6%
Blurring of Vision	8.5%	13.8%	59.1%	14.7%	3.8%
Double Vision	0.3%	1.2%	95.3%	0.9%	2.4%
Ghost Images**	0.3%	4.1%	91.2%	3.5%	0.9%
Fluctuation of Vision*	0.0%	7.5%	68.4%	20.0%	4.2%
Variation in Vision*:**					
In Bright Light	3.8%	20.1%	65.5%	10.3%	0.3%
In Normal Light	0.9%	8.6%	79.4%	8.8%	2.4%
In Dim Light	5.0%	20.4%	57.2%	14.7%	2.7%
Night Driving Difficulty	11.2%	29.1%	49.4%	9.1%	1.2%

* Fluctuation in Vision only reported on for n=336 eyes at 3 months and 335 eyes at 6 months

** Ghost images was reported on for n=339 eyes at 6 months

*** Variation in Vision was reported on for only n=339 eyes at 6 months

4.2.9.3 Influence Of Optic Zone Size On Patient Symptoms

Patient symptoms at 6 months were also analyzed by range of optic zone size used in the treatment. These results are provided in Table 15 below.

At 6 months, significant improvement in night driving difficulty was reported for all optic zones.

In addition, significant improvements (reduced symptoms) occurred for the parameters of headache, and redness for the optic zones of 5.75 to 6.24 mm and 6.25 to 6.74 mm. Significant improvements also occurred for the parameter of light sensitivity for both the 6.25-6.74 mm and the 6.75-7.24 mm optic zones. Additional significant improvements occurred for the parameters of pain, excessive tearing, burning, gritty feeling, and variations in vision under bright light for the 6.25-6.74 mm zone and in the parameters of blurry vision for the 6.75-7.24 mm optic zone.

Significant worsening occurred on the parameters of dryness for the smallest and largest zone. In addition significantly worse fluctuation in vision occurred for the smallest and mid-size optic zones. And there was significant worsening of double vision for the smallest optic zone.

As the optic zone size increased, there was a trend toward more symptoms showing significant improvement versus significant worsening of symptoms.

Extensive analyses were performed to evaluate the effect of both treatment (i.e., sphere only or spherocylindrical corrections) and of optical zone size on patient symptoms with the majority of patient symptoms remaining unchanged from baseline. More symptoms were described by patients as better or significantly better at both 3 and 6 months than were described as worse or significantly worse than at baseline, as shown in Table 15, below.

TABLE 15

COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY ANALYZED BY OPTIC ZONE AT 6 MONTHS

Symptom	Significantly Better	Better	No Change	Worse	Significantly Worse
6 Months (N=73) Optical Zone Size 5.75 to 6.24					
Light Sensitivity	2.7%	19.2%	68.5%	6.8%	2.7%
Headache	0.0%	16.4%	79.5%	2.7%	1.4%
Pain	0.0%	2.7%	97.3%	0.0%	0.0%
Redness	2.7%	15.1%	76.7%	5.5%	0.0%
Dryness	0.0%	11.0%	47.9%	35.6%	5.5%
Excessive Tearing	0.0%	6.8%	87.7%	5.5%	0 0%
Burning	0.0%	5.5%	82.2%	12.3%	0.0%
Gritty Feeling	0.0%	2.7%	89.0%	8.2%	0.0%
Glare	1.4%	21.9%	61.6%	9.6%	5 5%
Halos†	0.0%	6.8%	78.1%	9.6%	5.5%
Blurring of Vision	11.0%	5.5%	61.6%	15.1%	6 8%
Double Vision	0.0%	0.0%	91.8%	1.4%	6.8%
Ghost Images**	0.0%	4.1%	91.8%	2.7%	1.4%
Fluctuation of Vision*	0.0%	5.6%	66.2%	21.1%	7.0%
Variation in Vision***					
In Bright Light	0.0%	15.1%	71.2%	13.7%	0 0%
In Normal Light	0.0%	6.8%	82.2%	8.2%	2.7%
In Dim Light	4.1%	16.4%	63.0%	15.1%	1.4%
Night Driving Difficulty	8.2%	34.2%	47.9%	6.8%	2.7%
6 Months (N=246) Optical Zone Size 6.25 to 6.74					
Light Sensitivity	11.4%	28.0%	52.8%	7.7%	0.0%
Headache	8.1%	19.9%	65.9%	4.9%	1.2%
Pain	3.3%	4.5%	89.4%	2.8%	0.0%
Redness	1.6%	22 0%	64.6%	11.0%	0 8%
Dryness	4.1%	19.5%	49.2%	25.6%	1.6%
Excessive Tearing	2 0%	11.4%	82.9%	2.8%	0.8%
Burning	1.6%	15 4%	75.6%	6.9%	0.4%
Gritty Feeling	0.8%	10.2%	83.7%	5.3%	0.0%
Glare	4 1%	15.9%	65.4%	11.8%	2.8%
Halos	2.0%	12.6%	69.9%	13.4%	2.0%
Blurring of Vision	8.1%	13.8%	58.9%	15.9%	3.3%
Double Vision	0.0%	1.2%	96.7%	0.8%	1.2%
Ghost Images**	0.0%	3.3%	91.8%	4.1%	0.8%
Fluctuation of Vision*	0.0%	7.0%	68.3%	21.0%	3.7%
Variation in Vision***					
In Bright Light	4.9%	21.6%	62.9%	10.2%	0.4%
In Normal Light	1.2%	8.2%	78.4%	9.8%	2.4%
In Dim Light	3.7%	22.4%	55 5%	15.1%	3.3%
Night Driving Difficulty	11.8%	26.8%	50.0%	10 6%	0 8%

TABLE 15 CONT'D

COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY ANALYZED BY OPTIC ZONE AT 6 MONTHS

Symptom	Significantly Better	Better	No Change	Worse	Significantly Worse
6 Months (N=20) Optical Zone Size 6.75 to 7.24					
Light Sensitivity	5.0%	50.0%	45.0%	0.0%	0.0%
Headache	0.0%	25.0%	75.0%	0.0%	0.0%
Pain	0.0%	0.0%	100.0%	0.0%	0.0%
Redness	0.0%	40.0%	40.0%	10.0%	10.0%
Dryness	0.0%	0.0%	55.0%	45.0%	0.0%
Excessive Tearing	10.0%	5.0%	85.0%	0.0%	0.0%
Burning	0.0%	15.0%	85.0%	0.0%	0.0%
Gritty Feeling	0 0%	0.0%	90.0%	10.0%	0.0%
Glare	0.0%	20.0%	55.0%	25.0%	0.0%
Halos†	0.0%	20.0%	80.0%	0.0%	0.0%
Blurring of Vision	0.0%	45.0%	55.0%	0.0%	0.0%
Double Vision	0.0%	5.0%	95.0%	0.0%	0.0%
Ghost Images**	0.0%	15.0%	85.0%	0.0%	0.0%
Fluctuation of Vision*	0 0%	15.0%	80.0%	5.0%	0.0%
Variation in Vision***					
In Bright Light	0.0%	20.0%	80.0%	0.0%	0.0%
In Normal Light	0.0%	15.0%	85.0%	0 0%	0.0%
In Dim Light	20.0%	10.0%	60.0%	10.0%	0.0%
Night Driving Difficulty	10.0%	40.0%	50.0%	0.0%	0.0%

* Fluctuation in Vision only reported on for n=336 eyes at 3 months and 335 eyes at 6 months

** Ghost images was reported on for n=339 eyes at 6 months

*** Variation in Vision was reported on for only n=339 eyes at 6 months

4.2.9.4 Patient Subjective Evaluations

Presented in Table 16 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 16

SELF-EVALUATION OVERALL QUALITY OF VISION
ALL TREATED EYES

Overall Quality Of Vision After Excimer Laser?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported *	340	340	340
Not Reported **	0	0	0
Distribution Of Scores	% (n)	% (n)	% (n)
Extreme improvement	80.6 % (274)	81.8 % (278)	84.7 % (288)
Marked improvement	16.2 % (55)	14.1 % (48)	12.1 % (41)
Moderate improvement	2.4 % (8)	2.1 % (7)	1.8 % (6)
Slight improvement	0.9 % (3)	1.8 % (6)	1.2 % (4)
No improvement	0.0 % (0)	0.3 % (1)	0.3 % (1)

Choose Excimer Laser Again?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported *	337	338	340
Not Reported **	3	2	0
Distribution Of Scores	% (n)	% (n)	% (n)
Yes	97.0 % (327)	97.3 % (329)	98.2 % (334)
Unsure	3.0 % (10)	2.7 % (9)	1.2 % (4)
No	0.0 % (0)	0.0 % (0)	0.6 % (2)

How satisfied with the Excimer Laser Results?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported *	340	337	340
Not Reported **	0	3	0
Distribution Of Scores	% (n)	% (n)	% (n)
Very Satisfied	89.7 % (305)	91.1 % (307)	90.9 % (309)
Moderately Satisfied	8.8 % (30)	7.1 % (24)	7.9 % (27)
Neutral	0.9 % (3)	1.8 % (6)	1.2 % (4)
Dissatisfied	0.6 % (2)	0.0 % (0)	0.0 % (0)
Very Dissatisfied	0.0% (0)	0.0 % (0)	0.0 % (0)

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

4.2.10 RETREATMENT

No data is available for LASIK retreatment using the Zyoptix system.

4.2.11 COMPARISON TO CONVENTIONAL LASIK (BASED ON MANIFEST PHOROPTER REFRACTION)

A clinical trial was conducted in 40 patients who underwent conventional LASIK in one eye and Zyoptix LASIK in the other eye, to allow a comparison of the two procedures.

4.2.11.1 Changes in Amount of Higher Order Aberration Postoperative

In the contralateral study of 40 patients, the average increase in Higher Order Aberrations over a 6.0 mm Wavefront analysis diameter was evaluated. The amount of postoperative higher-order aberrations was less for Zyoptix LASIK eyes than for the Conventional LASIK eyes. The average increase in higher-order aberrations after surgery was:

- +13.4% at 6 months for Zyoptix LASIK eyes.
- +45.3% at 6 months for Conventional LASIK eyes.

Eyes with greater preoperative Higher Order Aberrations (HOA) were more likely to have a reduction in HOA or less of an increase 6 months after surgery.

When evaluated as a function of the optic zone size used, the results indicated that Higher Order Aberration increases were less in eyes treated with larger optical zones.

4.2.11.2 Proportion of the Population with a Decrease in Higher Order Aberrations Postoperative

For most patients, the Zyoptix LASIK did not reduce Higher Order Aberrations from baseline. In the contralateral study of 40 patients, the proportion of the population with reduced Higher Order Aberrations over the 6.0mm wavefront analysis diameter after surgery compared to before surgery is found below:

- 37.5% at 6 months for Zyoptix LASIK eyes.
- 12.8% at 6 months for Conventional LASIK eyes.

For the 40 patients in the study who received Zyoptix LASIK in one eye and Conventional LASIK in the other eye, there was no significant difference in subjective symptoms between the two treatments.

The analysis of the Higher Order Aberrations present preoperative and postoperative confirms that the Zyoptix LASIK procedure shows improvements to be primarily in 3rd order aberrations (coma and trefoil). The impact on reducing Higher Order Aberrations is directly correlated to the magnitude of the specific Order of Aberration present prior to treatment.

TABLE 17A

CHANGE FROM BASELINE IN WAVEFRONT ABERRATION RMS AT 6 MONTH VISIT AS A FUNCTION OF PREOPERATIVE HIGHER ORDER WAVEFRONT ABERRATION MAGNITUDE

6.0 MM WAVEFRONT ANALYSIS DIAMETER

	Preoperative Higher Order Root Mean Square (RMS)									
	0.00-0.24um		0.25-0.49um		0.50-0.74um		0.75-0.99um		1.00-1.24um	
N	47		200		78		9		2	
Induced Aberration	um	%	um	%	um	%	um	%	um	%
Total RMS	-3.46	-81 ⇓	-3.90	-80 ⇓	-4.21	-78 ⇓	-4.84	-79 ⇓	-5.23	-78 ⇓
Higher Order	0.21	99 ⇑	0.16	44 ⇑	0.05	8 ⇑	-0.09	-11 ⇓	-0.28	-25 ⇓
2nd Order	-3.59	-84 ⇓	-4.08	-84 ⇓	-4.42	-83 ⇓	-5.08	-83 ⇓	-5.43	-82 ⇓
3rd Order	0.12	81 ⇑	0.07	26 ⇑	-0.08	-16 ⇓	-0.26	-37 ⇓	-0.41	-40 ⇓
4th Order	0.17	140 ⇑	0.16	71 ⇑	0.16	53 ⇑	0.13	31 ⇑	0.10	21 ⇑
5th Order	0.01	14 ⇑	0.02	25 ⇑	0.02	31 ⇑	0.02	24 ⇑	0.01	5 ⇑

TABLE 17B

CHANGE FROM BASELINE IN WAVEFRONT ABERRATION RMS AT 6 MONTH VISIT AS A FUNCTION OF OPTIC ZONE SIZE 6.0MM WAVEFRONT ANALYSIS DIAMETER

	Optic Zone Size					
	5.75-6.24mm		6.25-6.74mm		6.75-7.00mm	
n	73		242		20	
Induced Aberration	um	%	um	%	um	%
Total RMS	-4.82	-81 ⇓	-3.72	-79 ⇓	-3.23	-76 ⇓
Higher Order	0.20	43 ⇑	0.12	29 ⇑	0.07	17 ⇑
2nd Order	-5.08	-87 ⇓	-3.88	-83 ⇓	-3.34	-79 ⇓
3rd Order	0.06	16 ⇑	0.03	10 ⇑	-0.04	-12 ⇓
4th Order	0.23	92 ⇑	0.14	60 ⇑	0.14	78 ⇑
5th Order	0.02	34 ⇑	0.02	24 ⇑	0.01	21 ⇑

4.2.11.3 Comparative Results for Wavefront-Guided LASIK vs. Conventional LASIK

Table 18 compares the change in total wavefront error and in higher-order aberrations for spherical myopic eyes treated with Wavefront-guided LASIK and Conventional LASIK with the Zyoptix System manifest refraction in the Subgroup Study with matched conventional and Zyoptix treatments (N=40 patients). On a percentage basis, the reduction in total wavefront RMS error is essentially equivalent between the treatment types. On third order aberrations (coma) the Zyoptix LASIK results in a reduction of 16% whereas the Conventional LASIK causes an increase of 30%.

TABLE 18

CHANGE FROM BASELINE IN WAVEFRONT ABERRATION RMS AT 6 MONTH VISIT FOR MATCHED CONVENTIONAL AND ZYOPTIX EYES 6.0MM WAVEFRONT ANALYSIS DIAMETER

	Zyoptix		Conventional	
n	40		39	
Induced Aberration	um	%	um	%
Total RMS	-3.51	-81 ⇓	-3.40	-78 ⇓
Higher Order	0.06	14 ⇑	0.17	45 ⇑
2nd Order	-3.67	-85 ⇓	-3.59	-82 ⇓
3rd Order	-0.05	-16 ⇓	0.09	30 ⇑
4th Order	0.14	70 ⇑	0.17	84 ⇑
5th Order	0.02	28 ⇑	0.00	1 ⇑

FACTS YOU NEED TO KNOW ABOUT WAVEFRONT-GUIDED LASER-ASSISTED IN SITU KERATOMILEUSIS (LASIK) SURGERY FOR THE REDUCTION OR ELIMINATION OF MYOPIC ASTIGMATISM WITH SPHERE UP TO -7.00 DIOPTERS OF NEARSIGHTEDNESS, ASTIGMATISM UP TO -3.00 DIOPTERS AND MRSE ≤ -7.50D AT THE SPECTACLE PLANE WITH THE BAUSCH AND LOMB TECHNOLAS® 217z ZYOPTIX™ SYSTEM FOR PERSONALIZED VISION CORRECTION

PATIENT INFORMATION BOOKLET

Please read this entire booklet. Discuss its content with your doctor so that all your questions are answered to your satisfaction. Ask any questions you may have before You agree to the surgery.

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A. INTRODUCTION

This booklet contains information to help you decide whether or not to have Laser in situ Keratomileusis (LASIK) laser surgery for the correction of nearsightedness. Eye surgery can help you see more clearly by changing the shape of the front surface of your *cornea,* which is the clear layer at the front of your eye. RK uses a scalpel to make fine cuts in the cornea. PRK and LASIK use a laser to reshape the cornea. For LASIK, an instrument called a *microkeratome* first cuts a thin flap of tissue from the front of your cornea. This *corneal flap* is folded back and the laser removes tissue under the flap to change the shape of the front surface of your eye. Then the flap is put back in place for the eye to heal.

Your eyeglass prescription is the usual way to tell how nearsighted you are. Another way is to measure the shape of the *wavefront* of reflected light coming out of your eye. A wavefront measurement gives more information about your nearsightedness than an eyeglass prescription. A wavefront measures all of the *focusing errors* in your eye, including complex errors that eyeglasses cannot correct. These complex focusing errors are called "higher-order *aberrations*". The combination of simple and complex wavefront errors in any eye is unique, and measurement of your wavefront provides your doctor with individualized information on your eye that is not otherwise available.

If you are nearsighted in both eyes, it may be necessary to have both eyes treated with LASIK. Sometimes, it is better to have LASIK done on only one eye. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK, PRK, and LASIK presently cannot meet.

Your doctor can use either your eyeglass prescription or a wavefront measurement to plan LASIK surgery. LASIK surgery based on the eyeglass prescription is called *Conventional LASIK.* LASIK surgery based on the wavefront is called wavefront-guided *LASIK.* Zyoptix LASIK is wavefront-guided surgery with the Bausch and Lomb **Technolas 217z Zyoptix System for Personalized Vision Correction.**

PERSONALIZED VISION CORRECTION.

LASIK surgery is permanent. You can have LASIK surgery on one eye at a time. The second eye may have surgery on the same day or later, depending upon your choice and your doctor's advice. Discuss with your doctor whether you are a good candidate for Zyoptix LASIK surgery.

How the Eye Functions

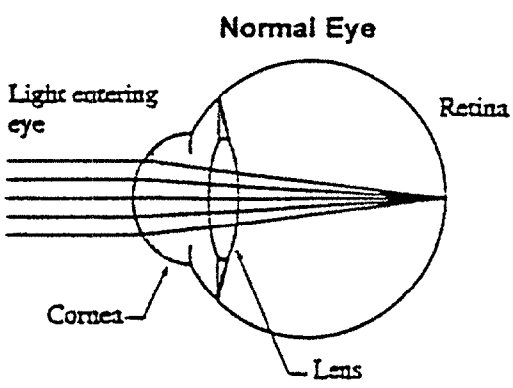
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

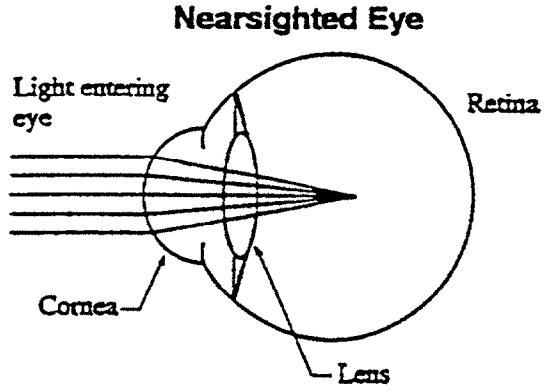
The cornea at the front of the eye bends the light toward your retina. The clear tissue of the cornea is responsible for two-thirds of the focusing power of the eye. The lens within the eye finishes the job of focusing the light onto your retina.

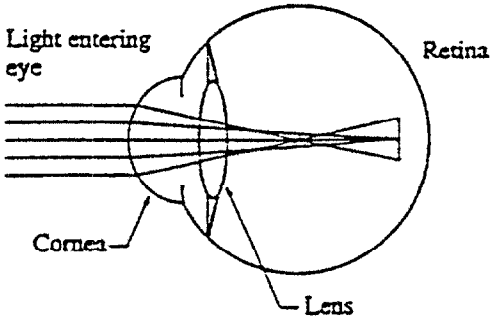
Focusing with Your Eye

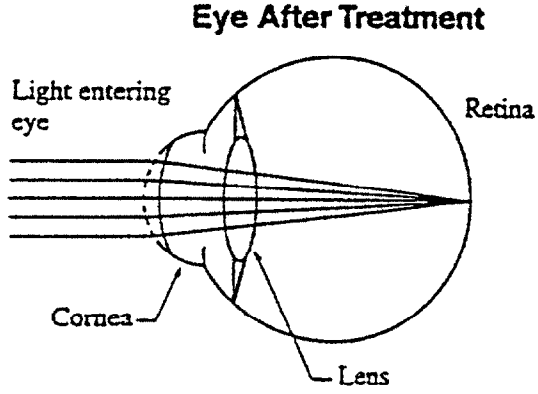
The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

The shape of the cornea determines the focusing power of the eye. The more sharply curved the cornea, the more that light rays are bent. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. If the cornea is curved too much, the image focuses in front of the retina and the eye is nearsighted. If the cornea is irregularly shaped (like a football rather than a basketball), it is called astigmatic.









Light focuses on the retina after surgery. Vision is clearer.

CHECKING YOUR FOCUS

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. The lens or combination of lenses used to correct the focus of your eye has a numerical value that is called the "manifest refraction spherical equivalent" or MRSE. MRSE is a measurement that describes the total refractive error of the eye.

Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

THE NEARSIGHTED EYE

One in four people in North America are nearsighted. They see near objects clearly, but distant objects are blurry. Light rays focus in front of the retina instead of directly on it. Nearsightedness tends to run in families. It usually starts in childhood and stabilizes in the late

teens or early adulthood. Nearsightedness can be corrected by glasses, contact lenses or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Wearing glasses and contact lenses help your eye focus light properly on the retina. LASIK surgery focuses light properly by reshaping the cornea. LASIK surgery uses an *excimer laser* to remove a tiny amount of tissue from the cornea. This type of laser does not change any other parts of the eye. The diagram of the eye after the Treatment shows that distant vision is clearer after LASIK.

B. WHAT IS WAVEFRONT GUIDED LASER IN SITU KERATOMILEUSIS (ZYOPTIX LASIK)?

BEFORE THE PROCEDURE

Before surgery, your doctor will determine your specific correction by measuring the wavefront of your eye, to capture all of the *focusing errors* in your eye and determine the amount of correction needed. This is accomplished by projecting light into your eye and measuring the reflected light that comes out to determine your wavefront. Zyoptix LASIK uses the wavefront to guide the laser in reshaping the cornea to correct focusing errors, in the manner described below.

Your doctor has the choice of setting the diameter of the area of the central cornea to which the LASIK treatment is delivered. This area is called the *Optic Zone*. The doctor will choose the optic zone best suited for you on the basis of providing the largest zone for the amount of correction needed that still leaves the appropriate amount of corneal tissue after the procedure.

THE PROCEDURE

A small surgical instrument called a microkeratome, which works much like a miniature carpenter's plane, is used to make a very thin flap of tissue on the cornea (the clear part on the front of the eye). This flap is then folded out of the way, and an excimer laser is used to flatten the front surface of the cornea below the flap. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea. This is different from RK (radial keratotomy). In RK, a surgical knife is used to make deep cuts around the center of the cornea to cause it to flatten.

An excimer laser is a piece of medical equipment that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. These laser pulses remove small and precise amounts of corneal tissue based on your individual wavefront analysis. The excimer laser produces little heat and leaves the tissue beneath unchanged.

The Zyoptix laser system also includes an active eye tracker system that automatically adjusts the laser beam to bring the laser pulses to the desired position in the event your eye moves during Zyoptix LASIK surgery

LASIK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor's evaluation of your particular case.

C. WHAT ARE THE BENEFITS OF ZYOPTIX LASIK?

Zyoptix LASIK surgery can correct up to –7 *diopters* (D) of nearsightedness with up to –3.00 D of *astigmatism,* and MRSE $\leq$ 7.50D at the spectacle plane. If you have nearsightedness within this range, Zyoptix® LASIK surgery may allow you to see clearly at long distances without eyeglasses or contact lenses.

CLINICAL STUDY TO EVALUATE BENEFITS

A clinical study was conducted to evaluate the benefits and risks of Zyoptix LASIK. The study included 342 eyes to determine benefits and risks. The study results are shown below and in "What are the Risks of Zyoptix LASIK." In the study the doctor made a choice of what the optic zone size should be based on the eye's wavefront measurement and the individual diameter of the pupil in low light conditions.

STUDY PATIENT DEMOGRAPHICS

Most patients in the study were Caucasian. No patients were under 21 years of age or over 61 years old. Table 1 shows the age, race, and gender of patients in the study. (Please note that in all tables, "N" or "n" represents the number of eyes treated in each category.)

TABLE 1. DEMOGRAPHICS OF 342 EYES OF 191 STUDY PATIENTS

			Total
Number of Eyes			342
Number of Enrolled Subjects			191
Age (yrs)	Mean		34.4
	SD		8.29
	Range		21-61
Gender	Male	% (n)	46.07% (88)
	Female	% (n)	53.93% (103)
Race	White	% (n)	90.58% (173)
	Black	% (n)	1.05% (2)
	Asian	% (n)	5.24% (10)
	Other	% (n)	3.14% (6)
Operative Eye	Right	% (n)	49.71% (170)
	Left	% (n)	50.29% (172)

Two eyes were unable to have the procedure completed. Therefore the results are based on the 340 eyes that successfully completed the procedure.

VISUAL ACUITY *WITHOUT* GLASSES AFTER SURGERY

In the clinical study of the Bausch & Lomb TECHNOLAS 217z Zyoptix Excimer Laser System, 91.5% of all treated eyes had 20/20 vision or better without glasses after a single LASIK procedure, and 99.4% had 20/40 vision or better at the 6-month visit. Most states require that your vision be 20/40 or better for you to drive **without** any glasses or contact lenses.

TABLE 2. VISUAL ACUITY *WITHOUT* GLASSES AFTER SURGERY (N=340 Eyes Tested)

Time after Surgery	1 Month	3 Months	6 Months
Percent of eyes with 20/16 or better	61%	69%	70%
Percent of eyes with 20/20 or better	86%	90%	92%
Percent of eyes with 20/25 or better	94%	95%	95%
Percent of eyes with 20/40 or better	99%	99%	99%

LASIK to correct distance vision does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

INFLUENCE OF OPTIC ZONE SIZE

The clinical results at 6 months were also analyzed by the size of the optic zone used in the treatment. This information is found in the table below. Larger optic zones tended to have better outcomes.

TABLE 3. SUMMARY OF KEY EFFICACY VARIABLES AT 6 MONTHS BY OPTICAL ZONE SIZE

	OPTICAL ZONE SIZE (mm)		
KEY EFFICACY VARIABLES	**5.75-6.24**	**6.25-6.74**	**6.75-7.24**
	% (n)	**% (n)**	**% (n)**
Total Eyes Reported*	73	246	20
UCVA 20/16 or Better	60.3% (44)	73.6% (181)	65.0% (13)
UCVA 20/20 or Better	83.6% (61)	93.5% (230)	95.0% (19)
UCVA 20/25 or Better	90.4% (66)	96.7% (238)	95.0% (19)
UCVA 20/32 or Better	94.5%(69)	99.6% (245)	100.0% (20)
UCVA 20/40 or Better	97.3% (71)	100.0% (246)	100.0% (20)

*One eye did not have optic zone size documented

VISUAL ACUITY AFTER SURGERY (NO GLASSES) COMPARED TO VISUAL ACUITY BEFORE SURGERY (WITH GLASSES)

Table 4 shows that at 6 months after the surgery, about **78%** of the patients saw as well ***without*** glasses after Zyoptix surgery as ***with*** glasses before surgery. A gain of lines means that patients could read 1 or more rows of letters on the eye chart (visual acuity chart) after surgery that they could not read before surgery.

TABLE 4. VISUAL ACUITY WITH NO GLASSES AFTER SURGERY COMPARED TO VISUAL ACUITY WHILE WEARING GLASSES BEFORE SURGERY (N=340 Eyes Tested)

Time after Surgery	3 Months % (n)	6 Months % (n)
Percent of eyes with 2 or more lines better vision than with glasses	13.5% (46)	14.1% (48)
Percent of eyes with 1 line better vision than with glasses	25.6% (87)	27.9% (95)
Percent of eyes with the same vision as with glasses	38.2% (130)	36.2% (123)
Percent of eyes with 1 line worse vision than with glasses	15.3% (52)	14.7% (50)
Percent of eyes with 2 or more lines worse vision than with glasses	7.4% (25)	7.1% (24)

D. WHAT ARE THE RISKS OF ZYOPTIX LASIK?

If you are not satisfied with your surgery results, your doctor may suggest another surgery. No data are available for Zyoptix LASIK retreatments.

Zyoptix LASIK does not take away the need for reading glasses. You may need reading glasses after Zyoptix LASIK even if you did not need them before.

In some cases, your best vision *with* your glasses or contact lenses may be worse after Zyoptix LASIK surgery than it was before surgery.

A number of risks from LASIK surgery are related to the corneal flap rather than the laser treatment. Some specific problems include: cutting an incomplete or irregular flap, loss of the flap, misalignment of the flap, and cutting all the way through the cornea with the microkeratome. These problems can lead to other complications, such as infections, *cataracts*, and permanent scarring or deformity of the eye.

CONTRAINDICATIONS

You should **NOT** have Zyoptix® LASIK surgery if you:

- are pregnant or nursing because these conditions may cause temporary and unpredictable changes in your cornea that may interfere with getting the right measurement of your cornea before the LASIK procedure.
- show signs of *keratoconus*. This is a condition of the cornea that results in a change in the shape of the cornea as well as thinning of the cornea. The unstable condition of the cornea makes it unsafe to do LASIK procedures on eyes with this condition.
- are taking medications with ocular side effects [for example, isotretinoin (Accutane[1]) for acne treatment or amiodarone hydrochloride (Cordarone[2]) for normalizing heart rhythm]. Such medications may affect the accuracy of the LASIK procedure or the way the cornea heals after surgery. This may result in poor vision after LASIK.
- have a *collagen vascular*, *autoimmune*, or *immunodeficiency disease*. These are conditions that affect your immune response (your body's ability to heal), or result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples are AIDS, lupus, and rheumatoid arthritis. These conditions affect the body's ability to heal properly.

WARNINGS

Discuss with your doctor if you have:

- diabetes. Diabetes may interfere with the healing of the cornea after LASIK.

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[1] Accutane Reg TM of Hoffmann-LaRoche, Inc.
[2] Cordarone Reg TM of Sanofi Corp.

- severe allergies. The medications taken for severe allergies may interfere with the ability of the eye to heal after LASIK.
- significant dry eye that is unresponsive to treatment. LASIK may increase the dry eye condition. This may or may not go away.
- a history of *herpes simplex* or *herpes zoster* infection that has affected your eyes. LASIK may be more risky for patients who have had herpes infections that affected their eyes.
- You have a systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status.

PRECAUTIONS

The safety and effectiveness of Bausch and Lomb Personalized Vision Correction System for Zyoptix LASIK have **NOT** been established in patients:

- with unstable or worsening nearsightedness. Eyes with unstable nearsightedness are unable to be correctly measured to determine the right amount of the vision correction to provide.
- with a cornea that is too thin for LASIK to be completed safely. A flap needs to be cut into the cornea for the LASIK procedure. Thin corneas cannot have a proper flap cut done.
- with a history of *glaucoma* (a condition usually associated with high eye pressure with damage to the nerve in the eye and possible loss of vision). It is unknown whether LASIK is safe for eyes with glaucoma.
- who are taking the medication sumatripin (Imitrex[3]) for migraine headaches. It is unknown whether the use of this medication will interfere with the measurement prior to LASIK or the healing of the eye after LASIK.
- under 21 because it is unknown if the eye has reached its adult vision refraction. This may result in measurement of the amount of correction to provide being incorrect.
- over the long term (more than 6 months).
- with greater than 7D of nearsightedness with greater than –3.00D of astigmatism and greater than –7.50D MRSE. Corrections falling outside of the approved range have not been studied.
- for retreatment with Zyoptix LASIK. Retreatments have not been done enough times to allow an understanding of whether it is safe and effective.
- The following conditions may interfere with the ability to properly measure the eye to determine the right amount of vision correction to provide and the may also affect the way the eye would heal after the procedure. Eyes with:
  - with disease or corneal condition (for example, scar, infection, etc.).
  - with injury to the center of the cornea where Zyoptix LASIK will reshape the cornea.
  - with previous surgery on the cornea or inside the eye (for example, cataract surgery).
  - with prior history of surgery to correct vision (for example, RK, PRK, LASIK).

[3] Imitrex Reg TM of Glaxo Group Limited

Before surgery, your doctor should evaluate your pupil size under dim lighting conditions. If your pupils in dim light are greater than the optical zone (which ranges from 6.0mm to 7.0mm) proposed by your doctor, consult with your doctor about the risk that the surgery may cause negative effects on your vision, such as glare, halos, and night driving difficulty.

Bausch & Lomb recommends selection of the largest optical zone between 6.0 and 7.0 mm, while ensuring residual stromal thickness of at least 250 microns.

Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.

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

Lower uncorrected visual acuity and accuracy of MRSE within $\leq \pm$ 0.5D of emmetropia (no remaining refraction error) may be anticipated following treatment of eyes that have higher levels of preoperative MRSE (greater than or equal to –7.00D MRSE). This means that outcomes were not as good in eyes with high refractive error, i.e., MRSE of –7.00D or greater.

During the first week following surgery

- You may feel pain, discomfort, or the sensation of something in your eye. This may last up to 7 days after surgery.
- Your vision may be blurry or you may become more sensitive to light as your eye heals.
- You may have temporary swelling of the front surface of your eye.
- The pressure inside your eye may increase, usually due to the use of *anti-inflammatory medication* (eye drops) after surgery. Using another medication or stopping the anti-inflammatory medication can control the abnormal increase in eye pressure.

During one to three months following surgery

- Your vision should be stable 3 to 6 months after surgery. Some patients may notice that their vision improves or worsens. These small changes may occur up to 3 months or more after surgery. You should contact your doctor if you notice any change or loss of vision.
- You may become more sensitive to light. You may notice glare or have difficulty in driving at night.

CLINICAL STUDY TO EVALUATE RISKS

In the clinical study on Zyoptix® LASIK, vision **without** glasses improved for all eyes. Some people still needed glasses or contact lenses after surgery, but in general, measuring vision with glasses is a good safety measure since it allows the number of eyes whose vision was worse after Zyoptix LASIK to be identified. Table 4 above, provided a comparison if vision without glasses after surgery to vision with glasses before surgery, while Table 5 and Table 6 compares vision with glasses after surgery to vision with glasses before surgery.

VISUAL ACUITY *WITH* GLASSES AFTER SURGERY

Table 5 shows that all eyes with nearsightedness saw 20/25 or better **with** glasses at 3 and 6 months and that all eyes with nearsightedness with astigmatism saw 20/32 or better **with** glasses at 3 and 6 months. (Please note that in all tables, "N" or "n" represents the number of eyes treated in each category.) As mentioned on an earlier page of this document, a gain of lines means that patients could read 1 or more rows of letters on the eye chart (visual acuity chart) after surgery than they could read before surgery.

TABLE 5. VISUAL ACUITY *WITH* GLASSES (BEST VISION) AFTER SURGERY

	Nearsightedness		Nearsightedness With Astigmatism	
	3 Months (N=117	6 Months (N=117)	3 Months (N=223)	6 Months (N=223)
20/16 or better	86.3%	93.2%	85.2%	86.1%
20/20 or better	98.3%	99.1%	98.2%	100.0%
20/25 or better	100.0%	100.0%	99.6%	100.0%
20/32 or better	100.0%	100.0%	100.0%	100.0%
20/40 or better	100.0%	100.0%	100.0%	100.0%

CHANGE IN VISUAL ACUITY *WITH* GLASSES AFTER SURGERY

Table 6 compares the change in vision **with** glasses at 3 and 6 months to vision before surgery for the patients from the clinical study. At 6 months after the procedure, best vision with glasses was unchanged or improved in 94.1% of eyes. No eyes lost more than 2 lines, and two eyes lost 2 lines. One of these eyes was 20/12.5 before surgery and 20/20 at 6 months; the other was 20/16 before surgery and 20/25 at 6 months.

TABLE 6. CHANGE IN VISUAL ACUITY *WITH* GLASSES AFTER SURGERY COMPARED TO BEFORE SURGERY (N=340 Eyes Tested)

PROPORTION OF THE POPULATION WITH CHANGE TO VISION WITH GLASSES	Time after surgery	
	3 Months	6 Months
% of eyes with loss of more than 2 lines	0.0%	0.0%
% of eyes with loss of 2 lines	1.2%	0.6%
% of eyes with loss of 1 line	6.9%	5.3%
% of eyes with no change	38.8%	33.8%
% of eyes with gain of 1 line	35.6%	41.5%
% of eyes with gain of 2 lines	15.3%	17.4%
% of eyes with gain of more than 2 lines	1.2%	1.5%

ADVERSE EVENTS AND COMPLICATIONS

Some patients from the clinical study experienced adverse events and complications after Zyoptix® LASIK surgery as shown below.

TABLE 7
ADVERSE EVENTS SUMMARY
ALL TREATED EYES

	VISITS		
ALL REPORTED ADVERSE EVENTS	1 MONTH	3 MONTHS	6 MONTHS
Total Eyes Reported	340	340	340
Not Reported	0	0	0
Distribution of Scores	% (n)	% (n)	% (n)
Decrease in best vision with glasses of ≥ 2 lines at ≥ 6 months	0.0% (0)	0.0% (0)	0.6% (2)
Lamellar keratitis	0.0% (0)	0.0% (0)	0.3% (1)

Adverse events and complications that occurred during the study included

- A decrease of 2 or more lines of vision in 2/340 eyes (0.6%) at 6 months
- Lamellar keratitis (inflammation of the cornea under the flap) in 1/340 eyes (0.3%) at 3 months
- Epithelium (cells) under the flap in 1/340 eyes (0.3%)
- Misplaced or loose flap or free cap in 1/340 eyes (0.3%)
- Foreign body sensation (feeling of something in the eye) in 1/340 eyes (0.3%)

Other complications included allergies, conjunctivitis (inflammation of the outer lining of the eye), abrasion of the cornea, inflammation under the flap, episcleritis, chalazion, and Bowman's wrinkle; all of these complications occurred at an incidence of less than 1%.

The following complications did not occur during the clinical trial: recurrent corneal erosions, size and shape of flap not as intended, corneal epithelial defect either on the flap or off the flap and epithelial in-growth.

PATIENT SYMPTOMS GRADED AS WORSE OR SIGNIFICANTLY WORSE AFTER SURGERY

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 in each eye. Patients were also asked to grade the severity of any symptoms they reported, as compared to the same symptoms before surgery. As shown in Table 8, a number of symptoms were graded as "worse" or "significantly" worse after surgery than before surgery.

TABLE 8
COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY
(AT 6 MONTHS, N = 340 EYES TESTED)

Symptom	Worse	Significantly Worse
Dryness	28.8%	2.4%
Fluctuation of Vision*	20.0%	4.2%
Variation in Vision***		
In Dim Light	14.7%	2.7%
In Bright Light	10.3%	0.3%
In Normal Light	8.8%	2.4%
Blurring of Vision	14.7%	3.8%
Glare	12.1%	3.2%
Halos	11.8%	2.6%
Redness	9.7%	1.2%
Night Driving Difficulty	9.1%	1.2%
Burning	7.6%	0.3%
Light Sensitivity	7.1%	0.6%
Gritty Feeling	6.2%	0.0%
Headache	4.1%	1.2%
Ghost Images**	3.5%	0.9%
Excessive Tearing	3.2%	0.6%
Pain	2.1%	0.0%
Double Vision	0.9%	2.4%

* Fluctuation in vision only reported on for n= 335 eyes at 6 months
**Ghost images was reported on for n=339 eyes at 6 months
***Variation in vision was reported on for only n=339 eyes at 6 months

Typical complications that may occur after the LASIK procedure are:

EARLY COMPLICATIONS (DURING THE FIRST FEW WEEKS AFTER LASIK)

Epithelium in the interface with loss of ≤ 2 lines of best vision with glasses, corneal edema, < stage 2 lamellar keratitis, debris in interface & episcleritis, chalazion, conjunctivitis, episcleritis, inflammation, lamellar keratitis, lamellar keratitis & debris in interface, superficial punctate keratitis, subconjunctival hemorrhage.

MEDIUM-TERM COMPLICATIONS (3 MONTHS AFTER SURGERY)

Corneal flap complication with ≤ 2 lines of best vision with glasses, ghost images, allergies, chalazion, conjunctivitis, debris in interface.

LONG-TERM COMPLICATIONS (6 MONTHS AFTER SURGERY)

Recurrent corneal erosion, Bowman's wrinkle, conjunctivitis, corneal abrasion, debris in interface, debris in interface & Bowman's wrinkle, lamellar keratitis.

PATIENT SELF-EVALUATION BEFORE AND AFTER LASIK

Patients in the study were asked to grade symptoms and to grade the overall quality of their vision both before and after surgery, to allow a comparison to be made.

SYMPTOM SEVERITY BEFORE AND AFTER SURGERY

Some symptoms were reported as better or significantly better after Zyoptix LASIK surgery and some symptoms were reported as worse or significantly worse after Zyoptix LASIK surgery, as shown in Table 9 below. (Symptoms described as worse or significantly worse were also shown in Table 8, above).

Six months after surgery, the majority of symptoms were reported as better or significantly better, however a number of symptoms were described as worse or significantly worse. Symptoms that were described as better after surgery include light sensitivity, headache, pain, redness, tearing, burning, and night driving difficulties. Symptoms reported as worse after surgery were dryness, halos, double vision, and fluctuation of vision.

TABLE 9
CHANGE IN GRADING OF SYMPTOMS BEFORE AND AFTER SURGERY
(AT 6 MONTHS, N = 340 EYES TESTED)

Symptom	Significantly Better	Better	No Change	Worse	Significantly Worse
Light Sensitivity	9.4%	27.4%	55.6%	7.1%	0.6%
Headache	5.9%	19.4%	69.4%	4.1%	1.2%
Pain	2.4%	3.8%	91.8%	2.1%	0.0%
Redness	1.8%	21.5%	65.9%	9.7%	1.2%
Dryness	2.9%	16.8%	49.1%	28.8%	2.4%
Excessive Tearing	2.1%	10.0%	84.1%	3.2%	0.6%
Burning	1.2%	13.2%	77.6%	7.6%	0.3%
Gritty Feeling	0.6%	7.9%	85.3%	6.2%	0.0%
Glare	3.5%	17.4%	63.8%	12.1%	3.2%
Halos	1.8%	11.8%	72.1%	11.8%	2.6%
Blurring of Vision	8.5%	13.8%	59.1%	14.7%	3.8%
Double Vision	0.3%	1.2%	95.3%	0.9%	2.4%
Ghost Images**	0.3%	4.1%	91.2%	3.5%	0.9%
Fluctuation of Vision*	0.0%	7.5%	68.4%	20.0%	4.2%
Variation in Vision*:**					
In Bright Light	3.8%	20.1%	65.5%	10.3%	0.3%
In Normal Light	0.9%	8.6%	79.4%	8.8%	2.4%
In Dim Light	5.0%	20.4%	57.2%	14.7%	2.7%
Night Driving Difficulty	11.2%	29.1%	49.4%	9.1%	1.2%

* Fluctuation in vision only reported on for n=336 eyes at 3 months and n=335 eyes at 6 months

** Ghost images was reported on for n=339 eyes at 6 months

*** Variation in vision was reported on for only n=339 eyes at 6 months

PATIENT SELF –EVALUATION OF VISION QUALITY

Patient self-evaluation of postoperative vision quality was evaluated in the study on the question of quality of vision, whether the patient would choose to have the procedure again, and how satisfied they were with the results. The data from the patient responses is found in Table 10 below:

TABLE 10
SELF-EVALUATION
OVERALL QUALITY OF VISION
ALL TREATED EYES

Overall Quality Of Vision After Excimer Laser?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	340	340	340
Not Reported	0	0	0
Distribution Of Scores	% (n)	% (n)	% (n)
Extreme improvement	80.6 % (274)	81.8 % (278)	84.7 % (288)
Marked improvement	16.2 % (55)	14.1 % (48)	12.1 % (41)
Moderate improvement	2.4 % (8)	2.1 % (7)	1.8 % (6)
Slight improvement	0.9 % (3)	1.8 % (6)	1.2 % (4)
No improvement	0.0 % (0)	0.3 % (1)	0.3 % (1)

Choose Excimer Laser Again?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	337	338	340
Not Reported	3	2	0
Distribution Of Scores	% (n)	% (n)	% (n)
Yes	97.0 % (327)	97.3 % (329)	98.2 % (334)
Unsure	3.0 % (10)	2.7 % (9)	1.2 % (4)
No	0.0 % (0)	0.0 % (0)	0.6 % (2)

How satisfied with the Excimer Laser Results?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	340	337	340
Not Reported	0	3	0
Distribution Of Scores	% (n)	% (n)	% (n)
Very Satisfied	89.7 % (305)	91.1 % (307)	90.9 % (309)
Moderately Satisfied	8.8 % (30)	7.1 % (24)	7.9 % (27)
Neutral	0.9 % (3)	1.8 % (6)	1.2 % (4)
Dissatisfied	0.6 % (2)	0.0 % (0)	0.0 % (0)
Very Dissatisfied	0.0% (0)	0.0 % (0)	0.0 % (0)

E. INDICATIONS FOR USE

The Bausch & Lomb Zyoptix System is indicated for laser in-situ keratomileusis (LASIK) treatments:

- for the reduction or elimination of myopic astigmatism, with sphere up to -7.00 D, cylinder up to -3.00 D with MRSE $\leq$ -7.50D at the spectacle plane;
- in patients with documented evidence of a change in manifest refraction of less than or equal to $\pm$ 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.

F. ARE YOU A GOOD CANDIDATE FOR ZYOPTIX LASIK?

If you are considering Zyoptix LASIK, you must:

- be at least 21 years of age.
- have a healthy eye with no eye disease or corneal condition (for example, scar, infection, retinal problems, etc.)
- have up to –7D of nearsightedness with up to –3.50D of astigmatism.
- have less than or equal to 0.50D change each year in your nearsightedness for at least one year before your eye examination before surgery.
- be able to lie flat on your back without difficulty
- be able to look at a red blinking fixation light during the entire surgery.
- be able to have eye drops that numb your eye and enlarge your pupil.
- understand the risks and benefits of Zyoptix LASIK compared to other available treatments for nearsightedness.

G. WHAT SHOULD YOU EXPECT DURING ZYOPTIX LASIK SURGERY?

BEFORE THE SURGERY

Before surgery, your doctor needs to determine your complete medical and eye history and check the health of both your eyes. As part of this exam, your doctor will use a computed program to map the front surface of your eye. This exam will determine if your eyes are healthy and if you are a good candidate for Zyoptix® LASIK.

WARNING: You must stop wearing any soft contact lenses at least 1 week and any hard or gas permeable lenses at least 3 weeks before this eye examination. Failure to do this may affect surgical results.

Tell your doctor if you take any medications or have any allergies. Ask your doctor if you should eat or drink right before the surgery. **You should also arrange for transportation since you must not drive right after the surgery.** Your doctor will let you know when your vision is good enough to drive again.

THE DAY OF SURGERY

To prepare for surgery, your doctor will use the wavefront system to take a picture of your eye. This helps to determine where the laser should treat your cornea. Your doctor will put eye drops to dilate (enlarge) the pupil in your eye(s). After 30-40 minutes, your doctor will measure the wavefront of your eye to determine the amount of laser treatment you need.

Your doctor will then place numbing eye drops and ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that can be moved to position you for surgery. Your doctor will instruct you to watch a blinking fixation light. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye that is not having surgery.

When the surgery begins, the surgeon will use a small instrument to create a thin flap of corneal tissue that is folded away from the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Even though the eye not having the surgery may be covered by a drape or a patch, try to keep both eyes open without squinting. This makes it easier to keep looking at the red light. You will then hear the noise the laser makes when it is delivering the laser energy.

WARNING: It is very important that you keep looking directly at the red light, even if the light fades or dims. Your results depend on how well you look directly at this red light throughout the treatment.

After the surgery is complete, your doctor will place some eye drops in your eye. Your doctor may cover your eye with a *bandage contact lens* to help heal the eye. For your eye protection and comfort, your doctor may apply a patch or shield over your eye. The surgery is painless because of the numbing eye drops. The effects of the numbing eye drops will wear off after about 45-60 minutes.

THE FIRST DAYS AFTER SURGERY

You may be mildly sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain

medication to make you more comfortable during the first few days after the surgery. A plastic shield may be used to protect your eye after LASIK. You will need to use lubricants, *antibiotic*, and *anti-inflammatory medications* in the first few days.

IMPORTANT: Use the lubricants and eye medications as directed by your doctor. Your results depend upon you following your doctor's instructions.

WARNING: Your doctor will monitor you for any side effects if you need to use a topical *steroid medication*. Possible side effects of prolonged topical steroid use are:

- *ocular hypertension* (an increase in the eye pressure);
- *glaucoma* (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision);
- *cataract formation* (an opacity or clouding of the lens inside the eye that can cause a loss of vision).

DO NOT rub your eyes for the first 3 to 5 days. Rubbing your eye may move the flap. If you notice any sudden decrease in your vision, you should contact your doctor immediately. The flap may have moved and the doctor may need to reposition the flap.

H. QUESTIONS TO ASK YOUR DOCTOR

You may want to ask the following questions to help you decide if Zyoptix LASIK with the Bausch and Lomb Technolas 217z System for Personalized Vision Correction is right for you:

- What are my other options to correct my nearsightedness?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of Zyoptix LASIK for my amount of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If Zyoptix LASIK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after Zyoptix LASIK if I need them?
- How is Zyoptix LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having Zyoptix LASIK?
- Should I have Zyoptix LASIK surgery in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have Zyoptix LASIK only on one eye?
- Do I have significant dry eye or large pupils that could produce undesirable side effects and decrease my satisfaction after surgery?

Discuss the cost of surgery and follow-up care needs with your doctor. Most health insurance policies do not cover laser vision correction.

I. SELF-TEST

ARE YOU AN INFORMED AND EDUCATED PATIENT?

Take the test below to see if you can answer the following questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser surgery is risk-free.	____	____
2. Excimer laser surgery is the same as Radial Keratotomy (RK).	____	____
3. It does not matter if I wear my contact lenses before surgery when my doctor told me not to wear them.	____	____
4. After the surgery, there is a good chance that I will depend less on eyeglasses or contact lenses.	____	____
5. I may need reading glasses after LASIK surgery, even if I did not need them before.	____	____
6. There is a risk that I may lose some vision after LASIK surgery.	____	____
7. It does not matter if I am pregnant.	____	____
8. If I have an autoimmune disease, I am still a good candidate for LASIK surgery.	____	____
9. Significant dry eye or large pupils may produce undesirable side effects and decrease my satisfaction after LASIK surgery.	____	____

You can find the answers to Self-Test on the following page.

J. SUMMARY OF IMPORTANT INFORMATION

- Zyoptix LASIK is a permanent surgery to the cornea.
- Zyoptix LASIK does not eliminate the need for reading glasses, even if you have never worn them before.
- Your vision must be stable before Zyoptix LASIK surgery. You must provide written evidence that your nearsightedness has changed less than or equal to 0.50D each year for at least 1 year.
- Pregnant and nursing women should wait until they are not pregnant and not nursing to have the surgery Zyoptix LASIK.
- You would not be a good candidate if you have collagen vascular or autoimmune diseases. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- Zyoptix LASIK surgery has some risks. Please read and understand this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- Zyoptix LASIK is not a laser version of RK. These surgeries are entirely different.
- Some other options to correct nearsightedness include glasses, contact lenses, RK, PRK, and Conventional LASIK.
- RK, PRK, Conventional LASIK or Zyoptix LASIK may not meet the vision requirements of some occupations, such as military service.
- Before considering Zyoptix LASIK surgery you should:
  a. have a complete eye examination.
  b. talk with at least one eye care professional about Zyoptix LASIK, especially the potential benefits, risks, and complications. You should discuss the time needed for healing after Zyoptix LASIK.

ANSWERS TO SELF-TEST QUESTIONS:

1. False (see Section D: Risks)
2. False (see Section A: Introduction)
3. False (see Section I: Before the Surgery)
4. True (see Section C: Benefits)
5. True (see Section D: Risks)
6. True (see Section D: Risks)
7. False (see Section E: Contraindications)
8. False (see Section E: Contraindications)
9. True (see Section G: Precautions)

K. GLOSSARY OF TERMS

This section summarizes important terms used in this information booklet. Please discuss any related questions with your doctor.

Aberration: Focusing errors in the eye detectable by wavefront measurements. Examples are nearsightedness and astigmatism (lower-order) and complex errors (higher-order).

Antibiotic Medication: A drug used to treat or prevent infection. Your doctor may prescribe this medication after LASIK surgery.

Anti-inflammatory Medication: A drug that reduces inflammation or the body's reaction to injury or disease. Any eye surgery can cause inflammation. Your doctor may prescribe this medication after LASIK surgery.

Astigmatism: Refractive error that prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the various meridians of the eye.

Autoimmune Disease: A condition in which the body attacks itself and results in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. If you have this type of condition, you should not have LASIK surgery.

Bandage Contact Lens: A soft contact lens placed on the cornea after surgery to cover the area that was treated with the laser.

Cataract An opacity, or clouding, of the lens inside the eye that can blur vision.

Collagen Vascular Disease: A condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples are lupus and rheumatoid arthritis. If you have this type of condition, you should not have LASIK surgery.

Contraindications: Any special condition that results in the treatment not being recommended.

Contrast Sensitivity: A measure of the ability of the eye to detect small lightness differences between objects and the background in daylight and in dim light. For example, black lines on a gray background are easier to see than gray lines on a gray background. Objects in daylight are also easier to see than in dim light. Contrast sensitivity testing is a way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

Conventional LASIK: LASIK surgery that uses an eyeglass prescription to plan the surgery.

Cornea: Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.

Corneal Flap: A thin slice of tissue on the surface of the cornea made with a microkeratome at the beginning of the LASIK procedure. This flap is folded back before the laser shapes the inner layers of the cornea.

Corneal Swelling: Abnormal fluid build-up in the cornea. This condition is usually temporary with no significant effect on vision.

Corneal Wrinkle: Temporary appearance of fine white lines in the cornea due to swelling.

Diopter: Unit of measurement of optical strength or refractive power of lenses.

Excimer laser: A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.

Farsightedness/ Hyperopia: Condition in which the eye is "under-powered," so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina." Corrected with additional optical power, supplied by a "plus" lens or by additional use of the eye's own focusing ability.

Focusing Error: A condition in which your eye forms a blurred image on your retina. Examples are nearsightedness, astigmatism, and higher-order aberrations (complex focusing errors).

Glaucoma: An eye disease usually associated with high eye pressure. Glaucoma damages the optic nerve of the eye and usually causes a progressive loss of vision.

Halos: Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).

Herpes Simplex: A type of viral infection that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

Herpes Zoster: A type of viral infection that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

Immunodeficiency Disease: A condition that compromises the body's ability to heal. An example is acquired immunodeficiency syndrome (AIDS). If you have this type of condition, you should not have LASIK surgery.

Inflammation: The body's reaction to injury or disease. Eye surgery, such as PRK and LASIK, can cause inflammation.

Keratoconus: Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

LASIK: An acronym for "laser in situ keratomileusis." This is a surgical procedure in which a very thin flap of tissue on the clear front part of the eye (cornea) is made using a small surgical instrument called a microkeratome, which is much like a carpenter's plane. The flap is then folded out of the way and an excimer laser is used to flatten the front surface of the cornea below the flap.

Lens: A transparent, colorless body located in the front third of the eyeball, between the aqueous and the vitreous, the function of which is to help bring rays of light to focus on the retina.

Low Contrast Visual Acuity: A measure of the sharpness of vision using a 10% low contrast chart with gray letters on a white background. Low contrast acuity testing is another way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

MRSE Manifest Refraction Spherical Equivalent is a measurement that describes the total refractive error of the eye. It is comprised of the myopia and one half of the astigmatism.

Microkeratome: A surgical instrument used in LASIK to cut a thin flap of tissue from the front surface of the eye before the laser treatment is applied.

Nearsightedness/ Myopia: "Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires "minus" lens correction to "weaken" the eye optically and permit clear distance vision.

Ocular Hypertension: Increased eye pressure.

Optic Zone: This is the diameter of the area of the central cornea to which the LASIK treatment is delivered.

Pupil: The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.

PRK: An acronym for "photorefractive keratectomy." This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner to re-shape the cornea to correct refractive errors of the eye.

Refractive surgery: Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.

Retina: The thin lining of the back of the eye that converts images from the eye's optical system into electrical impulses sent to the brain.

RK An acronym for "radial keratotomy." This is a surgical procedure in which a predetermined number of radial cuts are made in the periphery of the cornea. This allows the central cornea to flatten and thereby reduces nearsightedness.

Steroid Medication: A drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe this medication after LASIK surgery for a short time to modify the healing of your eye. If you are taking this medication for a disease condition, you should not have LASIK surgery.

Visual Acuity: A measure of the sharpness of vision using a letter chart.

Wavefront: A measure of the total focusing errors (aberrations) including nearsightedness, astigmatism, and complex focusing errors (higher-order aberrations). Light is projected into your eye and focused on the retina. Part of this light is reflected back out of your eye to form the wavefront.

L. PATIENT ASSISTANCE INFORMATION

PRIMARY EYE CARE PROFESSIONAL

Name:
Address:

Telephone Number:

LASIK DOCTOR

Name:
Address:

Telephone Number:

LOCATION WHERE TREATMENT WAS DONE

Name:
Address:

Telephone Number:

LASER MANUFACTURER

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M. INDEX