SUMMIT AUTONOMOUS INC.

LADARVision® EXCIMER LASER SYSTEM

PROFESSIONAL USE INFORMATION MANUAL

FOR PHOTOREFRACTIVE KERATECTOMY (PRK) OR LASER IN-SITU KERATOMILEUSIS (LASIK)

PHYSICIAN'S BOOKLET

For Myopia: up to –10.0D (PRK) or less than –9.0D (LASIK)
With or Without Astigmatism: -0.50 to –4D (PRK) or –0.50 to less than –3.0D (LASIK)

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 eye care practitioner. U.S. Federal Law restricts the use of 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 LADARVision® Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the LADARVision® Excimer Laser System *Operation 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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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.

WARNINGS:

WARNING! 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 eye care practitioner. U.S. Federal Law restricts the use of 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. **SPECIFIC TRAINING FROM SUMMIT AUTONOMOUS IS REQUIRED BEFORE ANYONE IS QUALIFIED TO OPERATE THE LADARVision® SYSTEM. READ AND UNDERSTAND THIS MANUAL AND THE OPERATION MANUAL PRIOR TO OPERATING THE SYSTEM.**

WARNING! Any adjustments to controls or calibration other than those specified herein may result in hazardous visible and/or invisible radiation exposure

WARNING! Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

WARNING! All patients must be given the opportunity to read and understand the Patient Information Booklet, and to have all their questions answered to their satisfaction before giving consent for Photorefractive Keratectomy (PRK) or Laser In-Situ Keratomileusis (LASIK) surgery.

WARNING! The system contains a pressurized bottle containing a low concentration of fluorine in argon and neon. Fluorine is a hazardous substance. Please refer to SYSTEM OPERATION MANUAL for additional information.

Summit Autonomous recommends that anyone working with the gas cylinders: (1) be trained in the proper handling of toxic and compressed gases, (2) know the location of the emergency exhaust fan/room purifier switch, and (3) be familiar with safety procedures provided by the site's safety officer. Gas discharge into the atmosphere may be evidenced by a sharp, penetrating odor and eye, nose, and throat irritations.

WARNING! SKIN AND EYE EXPOSURE: The LADARVision® Excimer Laser System contains a Class IV laser. Laser radiation exposure may occur at 193 nm up to 15 mJ in 10 nsec pulses at 150 Hz if the safety interlock switches (located on the service access panels) are defeated or if the excimer laser enclosure lid is lifted. This radiation is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. Hazardous invisible laser radiation is present in the area between the output window at the bottom of the optics module and the headrest whenever the excimer laser is operating. Do not place any objects in this area, as exposure to reflected hazardous radiation may result. Use caution during system setup and calibration procedures and during the therapeutic treatment of patients.

All healthcare personnel should avoid direct exposure to the skin or eye by the beam. All personnel in the laser room, except the patient and the surgeon (who is protected by the surgeon's microscope when he or she is looking through the microscope eyepieces), should wear safety glasses whenever the laser system is powered for operation, maintenance, or service. Safety eyewear with an optical density of 8 at 193 nm is recommended.

WARNING! Preliminary system setup and calibration procedures must be completed with satisfactory results prior to any surgery. If this cannot be accomplished, notify Summit Autonomous by telephone 1-877-LADARVISION (1-877-523-2784).

NOTES:

NOTE: THE FOOT SWITCH MUST BE DEPRESSED TO ALLOW THE LASER TO FIRE. THE LASER WILL BE DISABLED WHEN THE FOOT SWITCH IS RELEASED.

NOTE: No eating, drinking, or smoking permitted in the laser room at any time.

2. DEVICE DESCRIPTION

The LADARVision excimer laser beam is small in diameter and corneal sculpting is achieved by delivering hundreds to thousands of excimer laser pulses to the eye in a complex pattern of spatially overlapping spots. Precise shaping of the cornea depends on accurate placement of the laser pulses. The LADARVision system incorporates an infrared eye-tracking system (LADARTracking) to compensate for patient eye motion, including saccadic movements, during procedures, so that each excimer laser pulse is delivered to the appropriate location on the cornea.

- The ultraviolet laser used in the LADARVision system is an argon fluoride excimer laser. This laser produces 10 nanosecond pulses of ultraviolet radiation at a wavelength of 193 nanometers. The laser repetition rate is approximately 55 pulses per second. The characteristics of the laser beam at the corneal treatment plane are shown below.

Treatment Plane Characteristics of the LADARVision Excimer Laser Beam

Pulse energy (mJ)	2.4 - 3.0
Beam diameter (mm) [a]	0.80 - 0.90
Average fluence (mJ/cm^2) [b]	180-240

Note (a): The beam diameter is defined as the full width of the beam at the 1/e points in the Gaussian fluence distribution.

Note (b): This is the average value per pulse of the laser fluence over the ablated area.

- Optical transmission system
- Energy monitoring/control
- Gas handling
- Eye tracking system
- Operating microscope
- Fixation target
- System Software
- Laser shot patterns

The LADARVision® system utilizes an active eye tracking system (LADARTracking) to counter eye motion during refractive laser surgery. The word "active" here is used to denote two important characteristics of the device. First, the LADARTracker actively queries the position of the eye by irradiating it with pulses of 905 nm infrared energy and analyzing characteristics of the returning laser radiation. This measurement occurs 4000

times each second in order to detect even rapid eye motion before significant movement of the cornea has occurred.

The LADARTracker is also "active" in the sense that it actively compensates for the detected motion, rather than simply disabling the treatment laser when the eye position exceeds some tolerated error range. The LADARTracking system includes two mirrors that are continually repositioned to keep the eye centered in the field of view of the treatment laser. An independent set of mirrors is used to translate the treatment beam around within this field of view, delivering the ablation pulses to the cornea in a predetermined spatial pattern. The combined system allows for each ablation pulse in the complex pattern to be delivered to the appropriate corneal site, even in the presence of substantial eye movement.

The LADARTracker is instrumented so that precise mirror movements during the course of each surgery are recorded. Because the geometry involved is known, exact eye movements can be calculated from the compensatory movements of the mirrors. It is not possible to perform surgery using the LADARVision® system without the LADARTracker engaged, and no patient has ever been treated without concurrent tracking.

Note: Additional details regarding operation of this laser can be found in the LADARVision System Operation Manual.

3. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE EVENTS AND COMPLICATIONS

A. INDICATIONS FOR USE

The LADARVision System is indicated for use:

- In Photo-Refractive Keratectomy (PRK) treatments for the reduction or elimination of mild to moderate myopia (near-sightedness) of between -1.00 and -10.00D of sphere and less than or equal to -4.00D of astigmatism at the spectacle plane, the combination of which must result in an attempted correction between -0.50 and -10.00D spherical equivalent (SE) at the spectacle plane where sphere or cylinder is at least 1.00D.

- In Laser In-Situ Keratomileusis (LASIK) treatments for the reduction or elimination of myopia (nearsightedness) of less than –9.00D sphere and –0.50 to less than –3.00D of astigmatism at the spectacle plane.

- In subjects with documented stability of refraction for the prior 12 months, as demonstrated by a change of less than or equal to 0.50D for corrections up to -7.00D, and less than or equal to -1.00D for corrections greater than -7.00D SE.

- In subjects who are 21 years of age or older.

NOTE: Refer to the preceding General Warnings section of this *Physician's Booklet*, in addition to the warnings and precautions found in this section.

B. CONTRAINDICATIONS

PRK and LASIK are contraindicated:

- In pregnant or nursing women

- In patients with signs of keratoconus

- In patients who are taking one or both of the following medications: isotretinoin (Accutane); amiodarone hydrochloride (Cordarone)

- In patients who have an autoimmune disease, collagen vascular disease, or an immunodeficiency disease

C. WARNINGS

PRK and LASIK are not recommended in patients who:

- have insulin dependent diabetes
- have severe allergies
- have a history of herpes simplex or herpes zoster keratitis

A minimum pre-operative pupillary dilation of 7mm and a maximum dilation of 11mm must be achieved and maintained in all patients throughout the refractive procedure to optimize tracker performance.

D. PRECAUTIONS

The safety and effectiveness of the LADARVision® system have **NOT** been established:

- In patients with progressive myopia, ocular disease, corneal abnormality, previous corneal or intraocular surgery, or trauma in the ablation zone.
- In patients in whom the residual corneal thickness at the completion of ablation was less than 250 microns (see the section on Surgical Procedure).
- In patients with a history of glaucoma
- In patients with a history of keloid formation (PRK only)
- In patients who are taking the medication Sumatripin (Imitrex®)
- In patients under 21 years of age
- For the treatment of astigmatism less than 0.50 Diopters
- In patients over the long term (more than 12 months for PRK; 6 months for LASIK)
- For PRK refractive treatments greater than -10.0D of myopia combined with greater than –4.0D of astigmatism.
- For LASIK refractive treatments greater than or equal to –9.0D of myopia combined with greater than or equal to –3D of astigmatism.

Please be advised that eyes with prior intraocular or corneal surgery of any kind were excluded from clinical trials with the LADARVision system. Safety and effectiveness, as well as tracking performance, have not been established for such eyes.

Although the tracker system may acquire track in surgically altered eyes prior to ablation, the optics of the eye may change in the context of the ablation to potentially interfere with further tracking and compromise the completion of the ablation. Medical judgement should be exercised in the use of the LADARVision system in pseudophakic patients and others who have had prior intraocular or corneal surgery.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night.

In a contrast sensitivity study designed to assess the effects of LADARVision PRK surgery on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery.

In addition, U.S. clinical studies of the LADARVision® system have shown the following findings for PRK.

- Bandage contact lenses and non-steroidal anti-inflammatory drops used for pain management in the immediate postoperative period following PRK with this device are associated with sterile infiltrates. The rate of sterile infiltrates observed in the PRK study was 1.6%.

- Overcorrections with PRK greater than +1D may be more likely to occur in older patients, at low room humidity and when attempting higher corrections.

E. ADVERSE EVENTS AND COMPLICATIONS

1. PRK

Adverse events and complications reported in the U.S. Clinical studies for the LADARVision® system for PRK are summarized below.

Summary of PRK Adverse Events[1] and Complications[2]

	PRK Eyes (n=678)		
	Low Myopia	**Low Myopia with Astigmatism**	**High Myopia with and without Astigmatism**
Spherical equivalent:	-1 to -5.99D	-1 to -5.99D	-6 to -10D
Astigmatism:	0 to -0.75D	-0.50 to -6D	0 to -6D
Number of eyes:	386	144	148
Corneal Infiltrates (inflammation)[1]	1.3%	2.1%	2.0%
IOP increase above 25 mmHg[1]	0.5%	0.7%	2.7%
Feeling of something in the eye (≥1M)[2]	3.6%	7.6%	4.7%
Double/ghost images[2]	2.1%	5.6%	8.8%
Peripheral epithelial defect (≥1M)[2]	1.6%	1.4%	2.0%
Pain (≥1M)[2]	2.1%	2.1%	2.0%
Other complications[2]	3.9%	1.4%	4.1%

Other findings that occurred at a rate of less than or equal to 0.3% in all eyes treated (n=678) included: corneal ulcer, corneal edema, corneal erosion, scratchiness, epithelial irregularity, subconjunctival hemorrhage, light sensitivity, epithelial dots, iritis, ocular hypertension, retinal vascular accident (unrelated to surgery), superficial punctate keratitis, corneal foreign body, nebula post foreign body removal.

Other findings that occurred at a rate of less than or equal to 1.0% in all eyes treated (n=678) included: corneal abrasion and halos/starbursts.

Other events that did not occur in this study that could occur following PRK include significant corneal haze and significant loss of best corrected visual acuity.

Subjects were asked to rate the following conditions compared to before surgery. The percentage of patients that rated each condition as "significantly worse" at 12 months than preoperative are listed below:

	Low Myopia (n=386)	Low Myopia with Astigmatism (n=144)	High Myopia with and without Astigmatism (n=148)
Difficulty with night driving	2.1%	6.8%	9.4%
Glare	1.0%	1.7%	5.5%
Halos	1.7%	3.4%	7.0%
Feeling of something in eye	0.0%	1.7%	2.3%
Fluctuation of vision	1.7%	0.0%	2.3%
Blurring of vision	0.3%	0.9%	2.3%
Light sensitivity	1.0%	0.0%	0.8%
Headache	0.0%	0.0%	0.0%
Double vision	0.7%	0.0%	1.6%
Pain	0.3%	0.9%	0.0%
Excessive tearing	0.0%	0.0%	0.0%
Burning	0.0%	0.0%	0.0%

2. LASIK

Adverse events, complications, and ocular findings reported in the U.S. Clinical studies for the LADARVision® system for LASIK are summarized below.

The adverse event of miscreated flap occurred at a rate of 0.3% (n=325) on the day of surgery.

The following complications were reported within 1 week (n=313) at a rate of less than 1.0%: corneal folds/striae; epithelium in the interface; misaligned flap; and sterile interface inflammation.

In U.S. clinical studies of the LADARVision® system, the following adverse events and complications related to LASIK surgery have been reported at each visit 1 month or later. These events may result in a loss of vision.

Summary of LASIK Adverse Events and Complications

	1 Month (n=316)		3 Months (n=310)		6 Months (n=260)		9 Months (n=111)	
	n/N	%	n/N	%	n/N	%	n/N	%
Induced astigmatism -flap decentration	1/316	0.3	1/310	0.3	0/260	0.0	0/111	0.0
Feeling of something in the eye	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Double/ghost images	2/316	0.6	1/310	0.3	1/260	0.4	0/111	0.0
Epithelium in the interface	3/316	0.9	3/310	1.0	1/260	0.4	0/111	0.0
Sterile Interface Inflammation	2/316	0.6	2/310	0.6	0/260	0.0	0/111	0.0
Serous Macular Edema	0/316	0.0	0/310	0.0	0/260	0.0	1/111	0.9
Corneal Folds/Striae/Wrinkle	4/316	1.3	2/310	0.6	2/260	0.8	0/111	0.0
Interface debris	10/316	3.2	12/310	3.9	11/260	4.2	0/111	0.0
Interface haze/opacity	7/316	2.2	10/310	3.2	1/260	0.4	1/111	0.9
Superficial punctate keratitis (SPK)	15/316	4.7	8/310	2.6	6/260	2.3	3/111	2.7
Oil droplets/sheen	5/316	1.6	0/310	0.0	2/260	0.8	0/111	0.0
Flap distortion	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Fibrotic healing at flap edge	0/316	0.0	3/310	1.0	2/260	0.8	0/111	0.0
Epithelial defect	0/316	0.0	0/310	0.0	1/260	0.4	0/111	0.0
Conjunctival injection	0/316	0.0	0/310	0.0	2/260	0.8	0/111	0.0

The following adverse events and complications were reported at unscheduled visits at 1 month or later: increase in intraocular pressure >10mmHg above baseline (3 eyes); HSV dendrite (1 eye); corneal folds/striae/wrinkle (2 eyes); interface haze/opacity (3 eyes); superficial punctate keratitis (13 eyes); peau d' orange (2 eyes); flap distortion (1 eye); vacuoles (1 eye); and conjunctival injection (2 eyes).

The following ocular findings were reported at 6 months (n=260) at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters.

Subjects were asked to rate the following conditions compared to before LASIK surgery. The percentage of patients that rated each condition as "significantly worse" at 6 months than preoperative are listed below:

Subjective Responses	Eyes Without Astigmatism		Eyes With Astigmatism	
	n/N	%	n/N	%
Difficulty with night driving	8/140	5.7	15/101	14.9
Glare	4/141	2.8	10/101	9.9
Halos*	5/141	3.5	7/101	6.9
Light sensitivity	4/141	2.8	6/101	5.9
Dryness	6/141	4.3	3/101	3.0
Fluctuation of vision	3/141	2.1	2/101	2.0
Blurring of vision	3/141	2.1	1/101	1.0
Redness	1/141	0.7	2/101	1.0
Headache	1/141	0.7	0/101	0.0
Double vision	1/139	0.7	0/101	0.0
Pain	0/141	0.0	0/101	0.0
Excessive tearing	0/141	0.0	0/100	0.0
Burning	0/141	0.0	0/100	0.0
Feeling of something in eye	0/141	0.0	0/101	0.0

* Halos are circular flares or rings of light that may appear around a headlight or other lighted object.

4. CLINICAL STUDY

A. INTRODUCTION

A prospective, non-randomized, unmasked, multi-center clinical study was conducted to determine the safety and efficacy of LADARVision® to improve uncorrected visual acuity and predictably reduce myopia. Eligibility criteria for patients included: being at least 18 years of age; eyes with up to 10D myopia (PRK), 15D myopia (LASIK) spherical equivalent at the spectacle plane with astigmatism up to 6D; best spectacle corrected visual acuity of 20/40 or better in both eyes, and a stable manifest refraction as documented by a 0.5D change or less within the previous 12 months. Contact lens wearers had to abstain from contact lens use prior to baseline examination for 2 to 3 weeks.

Patients who exhibited any of the following conditions were excluded:

- significant corneal abnormalities
- keratoconus
- active ocular disease
- irregular astigmatism
- herpes keratitis
- use of topical ophthalmic medications
- history of keloid formation (PRK only)
- severe dry eye syndrome unresolved by treatment
- corneal thickness less than 400 microns
- previous corneal or intraocular surgery
- glaucoma
- use of systemic medications likely to affect wound healing
- immunocompromised
- pregnant
- insulin dependent diabetes
- severe atopy
- connective tissue or autoimmune disease

Procedure effectiveness was evaluated based on improvement in visual acuity and reduction in mean spherical equivalent and reduction in astigmatism. The stability of the refractive outcome through the post-operative evaluation period was also assessed.

Results for PRK have been stratified into 3 groups:

(1) **Low myopia** - 386 eyes with a spherical equivalent myopic correction between -1.00D and -5.99D at the spectacle plane and astigmatism of -0.75D or less.

(2) **Low myopia with astigmatism** - 144 eyes with a spherical equivalent myopic correction between -1.00D and -5.99D at the spectacle plane and astigmatism of between -0.50D and -6.00D.

(3) **High myopia** (with and without astigmatism) - 148 eyes with a spherical equivalent myopic correction between -6.00D and -10.00D at the spectacle plane and astigmatism of between 0.00D and -6.00D.

B. *LOW MYOPIA: PRK*

1. Demographics (PRK Low Myopia)

TABLE 1 DEMOGRAPHICS (PRK LOW MYOPIA) 386 Eyes of 321 Enrolled Patients			
		Number	Percentage
Gender:	Female	233	60.4%
	Male	153	39.6%
Race:	Caucasian	360	93.3%
	Asian	9	2.3%
	Black	9	2.3%
	Other	8	2.1%
Age (yrs):	Average ± SD	39.8 ± 9.7	
	Range	19-72	
Contact Lens History:	None	94	24.4%
	Soft	269	69.7%
	RGP	22	5.7%
	PMMA	1	0.3%
	Other	0	0.0%

2. Baseline Parameters (PRK Low Myopia)

TABLE 2 BASELINE PARAMETERS (PRK LOW MYOPIA)		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-3.43 ± 1.33	-1.00 to -5.875
Sphere	-3.28 ± 1.32	-0.75 to -5.75
Cylinder	-0.29 ± 0.28	0.00 to -0.75
Preoperative UCVA	n	%
20/100 or worse	315	81.6
20/50 to 20/80	54	14.0
20/25 to 20/40	17	4.4
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	14	3.6
≤20/20	372	96.4

3. Safety and Efficacy Results (PRK Low Myopia)

Table 3 presents a summary of the safety and efficacy results over time for low myopia. Table 4 shows the same parameters stratified by diopter of spherical equivalent correction. At 12 months, uncorrected visual acuity was better than preoperative best corrected visual acuity in 18.2% of eyes.

TABLE 3
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL EQUIVALENT MYOPIA -1 TO -5.99D
PRK LOW MYOPIA

EFFICACY VARIABLES	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
	n=355	n=346	n=337	n=311	n=318	n=90	n=26
UCVA 20/20 or better*	227 63.9%	250 72.3%	250 74.2%	223 71.7%	229 72.0%	69 76.7%	21 80.8%
UCVA 20/25 or better*	295 83.1%	295 85.3%	297 88.1%	273 87.8%	282 88.7%	80 88.9%	25 96.2%
UCVA 20/40 or better*	343 96.6%	333 96.2%	327 97.0%	304 97.7%	312 98.1%	88 97.8%	26 100%
	n=380	n=370	n=359	n=332	n=339	n=98	n=27
MRSE ±0.50D of intended	259 68.2%	288 78.0%	286 79.9%	265 79.8%	259 76.4%	81 82.7%	23 85.2%
MRSE ±1.00D of intended	340 89.5%	348 94.3%	338 94.4%	316 95.2%	320 94.4%	93 94.9%	26 96.3%
SAFETY VARIABLES	n=380	n=370	n=359	n=332	n=339	n=98	n=27
Loss of >2 Lines BSCVA	4 1.1%	2 0.5%	0 0.0%	2 0.6%	1 0.3%	0 0.0%	0 0.0%
Loss of 2 Lines BSCVA	11 2.9%	11 3.0%	3 0.8%	5 1.5%	6 1.8%	2 2.0%	0 0.0%
BSCVA worse than 20/40	1 0.3%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Increase >2D cylinder	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
	n=366	n=356	n=346	n=319	n=327	n=96	n=27
BSCVA worse than 20/25 if 20/20 or better preoperatively	7 1.9%	4 1.1%	0 0.0%	1 0.3%	1 0.3%	0 0.0%	0 0.0%%

*Not including monovision eyes.

TABLE 4 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES PRK LOW MYOPIA -1 TO -5.99D STRATIFIED BY DIOPTER 12 MONTHS						
Efficacy	1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.0 to 5.99	**Cumulative Total**
	n=57	n=69	n=81	n=60	n=51	**n=318**
UCVA 20/20 or better*	40 70.2%	51 73.9%	66 81.5%	40 66.7%	32 62.7%	**229** **72.0%**
UCVA 20/40 or better*	55 96.5%	69 100%	80 98.8%	59 98.3%	49 96.1%	**312** **98.1%**
	n=57	n=73	n=85	n=67	n=57	**n=339**
MRSE ±0.50D	49 86.0%	59 80.8%	70 82.4%	42 62.7%	39 68.4%	**259** **76.4%**
MRSE ±1.00D	57 100%	71 97.3%	82 96.5%	60 89.6%	50 87.7%	**320** **94.4%**
Safety	n=57	n=73	n=85	n=67	n=57	n=339
Loss of >2 Lines BSCVA	1 1.8%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**1** **0.3%**
Loss of 2 Lines BSCVA	2 3.5%	2 2.7%	0 0.0%	0 0.0%	2 3.5%	**6** **1.8%**
BSCVA worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0** **0.0%**
Increase >2D cyl	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0** **0.0%**
BSCVA 20/20 or better Preop	n=57	n=66	n=84	n=67	n=53	**n=327**
BSCVA worse than 20/25 if 20/20 or better preop	1 1.8%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**1** **0.3%**

*Not including monovision eyes.

Stability of refractive outcome is defined as the proportion of eyes with ≤1.00D change in spherical equivalent between 2 refractions taken 3 months apart. Table 5 shows that >95% of the spherical cohort achieves stability between 3 and 6 months.

TABLE 5 STABILITY OF MANIFEST REFRACTION PRK LOW MYOPIA: 12 MONTH COHORT				
Change in Spherical Equivalent Between	1 and 3 Months (n=296)	3 and 6 Months (n=296)	6 and 9 Months (n=296)	9 and 12 Months (n=296)
≤1.00	278 93.9%	290 98.0%	293 99.0%	295 99.7%

4. Patient Satisfaction (PRK Low Myopia)

Responses to the patient satisfaction questionnaire at 12 months indicated that in the low myopia cohort, the quality of vision was improved in 98.3% of eyes and 93.4% were satisfied or extremely satisfied with the results. There was no need for distance correction in 89.2% of eyes.

5. Retreatments (PRK Low Myopia)

Patients were eligible for re-treatment after 3 months of follow-up. Eleven eyes (2.8%) were re-treated with the laser. Results of the re-treated eyes at their last follow-up visit are shown in Table 6.

TABLE 6
SUMMARY OF RETREATMENTS
AT LAST REPORTED VISIT: PRK LOW MYOPIA

EFFICACY VARIABLES	Last Reported Visit
	n=11
UCVA 20/20 or better	4 36.4%
UCVA 20/25 or better	8 72.7%
UCVA 20/40 or better	11 100%
	n=11
MRSE ±0.50D of intended	8 72.7%
MRSE ±1.00D of intended	10 90.9%
SAFETY VARIABLES	n=11
Loss of >2 Lines BSCVA from preop before any treatment	0 0.0%
Loss of 2 Lines BSCVA from preop before any treatment	1 0.9%
BSCVA worse than 20/40	0 0.0%

C. *LOW MYOPIA WITH ASTIGMATISM: PRK*

1. Demographics (PRK Low Myopia with Astigmatism)

TABLE 7 DEMOGRAPHICS (PRK LOW MYOPIA WITH ASTIGMATISM)			
144 Eyes of 129 Patients Enrolled			
		Number	Percentage
Gender:	Female	85	59.0%
	Male	59	41.0%
Race:	Caucasian	136	94.4%
	Asian	4	2.8%
	Black	4	2.8%
Age (yrs):	Average ± SD	42 ± 8.8	
	Range	22-64	
Contact Lens History:	None	38	26.4%
	Soft	85	59.0%
	RGP	17	11.8%
	PMMA	2	1.4%
	Other	2	1.4%

2. Baseline Parameters (PRK Myopia with Astigmatism)

TABLE 8 BASELINE PARAMETERS (PRK LOW MYOPIA WITH ASTIGMATISM)		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-3.88 ± 1.23	-1.00 to -5.875
Sphere	-3.19 ± 1.26	0.0 to -5.50
Cylinder	-1.38 ± 0.74	-0.50 to -5.50
Preoperative UCVA	n	%
20/100 or worse	129	89.6
20/50 to 20/80	10	6.9
20/25 to 20/40	5	3.5
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	7	4.9
≤20/20	137	95.1

3. Safety and Efficacy Results (PRK Low Myopia with Astigmatism)

Table 9 presents a summary of the safety and efficacy results over time for myopia with astigmatism. Table 10 shows the same parameters stratified by diopter of spherical equivalent correction. At 12 months, uncorrected visual acuity was better than preoperative best corrected visual acuity in 11.3% of eyes.

TABLE 9
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL EQUIVALENT MYOPIA -1 TO -5.99D
PRK LOW MYOPIA WITH ASTIGMATISM

EFFICACY VARIABLES	1 Month	3 Months	6 Months	9 Months	12 Months
	n=139	n=139	n=131	n=123	n=116
UCVA 20/20 or better*	76 54.7%	82 59.0%	85 64.9%	85 69.1%	71 61.7%
UCVA 20/25 or better*	107 77.0%	112 80.6%	110 84.0%	101 82.1%	95 82.6%
UCVA 20/40 or better*	132 95.0%	129 92.8%	124 94.7%	122 99.2%	112 97.4%
	n=143	n=142	n=135	n=126	n=119
MRSE ±0.50D of intended	89 62.2%	109 76.8%	105 77.8%	101 80.2%	88 73.9%
MRSE ±1.00D of intended	128 89.5%	132 93.0%	125 92.6%	119 94.4%	113 95.0%
SAFETY VARIABLES	n=143	n=142	n=135	n=126	n=119
Loss of >2 Lines BSCVA	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Loss of 2 Lines BSCVA	5 3.5%	3 2.1%	1 0.7%	1 0.8%	3 2.5%
BSCVA worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Increase >2D cylinder	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
	n=136	n=135	n=130	n=121	n=115
BSCVA worse than 20/25 if 20/20 or better preoperatively	1 0.7%	1 0.7%	0 0.0%	1 0.8%	1 0.9%

*Not including monovision eyes.

TABLE 10 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES SPHERICAL EQUIVALENT MYOPIA -1 TO -5.99D STRATIFIED BY DIOPTER PRK LOW MYOPIA WITH ASTIGMATISM: 12 MONTHS						
Efficacy	1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.0 to 5.99	**Cumulative Total**
	n=10	n=14	n=33	n=36	n=22	**n=115****
UCVA 20/20 or better*	6 60.0%	12 85.7%	20 60.6%	20 55.6%	13 59.1%	**71 61.7%**
UCVA 20/40 or better*	10 100%	14 100%	31 93.9%	35 97.2%	22 100%	**112 97.4%**
	n=10	n=14	n=33	n=37	n=25	**n=119**
MRSE ±0.50D	10 100%	13 92.9%	22 66.7%	27 73.0%	16 64.0%	**88 73.9%**
MRSE ±1.00D	10 100%	14 100%	32 97.0%	36 97.3%	21 84.0%	**113 95.0%**
Safety	n=10	n=14	n=33	n=37	n=25	**n=119**
Loss of >2 Lines BSCVA	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0 0.0%**
Loss of 2 Lines BSCVA	0 0.0%	0 0.0%	0 0.0%	1 2.7%	2 8.0%	**3 2.5%**
BSCVA worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0 0.0%**
Increase >2D cyl	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0 0.0%**
BSCVA 20/20 or better preop	n=9	n=13	n=33	n=36	n=24	**n=115**
BSCVA worse than 20/25 if 20/20 or better preop	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 4.2%	**1 0.9%**

*Not including monovision eyes.
**One eye missing UCVA at 12 months; 116 eyes followed.

Stability of refractive outcome is defined as the proportion of eyes with ≤1.00D change in spherical equivalent between 2 refractions taken 3 months apart. Table 11 shows that >95% of the astigmatic cohort achieved stability between 3 and 6 months.

TABLE 11 STABILITY OF MANIFEST REFRACTION PRK LOW MYOPIA WITH ASTIGMATISM: 12 MONTH COHORT				
Change in Spherical Equivalent Between	1 and 3 Months (n=115)	3 and 6 Months (n=115)	6 and 9 Months (n=115)	9 and 12 Months (n=115)
≤1.00	109 94.8%	114 99.1%	112 97.4%	111 96.5%

4. Patient Satisfaction (PRK Low Myopia with Astigmatism)

In the low myopia with astigmatism group, the patient questionnaire at 12 months indicated that the quality of vision was improved in 94.0% of eyes and 88.0% were satisfied or extremely satisfied with the results. Distance correction was not required in 89.7% of eyes postoperatively.

5. Retreatments (PRK Low Myopia with Astigmatism)

Patients were eligible for re-treatment after 3 months of follow-up. In the astigmatic cohort 13 eyes (9.0%) were re-treated with the laser. Results of the retreated eyes at their last follow-up visit are shown in Table 12.

TABLE 12
SUMMARY OF RETREATMENTS AT LAST REPORTED VISIT
PRK LOW MYOPIA WITH ASTIGMATISM

EFFICACY VARIABLES	Last Reported Visit
	n=13
UCVA 20/20 or better	8 61.5%
UCVA 20/25 or better	11 84.6%
UCVA 20/40 or better	12 92.3%
	n=13
MRSE ±0.50D of intended	12 92.3%
MRSE ±1.00D of intended	13 100%
SAFETY VARIABLES	n=13
Loss of >2 Lines BSCVA from preop before any treatment	0 0.0%
Loss of 2 Lines BSCVA from preop before any treatment	1* 0.8%
BSCVA worse than 20/40	1* 0.8%

*Poor manifest refraction at last visit; cycloplegic BSCVA was 20/32 (same as preop BSCVA).

D. HIGH MYOPIA: PRK

1. Demographics (PRK High Myopia)

TABLE 13 DEMOGRAPHICS (PRK HIGH MYOPIA)			
148 Eyes of 139 Patients Enrolled			
		Number	Percentage
Gender:	Female	91	61.5%
	Male	57	38.5%
Race:	Caucasian	128	86.5%
	Asian	13	8.8%
	Black	5	3.4%
	Other	2	1.4%
Age (yrs):	Average ± SD	41.1 ± 9.1	
	Range	20-64	
Contact Lens History:	None	30	20.3%
	Soft	91	61.5%
	RGP	25	16.9%
	PMMA	1	0.7%
	Other	1	0.7%

2. Baseline Parameters (PRK High Myopia)

TABLE 14 BASELINE PARAMETERS (PRK HIGH MYOPIA)		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-7.22 ± 0.99	-6.00 to -10.00
Sphere	-6.79 ± 1.01	-4.00 to -9.50
Cylinder	-0.85 ± 0.78	0.00 to -5.00
Preoperative UCVA	n	%
20/100 or worse	148	100
20/50 to 20/80	0	0.0
20/25 to 20/40	0	0.0
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	24	16.2
≤20/20	124	83.8

3. Safety and Efficacy Results (PRK High Myopia)

Table 15 presents a summary of the safety and efficacy results over time for high myopia (with and without astigmatism). Table 16 shows the same parameters stratified by diopter of spherical equivalent correction. At 12 months, uncorrected visual acuity was better than preoperative best corrected visual acuity in 15.7% of eyes.

TABLE 15
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL EQUIVALENT MYOPIA -6.00 TO -10.00D
PRK HIGH MYOPIA

EFFICACY VARIABLES	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months
	n=134	n=134	n=133	n=125	n=121	n=9
UCVA 20/20 or better*	45 33.6%	70 52.2%	62 46.6%	59 47.2%	74 61.2%	7 77.8%
UCVA 20/25 or better*	77 57.5%	96 71.6%	89 66.9%	86 68.8%	93 76.9%	9 100%
UCVA 20/40 or better*	119 88.8%	126 94.0%	117 88.0%	116 92.8%	113 93.4%	9 100%
	n=147	n=147	n=146	n=135	n=131	n=11
MRSE ±0.50D of intended	61 41.5%	88 59.9%	91 62.3%	85 63.0%	88 67.2%	10 90.9%
MRSE ±1.00D of intended	100 68.0%	119 81.0%	123 84.2%	113 83.7%	115 87.8%	11 100%
SAFETY VARIABLES	n=147	n=147	n=146	n=135	n=131	n=11
Loss of >2 Lines BSCVA	2 1.4%	3 2.0%	3 2.1%	2 1.5%	0 0.0%	0 0.0%
Loss of 2 Lines BSCVA	3 2.0%	5 3.4%	4 2.7%	2 1.5%	3 2.3%	0 0.0%
BSCVA worse than 20/40	1 0.7%	0 0.0%	1 0.7%	0 0.0%	0 0.0%	0 0.0%
Increase >2D cylinder	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1** 0.8%	0 0.0%
	n=123	n=123	n=122	n=115	n=113	n=11
BSCVA worse than 20/25 if 20/20 or better preoperatively	3 2.4%	7 5.7%	3 2.4%	3 2.6%	1 0.9%	0 0.0%

*Not including monovision eyes.
**Patient under significant emotional stress at this visit and cylinder changed from 0.00D at 9 months to -3.00D at 12 months and then back to -0.50D at the next visit.

TABLE 16 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES SPHERICAL EQUIVALENT MYOPIA -6.00 TO -10.00D STRATIFIED BY DIOPTER PRK HIGH MYOPIA: 12 MONTHS					
Efficacy	6.0 to 6.99	7.0 to 7.99	8.0 to 8.99	9.0 to 10.0	**Cum Total**
	n=54	**n=41**	**n=16**	**n=10**	**n=121**
UCVA 20/20 or better*	35 64.8%	24 58.5%	10 62.5%	5 50.0%	**74** **61.2%**
UCVA 20/40 or better*	51 94.4%	39 95.1%	14 87.5%	9 90.0%	**113** **93.4%**
	n=60	**n=44**	**n=17**	**n=10**	**n=131**
MRSE ±0.50D	43 71.7%	28 63.6%	11 64.7%	6 60.0%	**88** **67.2%**
MRSE ±1.00D	57 95.0%	37 84.1%	13 76.5%	8 80.0%	**115** **87.8%**
Safety	**n=60**	**n=44**	**n=17**	**n=10**	**n=131**
Loss of >2 Lines BSCVA	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0** **0.0%**
Loss of 2 Lines BSCVA	2 3.3%	1 2.3%	0 0.0%	0 0.0%	**3** **2.3%**
BSCVA worse than 20/40	0 0.0%	0 0.0%	0 0.0%	0 0.0%	**0** **0.0%**
Increase >2D cyl	1** 1.7%	0 0.0%	0 0.0%	0 0.0%	**1** **0.8%**
BSCVA 20/20 or better preop	**n=52**	**n=38**	**n=16**	**n=7**	**n=113**
BSCVA worse than 20/25 if 20/20 or better preop	1 1.9%	0 0.0%	0 0.0%	0 0.0%	**1** **0.9%**

*Not including monovision eyes.
**Patient under significant emotional stress at this visit and cylinder changed from 0.00D at 9 months to -3.00D at 12 months and then back to -0.50D at the next visit.

Stability of refractive outcome is defined as the proportion of eyes with ≤1.00D change in spherical equivalent between 2 refractions taken 3 months apart. Table 17 shows that >95% of the high myopia cohort achieved stability between 6 and 9 months.

TABLE 17 STABILITY OF MANIFEST REFRACTION PRK HIGH MYOPIA: 12 MONTH COHORT				
Change in Spherical Equivalent Between	1 and 3 Months (n=126)	3 and 6 Months (n=126)	6 and 9 Months (n=126)	9 and 12 Months (n=126)
≤1.00	95 75.4%	115 91.3%	121 96.0%	123 97.6%

4. Patient Satisfaction (PRK High Myopia)

In the high myopia group, the patient questionnaire at 12 months indicated that the quality of vision was improved in 96.9% of eyes and 91.4% were satisfied or extremely satisfied with the results. Distance correction was not required in 87.5% of eyes postoperatively.

5. Retreatments (PRK High Myopia)

Patients were eligible for re-treatment after 3 months of follow-up. In the high myopia cohort 11 eyes (8.1%) were re-treated with the laser. Results of the re-treated eyes at their last follow-up visit are shown in Table 18.

TABLE 18
SUMMARY OF RETREATMENTS
AT LAST REPORTED VISIT: HIGH MYOPIA

EFFICACY VARIABLES	Last Reported Visit
	n=11
UCVA 20/20 or better*	0 0.0%
UCVA 20/25 or better	1 0.9%
UCVA 20/40 or better	9 81.8%
	n=11
MRSE ±0.50D of intended	7 63.6%
MRSE ±1.00D of intended	9 81.8%
SAFETY VARIABLES	n=11
Loss of >2 Lines BSCVA from preop BSCVA before any treatment	0 0.0%
Loss of 2 Lines BSCVA from preop BSCVA before any treatment	0 0.0%
BSCVA worse than 20/40	0 0.0%

*Four eyes (36%) had a preop BSCVA of 20/25 before any treatment.

E. ASTIGMATIC CORRECTION: PRK

Astigmatism correction was assessed based on the magnitude of cylinder and vector analysis (Table 19). At 6 months, 81.3% of eyes had ≤0.50D and 94.7% of eyes had ≤1.00D of residual cylinder.

TABLE 19
SUMMARY OF PRK CYLINDER CORRECTION
12 MONTHS

Absolute Magnitude		Vector Analysis	
Preoperative	1.47 ± 0.76	Intended Vector	1.47 ± 0.76
Postoperative	0.36 ± 0.46	Difference Vector	0.36 ± 0.46
Achieved Magnitude	1.14 ± 0.74	Achieved Vector	1.40 ± 0.75
% Achieved	76 ± 30	% Achieved	96 ± 27
Axis Shift*	29.6 ± 23.4	Angle of Error	6.4 ± 13.5

*Eyes with residual cylinder >0.

F. SPHERICAL MYOPIA: LASIK

1. Demographics (LASIK Spherical Myopia)

TABLE 20 DEMOGRAPHICS (LASIK SPHERICAL MYOPIA) 173 Eyes of 90 Enrolled Patients			
		Number	Percentage
Gender:	Female	84	48.6
	Male	89	51.4
Race:	Caucasian	168	97.1
	Hispanic	2	1.2
	Black	2	1.2
	Asian	1	0.6
Age (yrs):	Average ± SD	42.6 ± 9.5	
	Range	21 to 65	
Contact Lens History:	None	34	19.7
	Soft	132	76.3
	RGP	7	4.0
	PMMA	0	0.0

2. Baseline Parameters (LASIK Spherical Myopia)

TABLE 21 BASELINE PARAMETERS (LASIK SPHERICAL MYOPIA)		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-4.16 ± 1.90	-1.125 to –9.00
Sphere	-4.01 ±1.90	-0.75 to –8.75
Cylinder	-0.30 ± 0.27	0.00 to –0.75
Preoperative UCVA*	n	%
20/100 or worse	151	93.2
20/50 to 20/80	11	6.8
20/25 to 20/40	0	0.0
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	5	2.9
≤20/20	168	97.1

* not including monovision

3. Safety and Efficacy Results (LASIK Spherical Myopia)

TABLE 22
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL MYOPIA UP TO –8.99D SPHERE

Efficacy Variables		1 Month	3 Months	6 Months	9 Months
BSCVA ≥ 20/20 Preop*					
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	89/151	100/149	88/140	42/64
	%	58.9%	67.1%	62.9%	65.6%
	CI	(50.7, 66.9)	(59.0, 74.6)	(54.3, 70.9)	(52.7, 77.1)
UCVA 20/20 or better*	n	89/156	100/154	89/145	43/67
	%	57.1%	64.9%	61.4%	64.2%
	CI	(48.9, 64.9)	(56.8, 72.4)	(52.9, 69.3)	(51.5, 75.6)
UCVA 20/25 or better*	n	125/156	124/154	118/145	57/67
	%	80.1%	80.5%	81.4%	85.1%
	CI	(73.0, 86.1)	(73.4, 86.5)	(74.1, 87.4)	(74.3, 92.6)
UCVA 20/40 or better*	n	148/156	145/154	136/145	66/67
	%	94.9%	94.2%	93.8%	98.5%
	CI	(90.2, 97.8)	(89.2, 97.3)	(88.5, 97.1)	(92.0, 100)
MRSE ±0.50D of intended	n	135/163	133/163	116/155	59/70
	%	82.8%	81.6%	74.8%	84.3%
	CI	(76.1, 88.3)	(74.8, 87.2)	(67.3, 81.5)	(73.6, 91.9)
MRSE ±1.00D of intended	n	161/163	152/163	147/155	68/70
	%	98.8%	93.3%	94.8%	97.1%
	CI	(95.6, 99.9)	(88.3, 96.6)	(90.1, 97.8)	(90.1, 99.7)
MRSE ±2.00D of intended	n	163/163	163/163	155/155	70/70
	%	100.0%	100.0%	100.0%	100.0%
	CI	(97.8, 100)	(97.8, 100)	(97.7, 100)	(94.9, 100)
Safety Variables					
Loss of >2 Lines BSCVA	n	0/163	0/163	0/155	0/70
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.2)	(0.0, 2.2)	(0.0, 2.4)	(0.0, 5.1)
Loss of 2 Lines BSCVA	n	3/163	1/163	1/155	0/70
	%	1.8%	0.6%	0.6%	0.0%
	CI	(0.4, 5.3)	(0.0, 3.4)	(0.0, 3.5)	(0.0, 5.1)
BSCVA worse than 20/40	n	0/163	0/163	0/155	0/70
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.2)	(0.0, 2.2)	(0.0, 2.4)	(0.0, 5.1)
Increase >2D cylinder	n	0/163	0/163	0/155	0/70
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.2)	(0.0, 2.2)	(0.0, 2.4)	(0.0, 5.1)
BSCVA ≥ 20/20 Preop					
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	2/158	0/158	1/150	0/67
	%	1.2%	0.0%	0.7%	0.0%
	CI	(0.2, 4.5)	(0.0, 2.3)	(0.0, 3.7)	(0.0, 5.4)

*Not including monovision eyes CI = 95% Confidence Interval

TABLE 23
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES FOR SPHERICAL MYOPIA UP TO –8.99D SPHERE STRATIFIED BY DIOPTERS OF SPHERICAL EQUIVALENT: 6 MONTHS

Efficacy		-1.0 to -1.99	-2.0 to -2.99	-3.0 to -3.99	-4.0 to -4.99	-5.0 to -5.99	-6.0 to -6.99	Total <7D	-7.0 to -7.99	-8.0 to -9.0	Total ≥7D	Cum Total
BSCVA ≥ 20/20 Preop*												
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	7/12	25/34	16/27	17/28	8/14	3/8	**76/123**	5/9	7/8	**12/17**	88/140
	%	58.3%	73.5%	59.3%	60.7%	57.1%	37.5%	**61.8%**	55.6%	87.5%	**70.6%**	62.9%
UCVA 20/20 or better*	n	7/12	25/34	17/29	17/28	8/15	3/10	**77/128**	5/9	7/8	**12/17**	89/145
	%	58.3%	73.5%	58.6%	60.7%	53.3%	30.0%	**60.2%**	55.6%	87.5%	**70.6%**	61.4%
UCVA 20/25 or better*	n	10/12	32/34	22/29	22/28	10/15	6/10	**102/128**	8/9	8/8	**16/17**	118/145
	%	83.3%	94.1%	75.9%	78.6%	66.7%	60.0%	**79.7%**	88.9%	100.0%	**94.1%**	81.4%
UCVA 20/40 or better*	n	12/12	33/34	27/29	25/28	14/15	9/10	**120/128**	8/9	8/8	**16/17**	136/145
	%	100.0%	97.1%	93.1%	89.3%	93.3%	90.0%	**93.8%**	88.9%	100.0%	**94.1%**	93.8%
MRSE ±0.50D of intended	n	10/12	28/35	26/33	21/29	10/16	5/10	**100/135**	7/10	9/10	**16/20**	116/155
	%	83.3%	80.0%	78.8%	72.4%	62.5%	50.0%	**74.1%**	70.0%	90.0%	**80.0%**	74.8%
MRSE ±1.00D of intended	n	12/12	35/35	32/33	25/29	16/16	9/10	**129/135**	9/10	9/10	**18/20**	147/155
	%	100.0%	100.0%	97.0%	86.2%	100.0%	90.0%	**95.6%**	90.0%	90.0%	**90.0%**	94.8%
MRSE ±2.00D of intended	n	12/12	35/35	33/33	29/29	16/16	10/10	**135/135**	10/10	10/10	**20/20**	155/155
	%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	**100.0%**	100.0%	100.0%	**100.0%**	100.0%
Safety												
Loss of >2 Lines BSCVA	n	0/12	0/35	0/33	0/29	0/16	0/10	**0/135**	0/10	0/10	**0/20**	0/155
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%	0.0%	**0.0%**	0.0%
Loss of 2 Lines BSCVA	n	1/12	0/35	0/33	0/29	0/16	0/10	**1/135**	0/10	0/10	**0/20**	1/155
	%	8.3%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.7%**	0.0%	0.0%	**0.0%**	0.6%
BSCVA worse than 20/40	n	0/12	0/35	0/33	0/29	0/16	0/10	**0/135**	0/10	0/10	**0/20**	0/155
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%	0.0%	**0.0%**	0.0%
Increase >2D Cylinder	n	0/12	0/35	0/33	0/29	0/16	0/10	**0/135**	0/10	0/10	**0/20**	0/155
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%	0.0%	**0.0%**	0.0%
BSCVA ≥ 20/20 Preop												
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	1/12	0/35	0/31	0/29	0/15	0/8	**1/130**	0/10	0/10	**0/20**	1/150
	%	8.3%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.8%**	0.0%	0.0%	**0.0%**	0.7%

*Not including monovision eyes

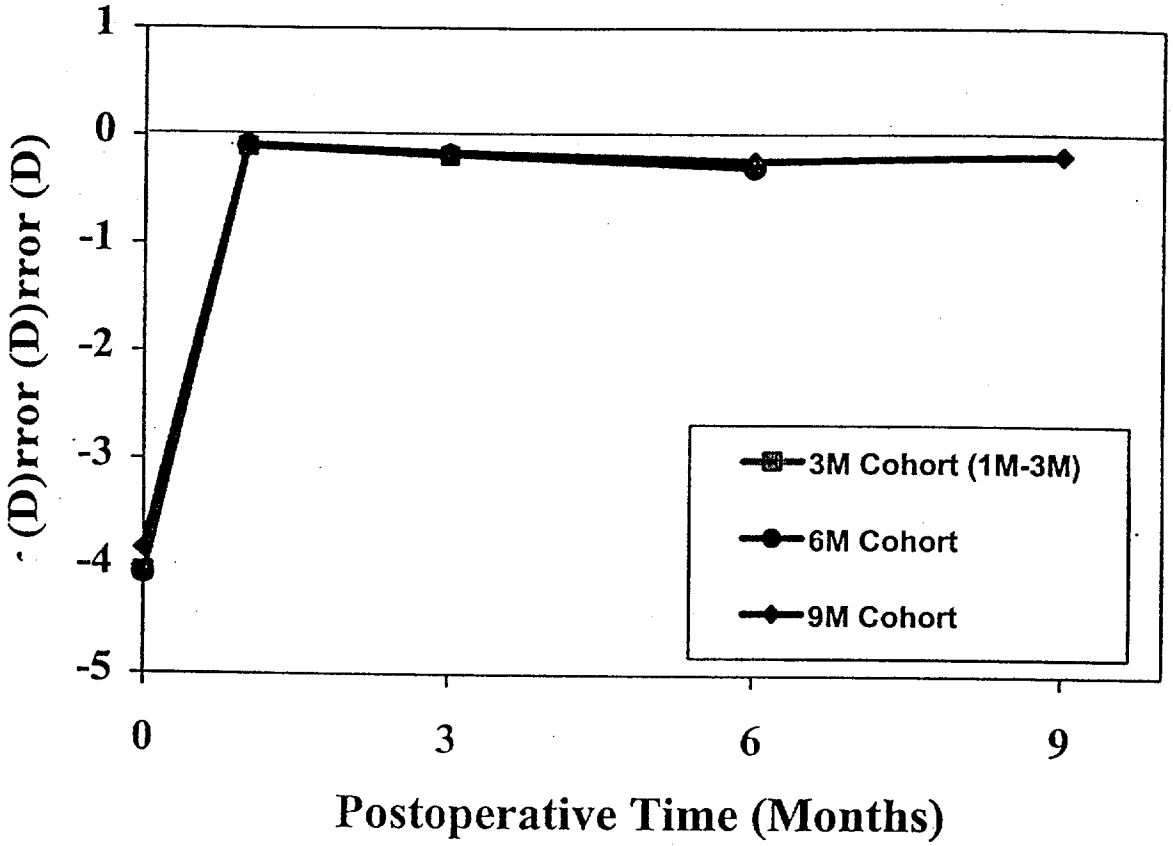

Figure 1. Manifest Refraction Spherical Equivalent vs. Time

MEAN ± SD MANIFEST REFRACTION SPHERICAL EQUIVALENT OVER TIME*						
Mean ± SD	**n**	**Preop**	**1 Month**	**3 Months**	**6 Months**	**9 Months**
3M Cohort (1M-3M)	145	-4.04 ± 1.84	-0.11 ± 0.39	-0.19 ± 0.44	--	--
6M Cohort	134	-4.06 ± 1.87	-0.10 ± 0.38	-0.18 ± 0.43	-0.29 ± 0.45	--
9M Cohort	64	-3.83 ± 1.71	-0.09 ± 0.40	-0.16 ± 0.38	-0.23 ± 0.43	-0.18 ± 0.42
Entire Cohort (All Available Eyes)	--	-4.11 ± 1.88	-0.11 ± 0.41	-0.20 ± 0.44	-0.28 ± 0.45	-0.16 ± 0.42

*Not including monovision

3 Month Cohort: includes all eyes with data at both 1 and 3 month intervals
6 Month Cohort: includes all eyes with data at every interval through 6 months(1, 3, and 6 months)
9 Month Cohort: includes all eyes with data at every interval through 9 months (1, 3, 6, and 9 months)
Entire Cohort: includes eyes in the cohort with data at any interval, but not necessarily at every interval

4. Patient Satisfaction (LASIK Spherical Myopia)

At 6 months, quality of vision was rated significantly better or better than preoperative in 66.0% of eyes and 83.5% of patients were extremely satisfied or satisfied with their results. Postoperatively, distance correction was never used by 94.5% of patients and near correction was not used by 70.0%.

5. Retreatments (LASIK Spherical Myopia)

Eighteen eyes (10.4%) were retreated for undercorrection. Postoperative data was available on 16 eyes. All eyes (100%) are within 0.50D of target and all eyes (100%) have UCVA of 20/32 or better.

G. MYOPIA WITH ASTIGMATISM: LASIK

1. Demographics (LASIK Myopia with Astigmatism)

TABLE 24 DEMOGRAPHICS (LASIK MYOPIA WITH ASTIGMATISM)			
152 Eyes of 84 Patients Enrolled			
		Number	Percentage
Gender:	Female	86	56.6
	Male	66	43.4
Race:	Caucasian	141	92.8
	Hispanic	9	5.9
	Asian	2	1.3
	Black	0	0.0
Age (yrs):	Average ± SD	43.9 ± 8.9	
	Range	21 to 62	
Contact Lens History:	None	46	30.3
	Soft	91	59.9
	RGP	15	9.9
	PMMA	0	0.0

2. Baseline Parameters (LASIK Myopia with Astigmatism)

TABLE 25 BASELINE PARAMETERS (LASIK MYOPIA WITH ASTIGMATISM)		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-4.66 ± 2.09	-1.00 to –10.125
Sphere	-3.93 ± 2.14	0.00 to –8.75
Cylinder	-1.45 ± 0.61	-0.50 to –2.75
Preoperative UCVA*	n	%
20/100 or worse	121	89.0
20/50 to 20/80	12	8.8
20/25 to 20/40	3	2.2
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	9	5.9
≤20/20	143	94.1

* not including monovision

3. Safety and Efficacy Results (LASIK Myopia with Astigmatism)

TABLE 26
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
ASTIGMATIC MYOPIA UP TO –8.99D SPHERE & UP TO –2.99D CYLINDER

Efficacy Variables		1 Month	3 Months	6 Months	9 Months
BSCVA ≥ 20/20 Preop*					
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	67/126	57/123	47/89	20/37
	%	53.2%	46.3%	52.8%	54.1%
	CI	(44.1, 62.1)	(37.3, 55.6)	(41.9, 63.5)	(36.9, 70.5)
UCVA 20/20 or better*	n	68/133	58/130	47/94	20/40
	%	51.1%	44.6%	50.0%	50.0%
	CI	(42.3, 59.9)	(35.9, 53.6)	(39.5, 60.5)	(33.8, 66.2)
UCVA 20/25 or better*	n	96/133	85/130	69/94	28/40
	%	72.2%	65.4%	73.4%	70.0%
	CI	(63.8, 79.6)	(56.5, 73.5)	(63.3, 82.0)	(53.5, 83.4)
UCVA 20/40 or better*	n	121/133	113/130	88/94	38/40
	%	91.0%	86.9%	93.6%	95.0%
	CI	(84.8, 95.3)	(79.9, 92.2)	(86.6, 97.6)	(83.1, 99.4)
MRSE ±0.50D of intended	n	109/147	101/144	77/105	31/41
	%	74.1%	70.1%	73.3%	75.6%
	CI	(66.3, 81.0)	(62.0, 77.5)	(63.8, 81.5)	(59.7, 87.6)
MRSE ±1.00D of intended	n	135/147	132/144	100/105	39/41
	%	91.8%	91.7%	95.2%	95.1%
	CI	(86.2, 95.7)	(85.9, 95.6)	(89.2, 98.4)	(83.5, 99.4)
MRSE ±2.00D of intended	n	145/147	141/144	104/105	40/41
	%	98.6%	97.9%	99.0%	97.6%
	CI	(95.2, 99.8)	(94.0, 99.6)	(94.8, 100)	(87.1, 99.9)
Safety Variables					
Loss of >2 Lines BSCVA	n	2/146	0/144	0/105	0/41
	%	1.4%	0.0%	0.0%	0.0%
	CI	(0.2, 4.9)	(0.0, 2.5)	(0.0, 3.5)	(0.0, 8.6)
Loss of 2 Lines BSCVA	n	4/146	3/144	1/105	0/41
	%	2.7%	2.1%	1.0%	0.0%
	CI	(0.8, 6.9)	(0.4, 6.0)	(0.0, 5.2)	(0.0, 8.6)
BSCVA worse than 20/40	n	0/146	0/144	0/105	0/41
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.5)	(0.0, 2.5)	(0.0, 3.5)	(0.0, 8.6)
Increase >2D cylinder	n	0/147	0/144	0/105	0/41
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.5)	(0.0, 2.5)	(0.0, 3.5)	(0.0, 8.6)
BSCVA ≥ 20/20 Preop					
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	5/138	1/135	1/98	0/37
	%	3.6%	0.7%	1.0%	0.0%
	CI	(1.2, 8.3)	(0.0, 4.1)	(0.0, 5.6)	(0.0, 9.5)

*Not including monovision eyes CI = 95% Confidence

TABLE 27
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES FOR ASTIGMATIC MYOPIA UP TO –8.99D SPHERE WITH UP TO –2.99D CYLINDER STRATIFIED BY DIOPTERS SPHERICAL EQUIV.: 6 MONTHS

Efficacy		-1.0 to -1.99	-2.0 to -2.99	-3.0 to -3.99	-4.0 to -4.99	-5.0 to -5.99	-6.0 to -6.99	Total <7D	-7.0 to -7.99	-8.0 to -8.99	-9.0 to -10.125	Total ≥7D	Cum Total
BSCVA ≥ 20/20 Preop*													
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	7/7	8/13	7/9	9/16	7/18	3/6	41/69	3/10	3/8	0/2	**6/20**	47/89
	%	100.0%	61.5%	77.8%	56.3%	38.9%	50.0%	59.4%	30.0%	37.5%	0.0%	**30.0%**	52.8%
UCVA 20/20 or better*	n	7/7	8/14	7/10	9/16	7/18	3/6	41/71	3/13	3/8	0/2	**6/23**	47/94
	%	100.0%	57.1%	70.0%	56.3%	38.9%	50.0%	57.7%	23.1%	37.5%	0.0%	**26.1%**	50.0%
UCVA 20/25 or better*	n	7/7	12/14	8/10	11/16	13/18	4/6	55/71	8/13	4/8	2/2	**14/23**	69/94
	%	100.0%	85.7%	80.0%	68.8%	72.2%	66.7%	77.5%	61.5%	50.0%	100.0%	**60.9%**	73.4%
UCVA 20/40 or better*	n	7/7	14/14	8/10	15/16	17/18	5/6	66/71	12/13	8/8	2/2	**22/23**	88/94
	%	100.0%	100.0%	80.0%	93.8%	94.4%	83.3%	93.0%	92.3%	100.0%	100.0%	**95.7%**	93.6%
MRSE ±0.50D of intended	n	6/7	12/14	9/14	16/18	17/20	4/7	64/80	7/14	6/9	0/2	**13/25**	77/105
	%	85.7%	85.7%	64.3%	88.9%	85.0%	57.1%	80.0%	50.0%	66.7%	0.0%	**52.0%**	73.3%
MRSE ±1.00D of intended	n	7/7	14/14	13/14	18/18	18/20	6/7	76/80	13/14	9/9	2/2	**24/25**	100/105
	%	100.0%	100.0%	92.9%	100.0%	90.0%	85.7%	95.0%	92.9%	100.0%	100.0%	**96.0%**	95.2%
MRSE ±2.00D of intended	n	7/7	14/14	14/14	18/18	20/20	6/7	79/80	14/14	9/9	2/2	**25/25**	104/105
	%	100.0%	100.0%	100.0%	100.0%	100.0%	85.7%	98.8%	100.0%	100.0%	100.0%	**100.0%**	99.0%
Safety													
Loss of >2 Lines BSCVA	n	0/7	0/14	0/14	0/18	0/20	0/7	0/80	0/14	0/9	0/2	**0/25**	0/105
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%
Loss of 2 Lines BSCVA	n	0/7	0/14	0/14	0/18	0/20	0/7	0/80	1/14	0/9	0/2	**1/25**	1/105
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	7.1%	0.0%	0.0%	**4.0%**	1.0%
BSCVA worse than 20/40	n	0/7	0/14	0/14	0/18	0/20	0/7	0/80	0/14	0/9	0/2	**0/25**	0/105
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%
Increase >2D Cylinder	n	0/7	0/14	0/14	0/18	0/20	0/7	0/80	0/14	0/9	0/2	**0/25**	0/105
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	**0.0%**	0.0%
BSCVA ≥ 20/20 Preop													
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	0/7	0/13	0/13	0/17	0/20	0/7	0/77	1/10	0/9	0/2	**1/21**	1/98
	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	0.0%	0.0%	**4.8%**	1.0%

*Not including monovision eyes

Astigmatism correction was assessed based on the magnitude of cylinder and vector analysis (Table 28). At 6 months, 83.8% of eyes had ≤0.50D and 93.3% of eyes had ≤1.00D of residual cylinder.

TABLE 28
SUMMARY OF LASIK MYOPIA WITH ASTIGMATISM CYLINDER CORRECTION
6 MONTHS

Absolute Magnitude		Vector Analysis	
Preoperative	1.42 ± 0.59	Intended Vector	1.42 ± 0.59
Postoperative	0.30 ± 0.42	Difference Vector	0.30 ± 0.42
Achieved Magnitude	1.15 ± 0.65	Achieved Vector	1.37 ± 0.62
% Achieved	80 ± 27	% Achieved	99 ± 38
Axis Shift*	30.9 ± 24.7	Angle of Error	4.4 ± 7.2

*Eyes with residual cylinder >0

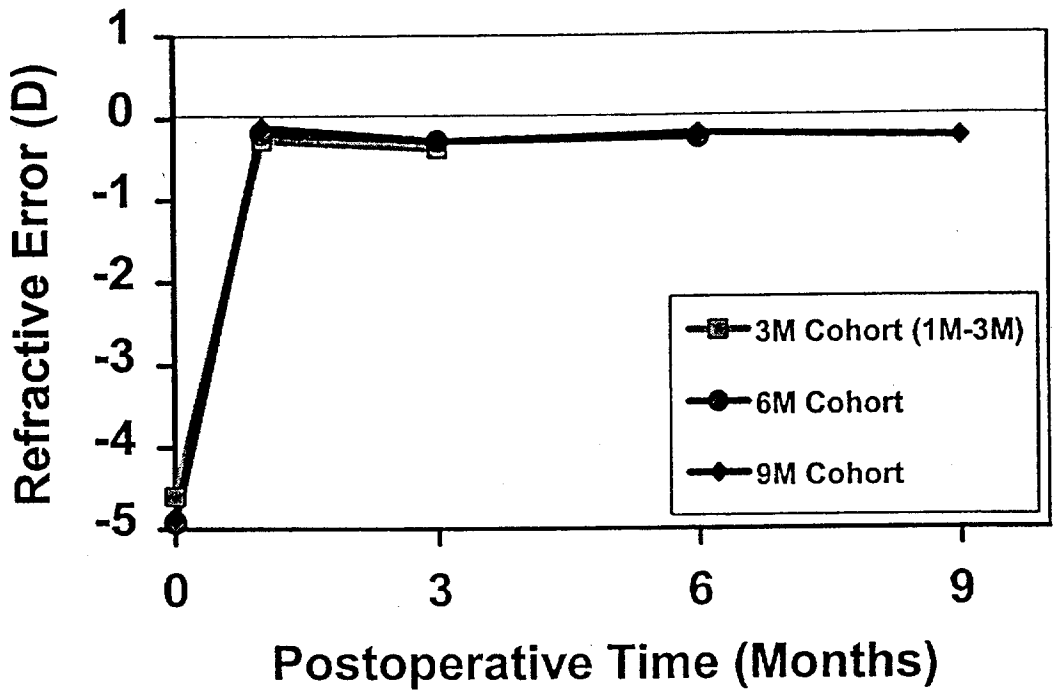

Figure 2. Manifest Refraction Spherical Equivalent vs. Postop Time

MEAN ± SD MANIFEST REFRACTION SPHERICAL EQUIVALENT OVER TIME*						
	n	Preop	1 Month	3 Months	6 Months	9 Months
3M Cohort (1M-3M)	124	-4.60 ± 2.20	-0.27 ± 0.53	-0.37 ± 0.55	--	--
6M Cohort	89	-4.93 ± 2.18	-0.18 ± 0.44	-0.28 ± 0.43	-0.24 ± 0.51	--
9M Cohort	36	-4.85 ± 2.15	-0.11 ± 0.48	-0.28 ± 0.49	-0.19 ± 0.61	-0.24 ± 0.56
Entire Cohort (All Available Eyes)	--	-4.65 ± 2.15	-0.31 ± 0.55	-0.37 ± 0.58	-0.22 ± 0.51	-0.23 ± 0.53

*Not including monovision

3 Month Cohort: includes all eyes with data at both 1 and 3 month intervals
6 Month Cohort: includes all eyes with data at every interval through 6 months(1, 3, and 6 months)
9 Month Cohort: includes all eyes with data at every interval through 9 months (1, 3, 6, and 9 months)
Entire Cohort: includes eyes in the cohort with data at any interval, but not necessarily at every interval

4. Patient Satisfaction (LASIK Myopia with Astigmatism)

At 6 months, quality of vision was rated significantly better or better than preoperative in 71.3% of eyes and 80.0% of patients were extremely satisfied or satisfied with their results. Postoperatively, distance correction was never used by 92.9% of patients and near correction was not used by 71.0%.

5. Retreatments (LASIK Myopia with Astigmatism)

Sixteen eyes (10.5%) were retreated for undercorrection. Data was available on 12 eyes postoperatively. All eyes except one (91.6%) were within 0.50D of target and 100% have UCVA of 20/32 or better.

H. TRACKER EFFECTIVENESS

The LADARVision® System incorporates an active tracking mechanism (LADARTracking), which compensates for eye movement during the ablation process. The measurement speed of the LADARTracker (4000 measures /second) allows for detection and compensation for saccadic (involuntary) eye movement.

Analysis of eye movement data gathered electronically during the surgical procedures of 554 eyes treated in this study demonstrated that:

- All patients exhibit eye movement during surgery. The average eye motion, defined as the standard deviation in the eye position during the procedure, ranged from 0.04 mm to 1.16 mm, with a mean of 0.35 ± 0.19 mm.
- The LADARTracker was able to compensate for the eye movement, resulting in visual and refractive outcomes that were independent of the amplitude of the motion. Patients who had large eye movements during surgery had an equally effective visual acuity outcome as those patients with small eye movements during surgery.
- Computer simulations of surgeries, where the detected movements were not countered by active eye tracking, demonstrate that uncompensated eye motion can increase corneal irregularities.
- Measurements of patients' visual acuity indicates that visual acuity tends to decrease with an increase in corneal irregularities.
- Active eye tracking with LADARTracking improves the accuracy of corneal shaping.

5. PLANNING AND PROCEDURES

A. PATIENT SELECTION

In addition to the information listed in the indications, contraindications, precautions, and warnings section of this booklet, consideration should be given to the following in determining the appropriate patients for PRK or LASIK:

- Patients who are contact lens wearers must be requested to discontinue contact lens wear in both eyes at least 2 to 3 weeks prior to the preoperative examination. Patients who wear RGP and PMMA should have two examinations conducted 2-3 weeks apart which show stability of refraction without lens wear.
- Baseline evaluation of patients requesting refractive surgery should be performed within 60 days of the PRK or LASIK surgery.
- The patient should have the ability to tolerate local or topical anesthesia and drops to dilate the pupil.
- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the PRK or LASIK procedure.
- The patient must be able to understand and give an informed consent.
- Patients should be clearly informed of all alternatives for the correction of their myopia by use of spectacles, contact lenses and other refractive surgeries such as radial keratotomy.

B. PROCEDURE

1. PRE-OPERATIVE (EXAMINATION OF THE PATIENT)

A pupil dilation of at least 7mm to 11mm is required for surgery to proceed. During preoperative procedures that involve dilation of the pupil, it is important to assess that the minimum amount of dilation is achievable.

A complete examination, including cycloplegic refraction and visual acuity evaluation, must be performed. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. Pre-operative corneal topography is essential on all patients to exclude abnormalities. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 60 days of PRK or LASIK surgery.

It is essential that the refractive information upon which this surgical procedure is based is accurate (including axis of astigmatism treatment) and is correctly transmitted to the laser. **It is the sole responsibility of the operating doctor to ensure the information for each individual patient is accurate.**

2. OPERATING PROCEDURE SUMMARY

Note: Before proceeding, please refer to the laser preparation and shut-down procedures presented in the LADARVision® System Operation Manual.

Prior to surgery, patient details (name and study number) and refractive correction (spherical equivalent at the spectacle plane, vertex distance and ablation zone diameter) are entered into the laser system computer (Figure 3). The system automatically converts the correction to the corneal plane and displays the conversion on the screen. If the correction or zone diameter is outside of the protocol limits, the system will not accept the values. To receive a spherical treatment, refractive astigmatism has to be less than 1.00D. For the astigmatism algorithm to be used, at least 0.50D of spectacle astigmatism is required. Therefore the surgeon has the choice as to whether to treat 0.50D or 0.75D of cylinder or to treat the spherical equivalent instead. The spherical and cylindrical component of the ablation are applied simultaneously. It is possible to treat eyes with cylinder only (plano sphere). The ablation zone diameter for myopic spherical treatments is 6.0mm and for myopic astigmatic treatments is 5.5mm x 7.5mm. Table 29 shows the ablation depth per diopter of correction at the 6.0 and 5.5mm optic zone sizes.

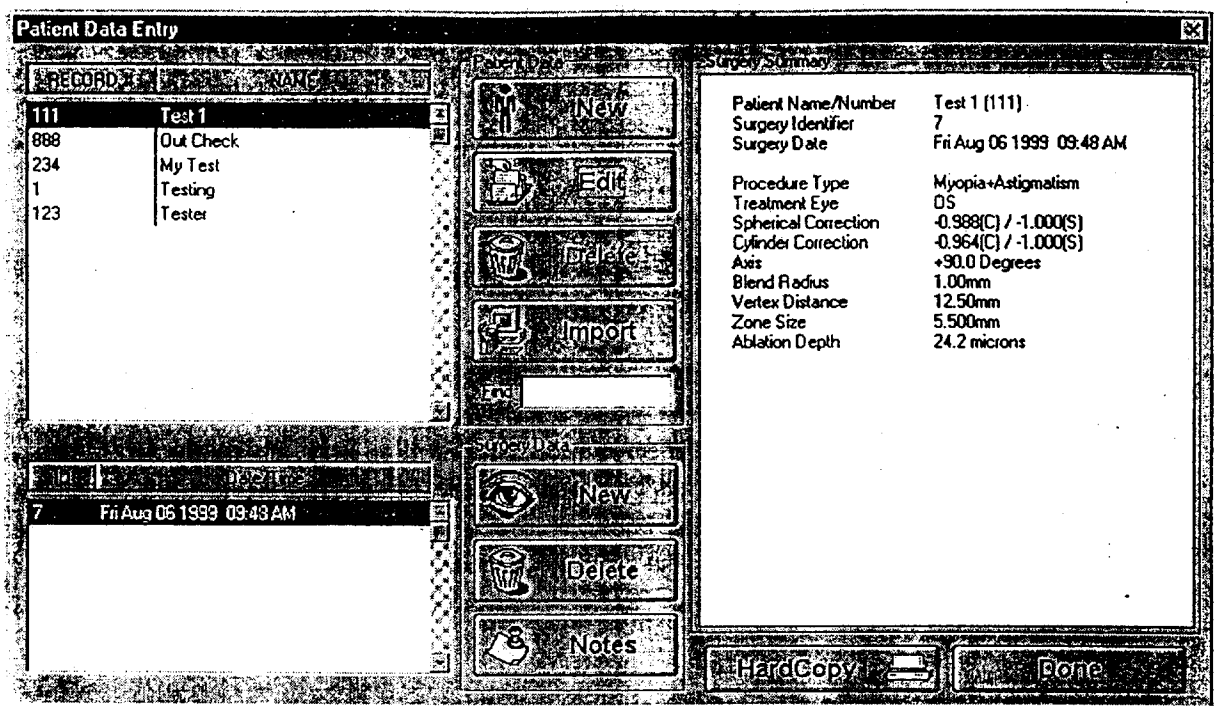

Figure 3. Patient Data Entry Screen

Table 29 provides a reference with respect to the calculated ablation depth (microns) per diopter of correction for spherical (6mm) and astigmatic (5.5mm) optic zones.

TABLE 29
ABLATION DEPTH IN MICRONS AS A FUNCTION OF TREATMENT DIAMETER AND CORRECTION

	Optic Zone Diameter			Optic Zone Diameter	
Power (D)*	**5.5**	**6.0**	**Power (D)***	**5.5**	**6.0**
0.5	6	8	**6.5**	79	96
1.0	12	15	**7.0**	85	103
1.5	18	22	**7.5**	91	110
2.0	25	30	**8.0**	97	118
2.5	31	37	**8.5**	103	125
3.0	37	45	**9.0**	109	132
3.5	43	52	**9.5**	115	139
4.0	49	59	**10.0**	121	146
4.5	55	67	**10.5**	127	153
5.0	61	74	**11.0**	133	161
5.5	67	81	**11.5**	139	168
6.0	73	89	**12.0**	145	175

*For spherical myopic corrections: spherical equivalent power at the corneal plane

**For myopic astigmatic corrections: corneal plane power of the highest dioptric meridian (spherical and cylindrical power combined). For example: -8D sphere/-4D cylinder equals a maximum power correction of –12D in one meridian

The majority of the surgical procedure is controlled by computer software. The doctor must position and align the patient's head and eye under the laser so that an image of the eye can be easily seen in the computer monitor. The view on the computer screen is the same field of view as through the operating microscope on low power.

The computer monitor displays two images of the patient's eye. A large screen displays the "tracked" image and a smaller screen displays the "untracked" image. The eye seen in the "tracked" image will appear to move normally until the tracker is engaged at which time the eye appears still. This image is used to adjust the tracker and position the ablation zone. The eye in the "untracked" is "live" and the eye will always be seen to move normally. This image is used to aid the doctor in maintaining the position of the patient's head during the procedure.

The LADARVision surgical procedure consists of four basic steps: (a) centration (b) pupil dilation and (c) laser calibration and (d) ablation. Each step is summarized below.

Centration

The ablation zone is centered over the non-dilated pupil when the patient is in a supine position. The positioning of the ablation zone is determined prior to pupil dilation since the pupil center may shift during dilation. Since the position and size of the limbus do not change during pupil dilation, it is used as a reference point for centration as described in the following procedure.

The patient is positioned under the laser and brought into focus by adjusting the headrest in the same place as for the surgical procedure. The eyelids are held open manually or with a speculum and the patient is instructed to fixate on the blinking fixation target. A video image encompassing the limbus, cornea, and iris is captured with the laser system computer software. With the captured image on the computer monitor, the position and size of the limbus and undilated pupil are superimposed with software generated rings (Figure 4). The geometry and position of these rings relative to each other are stored in computer memory and recalled just prior to surgery and used to realign the ablation zone, while the patient is fixating on the blinking fixation target.

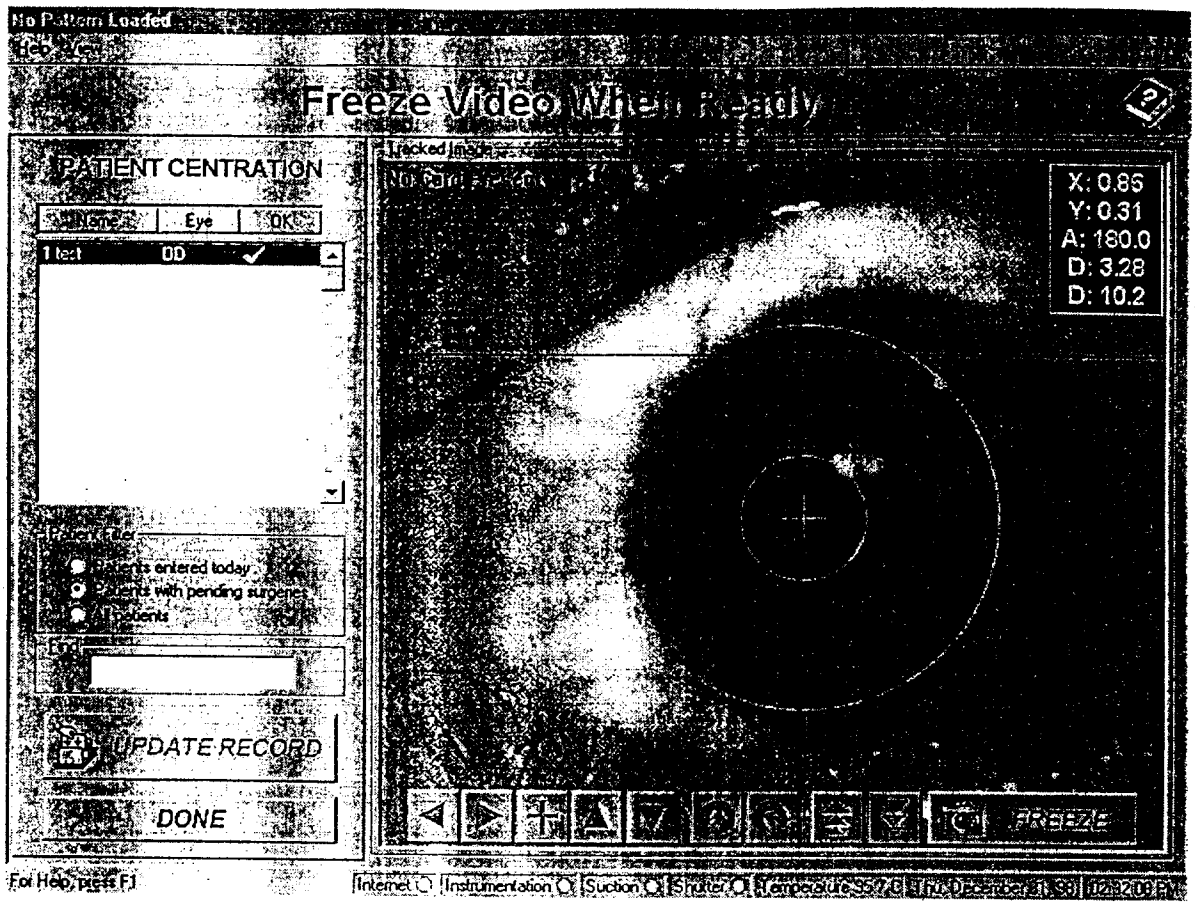

Figure 4. Undilated Pupil and Limbus Reticles

Pupil Dilation

It is necessary to dilate the pupil prior to surgery to engage the tracker and optimize the tracker performance. Pupil dilation must be a minimum of 7mm and a maximum of 11mm prior to epithelial removal (PRK) or flap creation (LASIK) to proceed into surgery with confidence. A combination of 2.5% phenylephrine (Mydfrin, Alcon Laboratories, Fort Worth, TX) and 1% tropicamide (Mydriacyl, Alcon Laboratories, Fort Worth, TX) are used. Approximately 45 minutes prior to the procedure one drop of each mydriatic is instilled followed by a second drop 10 minutes later.

Laser Calibration

The laser system must be calibrated immediately before each patient in order for the treatment to be allowed. Three brief calibration steps are performed by the laser operator: Configure Laser, Geometry Adjust and Volume Per Shot.

Configure laser is performed to set the laser energy for the procedure. Geometry adjust is necessary to insure that all system alignment errors are compensated for by software. Finally, the Volume Per Shot step adjusts the correction algorithm based on the level of laser energy.

These three calibration steps must be completed and within the safe operating parameters set in the system before the system will enable the laser to begin a surgery. Once the patient's refractive information is recalled and verified to be correct by the surgeon, the ablation shot pattern is loaded and the laser is ready for activation.

Ablation

A sterile instrument tray is prepared for each patient and all members of the surgical support team, who touch the eye of the patient, wear a fresh pair of sterile gloves.

For astigmatic treatments, a dye marker is used to mark the 3 and 9 o'clock positions on the limbus behind the slit lamp immediately prior to the procedure. This is done to facilitate accurate alignment of the axis of cylinder relative to the horizontal plane of the cornea when the patient is beneath the laser.

Starting approximately 15 minutes prior to surgery, one drop of topical anesthetic is administered to the operative eye every 5 minutes. The patient is brought into the laser room, positioned under the laser and a speculum is inserted. Prior to epithelial removal (PRK) or creation of the flap (LASIK), the adequacy of pupil dilation is checked by testing the tracker. If the tracker cannot acquire the eye due to insufficient dilation, a message stating such will be displayed on the screen. Additional dilation time or stronger dilation agents are used.

PRK: Once the tracker is set, the epithelium is mechanically removed using a rotating brush, blunt spatula or surgical blade. The desired time between the initiation of epithelial removal and the start of ablation is standardized to two minutes to standardize corneal hydration. The software allows the surgeon to check if a sufficient zone of epithelium has been removed using an ablation zone indicator on the computer screen (Figure 5).

LASIK: Once sufficient pupil dilation is confirmed, the LASIK flap is created using a microkeratome. The software allows the surgeon to check if the ablation zone impinges on the flap hinge using an ablation zone indicator on the computer screen (Figure 5). If the ablation zone covers the hinge, the hinge protection feature is activated to prevent pulses from being fired onto the hinge.

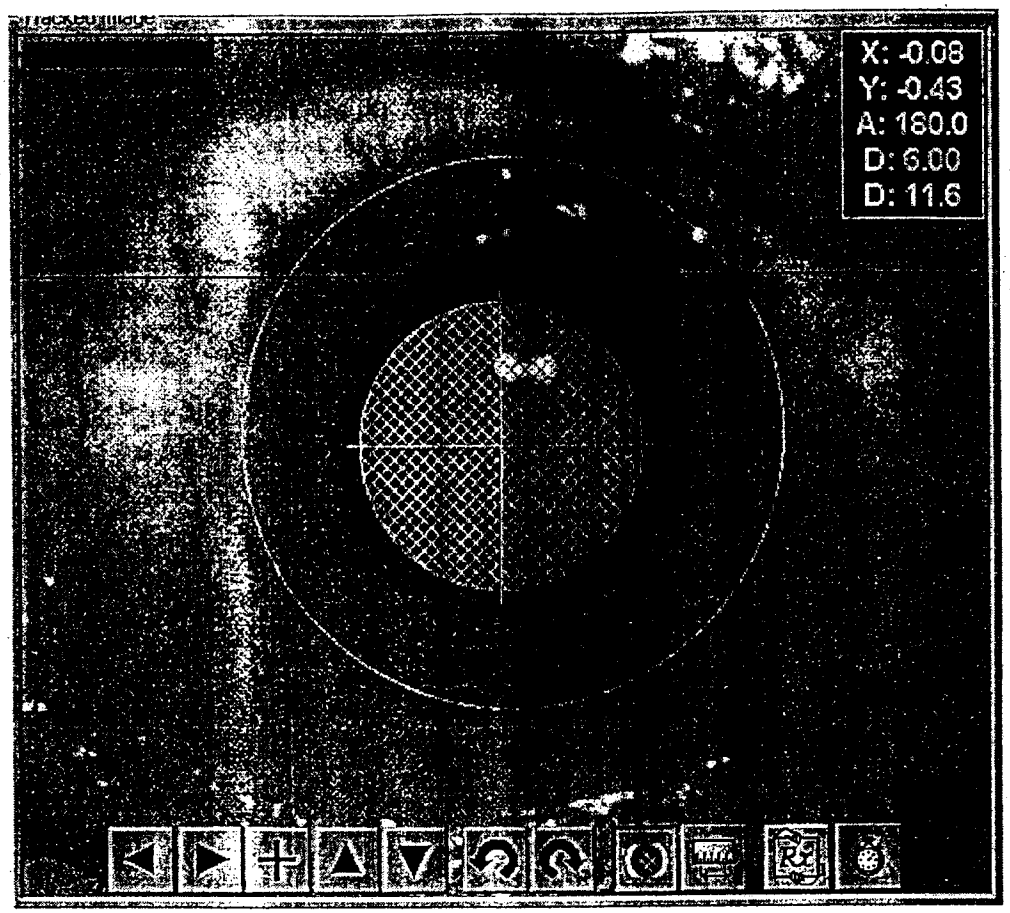

Figure 5. Showing Extent of Ablation Zone

When sufficient epithelium is removed or the LASIK flap pulled back, the tracking device is activated and the position of the ablation zone is determined by recalling the geometry of the centration rings stored prior to dilation. The previously stored limbus ring is re-positioned so that the ablation occurs over the center of the undilated pupil. For astigmatic treatments, the axis of astigmatism is aligned relative to the marks made at 3 and 9 o'clock to compensate for cyclotorsion or head tilt. A suction tube is positioned 1 inch away from the eye to remove the ablation effluent. The patient is reminded to fixate on the blinking LED target throughout the procedure. The laser operator then activates the "ablate" button on the computer screen and the surgeon controls the application of the ablation pulses to the cornea via the footswitch. The laser will not fire without the tracker being activated. At any time, the surgeon can interrupt the procedure (stop the laser from firing) by releasing the foot pedal. In an emergency situation, the laser operator can also interrupt by activating the appropriate button on the computer screen or on the control panel. If at any time during the procedure the tracker disengages, the laser will stop firing. This rarely occurs but is possible if the pupil is not visible to the tracker (such as when the eye rolls back under the upper lid or if surgical instruments are inadvertently placed between the eye and the laser) or if the pupil

constricts significantly during the procedure. In such a case, it is possible to continue the procedure from the last laser pulse fired after tracking and centration have been reestablished.

At the end of the ablation, the laser system disengages the tracker and displays the surgical parameters (including details of any interruption) on the computer screen.

3. POST-PROCEDURE

PRK: Postoperative pharmaceutical treatment consists of one drop each of diclofenac sodium 0.1% (Voltaren, CIBAVision Ophthalmics, Atlanta, GA) and a combination of an antibiotic and a corticosteroid drop. A bandage contact lens is applied to all eyes treated. On the day after surgery, the patient is instructed to use the antibiotic/steroid drop four times daily and the Voltaren every 4 hours. The Voltaren is only to be used if need on Day 2. The antibiotic/steroid is self-administered by the patient three times daily from Day 2 until healed. The bandage contact lens is removed on Day 4 or sooner if re-epithelialization is complete. Patients are given instructions to take home regarding instillation of the drops and general postoperative guidelines.

A slit lamp examination should be performed on a daily basis until re-epithelialization is complete. After re-epithelialization, the following examinations are recommended at a schedule of at least 1, 3, 6 and 12 months: Uncorrected Visual Acuity (UCVA); Manifest refraction with the Best Spectacle Corrected Visual Acuity (BSCVA); and Slit lamp examination, including corneal clarity evaluation. If topical steroids are used post-operatively, IOP should be measured and patients should be monitored for development of possible steroid side effects such as ocular hypertension, glaucoma and/or cataract.

LASIK: Postoperative pharmaceutical treatment consists of one drop of a broad spectrum antibiotic and, if desired, a steroid and NSAID. For the three days following surgery, the patients are given an antibiotic/steroid combination to be instilled 3 to 4 times a day.

A slit lamp examination should be performed at one day. Examinations are recommended at a schedule of 1 day, 1 week, 1, 3, 6 and 12 months including UCVA, manifest refraction, BSCVA and slit lamp examination.

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FACTS YOU NEED TO KNOW ABOUT LADARVision® PHOTOREFRACTIVE KERATECTOMY (PRK) AND LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY

PATIENT INFORMATION BOOKLET

For

For Nearsightedness (Myopia): up to –10.0D (PRK) or less than –9.0D (LASIK)
With or Without Astigmatism: -0.50 to –4D (PRK) or –0.50 to less than –3.0D (LASIK)

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

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A. Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions that you may have about these terms. Your doctor can provide you with answers to your medical questions.

Astigmatism: a condition of the eye that results in blurred distance and/or near vision. The surfaces of the eye focus the light rays at different points inside the eye. The different points of focus create a blur of parts of objects you see.

Antibiotic Medication: a drug used to treat or prevent infection. Your doctor may prescribe this type of medication after surgery.

Anti-inflammatory Medication: a drug that reduces inflammation or the body's reaction to injury or disease. Surgery that alters the eye, such as PRK or LASIK, can also cause inflammation. Your doctor may prescribe this type of medication after surgery.

Autoimmune Disease: a condition in which the body attacks itself that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this condition are multiple sclerosis and myasthenia gravis. If you have this type of condition, you should not have PRK or 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.

Blepharitis: inflammation of the eyelid margins

Cataract: an opacity, or clouding, of the lens inside the eye that can cause a loss of 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 of this type of disease are lupus and rheumatoid arthritis. If you have this type of condition, you should not have PRK or LASIK surgery.

Conjunctival Injection: increased redness of the blood vessels in the front of the eye

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

Cornea: the clear front surface of the eye. Surgery such as PRK, LASIK and RK reshape or flatten this surface to correct distance vision.

Corneal Abrasion: a scratch in the outer layer of the cornea often from an eye injury.

Corneal Epithelium: the top layer of the cornea. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

Corneal Erosion: a defect in the outer layers of the cornea that may occur without injury.

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 is applied to the inner layers of the cornea.

Corneal Folds/Striae/Wrinkles: the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling.

Corneal Foreign Body: foreign debris in outer layer of the cornea.

Corneal Haze: a cloudiness of the cornea that may occur after PRK.

Corneal Infiltrate: inflammation of the cornea.

Corneal Swelling: : an accumulation of fluid in the cornea that is not normally present. This condition is usually temporary with no significant effect on vision.

Corneal Ulcer: an infection of the cornea that may result in a loss of vision.

Diopter: a unit used to measure the amount of myopia and astigmatism of an eye..

Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect could occur anywhere on the surface of the cornea. This condition is usually temporary and may result in some discomfort or pain.

Epithelial Dots: small spots in the outer layer of the cornea, that have no effect on vision.

Epithelial Irregularity: an area of the outer layer of the cornea that is not smooth.

Epithelium in the Interface: this condition can occur after LASIK surgery when epithelial cells from the surface of the cornea move or grow underneath the corneal flap. This can result in loss of vision.

Excimer Laser: a type of laser used in PRK or LASIK that removes tissue from the cornea.

Fibrotic Healing of Flap Edge: slight scarring appearance of the edge of the corneal flap.

Flap Distortion: : irregular appearance of the corneal flap.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object. This symptom may occur after surgery.

Herpes Simplex: a type of infection caused by a virus 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 PRK or LASIK surgery.

Herpes Zoster: a type of infection caused by a virus 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 PRK or LASIK surgery.

HSV Dendrite.: a branching treelike lesion in the cornea due to herpes simplex infection.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS. If you have this type of condition, you should not have surgery.

Induced Astigmatism: the case when the eye has a greater amount of astigmatism after surgery than before surgery. This can happen if the corneal flap is created off-center (decentered flap) in LASIK.

Inflammation: the body's reaction to injury or disease. Surgery that alters the eye, such as PRK and LASIK, can also cause inflammation.

Interface debris: cellular and foreign material underneath the flap after LASIK surgery.

Interface haze/opacity: a cloudiness of the cornea underneath the flap, either diffuse or localized areas that may occur after LASIK.

Iritis: inflammation of the inside of the eye behind the cornea.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs. If you have this type of condition, you should not have PRK or LASIK surgery.

Laser In-Situ Keratomileusis (LASIK): a procedure where a device called a microkeratome is used to surgically create a thin, hinged flap of corneal tissue. The flap is folded back, the laser is directed to the corneal surface exposed beneath the flap and the flap is brought back into place.

Lattice Degeneration: area of thinning in the back of the eye (retina), which is more common in nearsighted eyes and unrelated to surgery

Lens: a structure inside the eye that helps to focus light onto the back of the eye.

Microkeratome: a surgical instrument used to cut a flap of corneal tissue as the first step in the LASIK procedure.

Misaligned Flap: the flap created with the microkeratome has not returned to its correct position after the ablation is complete. It is sometimes possible to reposition the flap.

Miscreated Flap: the flap created with the microkeratome was of poor quality (e.g. too small or irregular) and the laser ablation was not attempted. In this situation, a new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

Monovision: optical correction of one eye so that it sees clearly in the distance and the other eye sees clearly up close.

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Myopia: a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from distant objects in front of the retina. This incorrect focusing of light results in blurred images of objects at a distance.

Nearsightedness: another term for myopia. Nearsighted eyes see better at near than at a distance without glasses or contact lenses.

Nebula After Foreign Body Removal: area of haze in the outer layer of the cornea where foreign body was removed.

Non-Steroidal Anti-inflammatory Drug (NSAID): a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe this type of medication after surgery.

Ocular Hypertension: an increase in the pressure inside the eye.

Oil droplets/sheen: oily appearance of the cornea

Overcorrection: too much correction after surgery that may cause blurred distance and/or near vision without glasses.

Peau d' orange: orange peel appearance of the cornea

Peripheral Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect occurs in the periphery or outer part of the cornea.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the surface of the cornea using an excimer laser. Tissue is removed from the outermost surface of the cornea just beneath the epithelium.

Radial Keratotomy (RK): a type of surgery used to correct vision by flattening the cornea with a scalpel.

Regression: a decrease in the amount of vision correction after surgery.

Retina: the back surface of the eye. The retina takes focused light and transfers the image to the brain.

Retinal Vascular Accident: blockage of a blood vessel in the back of the eye.

Retinal Vessel Tortuosity: curving of blood vessels in the back of the eye unrelated to surgery

Serous Macular Edema: a sudden accumulation of fluid in the part of the retina responsible for central vision (macula) resulting in distortion of central vision.

Starbursts: flares of light seen around a lighted object that may appear like a star. This symptom is similar to halos and may occur after surgery.

Sterile Interface Inflammation: an inflammatory reaction underneath the corneal flap after LASIK surgery that is not due to bacteria. This condition may result in vision loss.

Steroid Medication: a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe a steroid for use in the eye after surgery to modify the healing of the cornea. If you are taking this drug for a disease condition, you should not have PRK or LASIK surgery.

Subconjunctival Hemorrhage: an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.

Superficial Punctate Keratitis (SPK): surface irritation in the outer layer of the cornea.

B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly in the distance? One option to see more clearly at a distance is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. Radial Keratotomy (RK) is one type of surgery that uses a scalpel to make fine cuts in the cornea. A more recent type of surgery is Photorefractive Keratectomy (PRK). PRK uses a laser instead of a scalpel to carefully shape the corneal surface. Another procedure, which uses the laser is called LASIK. In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. PRK or LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision® Excimer Laser System is a unique system that tracks all movements of the eye during surgery. Tracking movements of the eye allows the system to accurately place the laser beam. The system applies hundreds to thousands of laser beam pulses to the cornea to correct vision. Accurate placement of these laser beam pulses provides precise shaping of the cornea. The purpose of this booklet is to inform you about PRK and LASIK with the tracker-guided LADARVision® system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about PRK or LASIK with the help of your doctor.

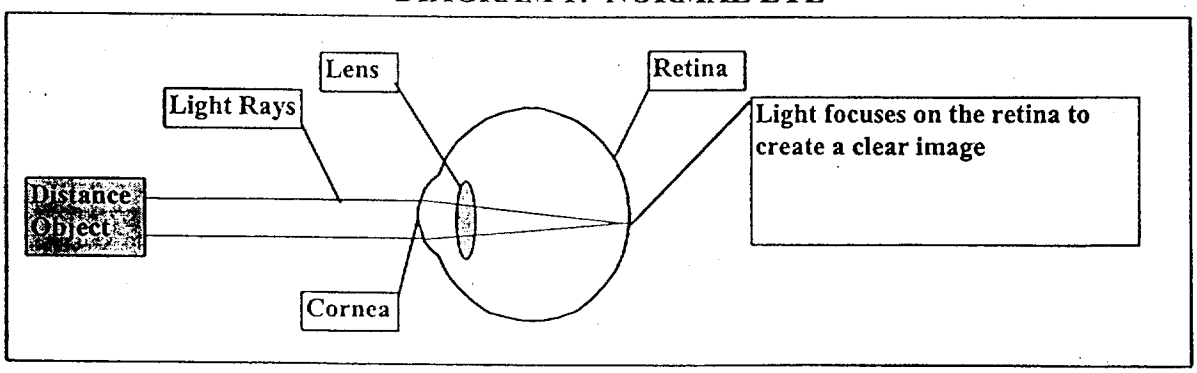
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after PRK or LASIK. PRK or LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having RK, PRK or LASIK.

NOTE: You may need reading glasses after PRK or LASIK even if you did not wear them before.

C. How Does PRK or LASIK Correct Myopia With or Without Astigmatism?

The human eye functions like a camera. The lens in a camera focuses light into images on to film. In the same way, the cornea and the lens inside the eye focus light into images on to the retina, the back surface of the eye (Diagram 1). Blurred vision occurs when the light does not focus precisely on the retina.

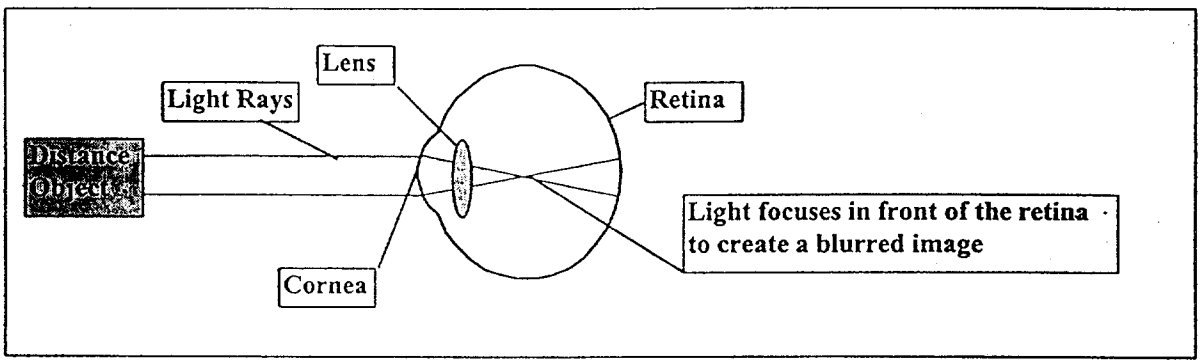
DIAGRAM 1: NORMAL EYE



Myopia (Nearsightedness) is a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from a distant object in front of the retina.

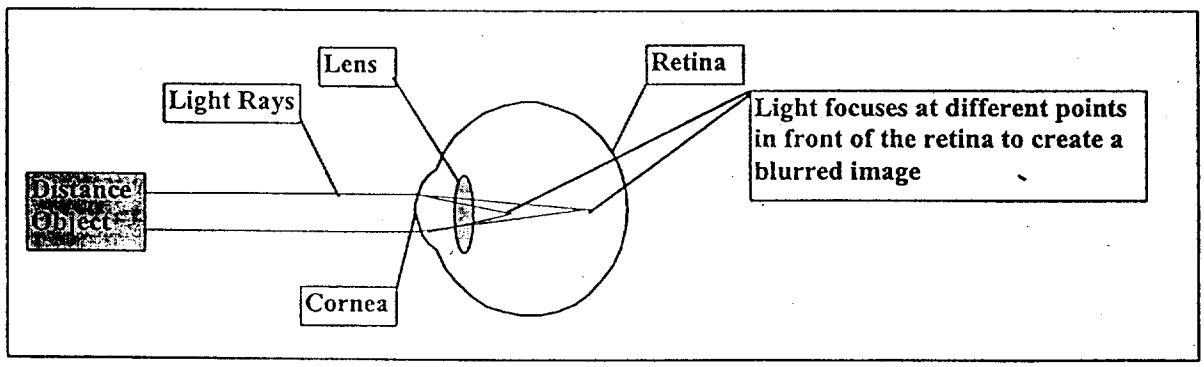
This incorrect focusing of light results in blurred images of objects at a distance. Diagram 2 shows how light focuses in front of the retina to cause a blurred image.

DIAGRAM 2: MYOPIA



Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points in front of the retina. The different points of focus create blur of parts of the images. For example, a person with astigmatism might confuse an "R" with a "P" or an "F" on a sign. This confusion about the letter occurs because only part of the letter is in focus. Diagram 3 shows how light rays focus at different points causing a blurred image.

DIAGRAM 3: MYOPIA WITH ASTIGMATISM



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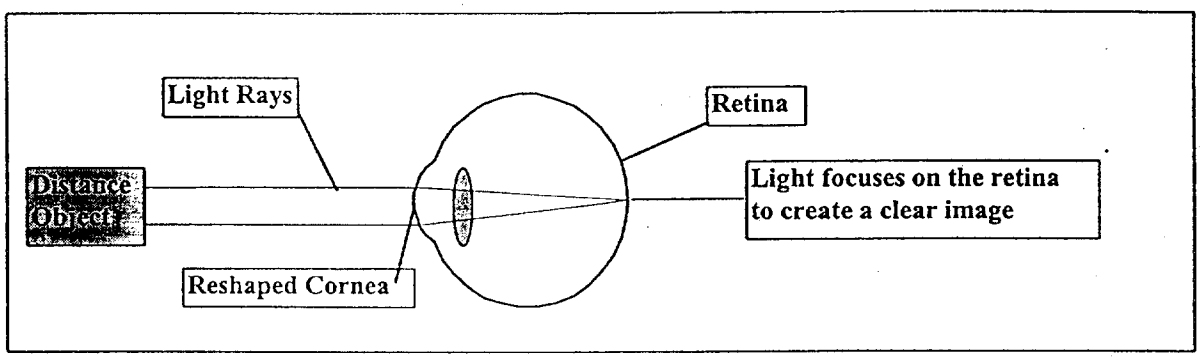
Glasses and contact lenses help focus all of the light rays on to the retina. By focusing all of the light rays properly, the vision in the distance is clear. Another way to change the way the eye focuses light is to reshape the cornea. For treatment of myopia, flattening the center of the cornea helps to focus all of the light rays on to the retina to provide clear vision. PRK and LASIK flatten the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in PRK and in LASIK that removes tissue from the cornea. This type of laser reshapes the cornea without changing any other parts of the eye.

Diagram 5 shows how these procedures can reshape the cornea to provide clearer vision.

DIAGRAM 5: CORRECTION OF VISION AFTER PRK OR LASIK



The LADARVision® System incorporates an active eye tracking mechanism (LADARTracking), which compensates for eye movement during the surgery. The measurement speed of the LADARTracker (4000 measures/second) allows the system to detect eye movement and move the laser beam to compensate for this movement.

A very small laser beam is used to shape your cornea with this system. Therefore, precise shaping of the cornea depends on accurate placement of the laser beam. Without a system to track eye movements, any movement of the eye could affect the placement of the laser beam. Your eyes are constantly making fine eye movements even though you may not be aware of the movement. Many of these movements are beyond your control. In addition, you would not be able to hold your eye perfectly still even if you tried. By tracking all eye movements, the LADARVision® system maintains accurate placement of the laser beam.

Analysis of eye movement data gathered electronically during the surgical procedures of 554 eyes treated in the clinical study on myopia and astigmatism demonstrated that:

- All eyes moved during surgery.
- The LADARTracker compensated for this eye movement so that eyes with large movements and eyes with small movements had similar results.
- Active eye tracking with LADARTracking improves the accuracy of corneal shaping.

D. What Are Benefits Of PRK or LASIK?

Either PRK or LASIK may reduce overall nearsightedness. PRK or LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- PRK surgery performed with the LADARVision® system is effective in reducing myopia between -1.0 and -10.0 Diopters. In patients with myopia, the LADARVision® system is effective in reducing astigmatism of up to 4 Diopters.

- LASIK surgery performed with the LADARVision system is effective in reducing myopia less than –9.0 Diopters. In patients with myopia, the LADARVision system is effective in reducing astigmatism of 0.50 Diopters to less than 3.0 Diopters.

The results listed in the following section are from U.S. clinical studies of the LADARVision® system for PRK and LASIK.

U.S. CLINICAL STUDY RESULTS AT 12 MONTHS AFTER PRK SURGERY

	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Visual Acuity 20/20 or better **without** glasses*	72.0%	61.7%	61.2%
Visual Acuity 20/25 or better **without** glasses*	88.7%	82.6%	76.9%
Visual Acuity 20/40 or better **without** glasses*	98.1%	97.4%	93.4%
Visual Acuity 20/20 or better **with** glasses	97.0%	94.1%	92.4%
Visual Acuity 20/40 or better **with** glasses	100%	100%	100%
Loss of more than 2 lines of visual acuity with glasses	0.3%	0.0%	0.0%

*not including eyes treated for monovision

U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY				
	Eyes without astigmatism		Eyes with astigmatism	
	n/N	%	n/N	%
Visual Acuity 20/20 or better **without** glasses**	88/140	62.9%	47/89	52.8%
Visual Acuity 20/20 or better **without** glasses*	89/145	61.4%	47/94	50.0%
Visual Acuity 20/25 or better **without** glasses*	118/145	81.4%	69/94	73.4%
Visual Acuity 20/40 or better **without** glasses*	136/145	93.8%	88/94	93.6%
Visual Acuity 20/20 or better **with** glasses**	146/150	97.3%	88/98	89.8%
Visual Acuity 20/20 or better **with** glasses	148/155	95.5%	90/105	85.7%
Visual Acuity 20/40 or better **with** glasses	155/155	100.0%	105/105	100.0%
Loss of more than 2 lines of visual acuity with glasses	0/155	0.0%	0/105	0.0%

*Not including eyes treated for monovision
**If vision with glasses was 20/20 or better before surgery

E. Contraindications

You should NOT have PRK or LASIK surgery if:

- **You are pregnant or nursing**
- **You show signs of keratoconus** (This is a condition of the cornea that results in a change in the shape of the cornea.)
- **You are taking medications with ocular side effects** (for example, Isotretinoin (Accutane®) and Amiodarone hydrochloride (Cordarone®)
- **You 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 of these diseases are AIDS, lupus, rheumatoid arthritis, multiple sclerosis and myasthenia gravis.

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F. Warnings

Discuss with your doctor if:

- You are an insulin dependent diabetic
- You have severe allergies
- You have had a Herpes simplex or Herpes zoster infection that has affected your eyes

It will be necessary to use eye drops to enlarge your pupil to a certain size (7mm to 11mm) before surgery to optimize the tracker operation. This effect is only temporary.

G. Precautions

The safety and effectiveness of the LADARVision® system have **NOT** been established:

- In eyes with unstable or worsening myopia (nearsightedness)
- In eyes with disease or corneal condition (for example, scar, infection, etc.).
- In eyes with injury to the center of the cornea where PRK or LASIK will reshape the cornea
- In patients with a cornea that is too thin for the procedure to be completed safely
- In patients with a history of glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision)
- In patients with a tendency to form scars (PRK only)
- In patients who are taking the medication Sumatripin (Imitrex®).
- In patients under 21 years of age
- For the treatment of astigmatism less than 0.50 Diopters
- In patients over the long term (more than 12 months for PRK; 6 months for LASIK)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery).
- For PRK refractive treatments greater than -10.0D of myopia combined with greater than –4.0D of astigmatism.
- For LASIK refractive treatments greater than or equal to –9.0D of myopia combined with greater than or equal to –3D of astigmatism.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it mire difficult to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

In a contrast sensitivity study designed to assess the effects of LADARVision PRK surgery on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery.

In addition, U.S. clinical studies of the LADARVision® system have shown the following findings for PRK.

- Corneal infiltrates (inflammation) have been seen after PRK with the system in 1.6% of PRK eyes treated. All patients in the PRK study received bandage contact lenses and anti-inflammatory drops for pain management after surgery.

- Overcorrection of more than 1 Diopter with PRK has been associated with corrections of higher amounts of myopia, older patient age, and lower humidity in the laser room. An overcorrection is too much correction that may cause blurred distance and/or near vision without glasses.

H. What Are The Risks of PRK and of LASIK?

If the results of the surgery are not satisfactory, you may need to have additional PRK or LASIK surgery in the same eye.

PRK

The First Week Following PRK Surgery

- Pain and discomfort may last from 1 up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.
- You may have difficulty seeing in low light conditions (e.g. rain, snow, fog or glare).
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.

The First One To Six Months Following PRK Surgery

- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.

- Your cornea may become hazy or cloudy enough to affect your vision. Haze may occur as the cornea heals. The haze typically goes away over time. Some patients continue to have some haze over a longer period of time.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- You should contact your doctor if you notice any pain or change or loss of vision in the eye.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail in the following section. In U.S. clinical studies of the LADARVision® system, the following events related to the surgery have occurred. These events may result in a loss of vision.

Summary of PRK Adverse Events[1] and Complications[2]

	Mildly Nearsighted (n=386)	Mildly Nearsighted with Astigmatism (n=144)	Highly Nearsighted with and without Astigmatism (n=148)
Corneal Infiltrates (inflammation)[1]	1.3%	2.1%	2.0%
IOP increase above 25 mmHg[1]	0.5%	0.7%	2.7%
Feeling of something in the eye[2]	3.6%	7.6%	4.7%
Double or ghost images[2]	2.1%	5.6%	8.8%
Peripheral epithelial defect[2]	1.6%	1.4%	2.0%
Pain[2]	2.1%	2.1%	2.0%
Other[2]	3.9%	1.4%	4.1%

Other findings that occurred at a rate of less than or equal to 0.3% in all eyes treated (n=678) included:

- corneal edema (swelling in the cornea)
- corneal ulcer
- light sensitivity
- corneal erosion (a defect in the outer layer of the cornea that may recur)
- epithelial dots (small spots in the outer layer of the cornea with no adverse effects)
- epithelial irregularity (an area of the outer layer of the cornea that is not smooth)
- scratchiness (similar to a feeling of something in the eye)
- iritis (inflammation of the inside of the eye behind the cornea)
- ocular hypertension (an increase in the pressure inside the eye)
- subconjunctival hemorrhage (an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.)
- superficial punctate keratitis (surface irritation in the outer layer of the cornea)
- corneal foreign body (foreign debris in the outer layer of the cornea)
- nebula after foreign body removal (area of haze in outer layer of the cornea where foreign body was removed)
- retinal vascular accident (blockage of a blood vessel in the back of the eye unrelated to the surgery)

Other findings that occurred at a rate of less than or equal to 1.0% in all eyes treated (n=678) included:

- corneal abrasion (a scratch in the outer layer of the cornea often from an eye injury)
- halos/starbursts (circular or star-shaped flares of light that may appear around a headlight or other lighted object)

Other events that did not occur in this study that could occur following PRK include significant corneal haze and loss of best corrected visual acuity.

U.S. clinical studies of the LADARVision® system have shown the following conditions may occur after PRK surgery. At 12 months or more after surgery, some patients noted on a questionnaire that these conditions were significantly worse than before surgery, as shown in the table below.

	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Difficulty with night driving	2.1%	6.8%	9.4%
Glare	1.0%	1.7%	5.5%
Halos*	1.7%	3.4%	7.0%
Feeling of something in eye	0.0%	1.7%	2.3%
Fluctuation of vision	1.7%	0.0%	2.3%
Blurring of vision	0.3%	0.9%	2.3%
Light sensitivity	1.0%	0.0%	0.8%
Headache	0.0%	0.0%	0.0%
Double vision	0.7%	0.0%	1.6%
Pain	0.3%	0.9%	0.0%
Excessive tearing	0.0%	0.0%	0.0%
Burning	0.0%	0.0%	0.0%

* Halos are circular flares or rings of light that may appear around a headlight or other lighted object.

LASIK

On the day of LASIK Surgery

- In clinical studies of the LADARVision® system for LASIK surgery, the following adverse event was reported on the day of surgery (n=325) at a rate of 0.3%: miscreated flap (e.g. too small or irregular) related to use of the microkeratome. In this situation, laser ablation is not attempted. A new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

The First Week Following LASIK Surgery

- Pain, discomfort and a feeling of something in the eye may last from 1 up to 3 days after surgery.
- Blurred vision may be present for the first week as the corneal flap settles.
- Do not rub your eye as this may move the corneal flap. If you notice any sudden decrease in your vision, the corneal flap may have moved and you should contact your doctor immediately. The doctor may have to re-position the flap.
- Swelling of the eye may occur.
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.
- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.
- In clinical studies of the LADARVision® system for LASIK surgery, the following complications were reported within 1 week (n=313) at a rate of less than 1.0%: corneal folds/striae, epithelium in the interface, misaligned flap and sterile interface inflammation.

The First One Month Following LASIK Surgery

- You should contact your doctor if you notice any pain or change or loss of vision in the eye.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

In U.S. clinical studies of the LADARVision® system, the following adverse events and complications related to LASIK surgery have occurred at 1 month or later. These events may result in a loss of vision.

Summary of LASIK Adverse Events and Complications

	1 Month (n=316)		3 Months (n=310)		6 Months (n=260)		9 Months (n=111)	
	n/N	%	n/N	%	n/N	%	n/N	%
Induced astigmatism-flap decentration	1/316	0.3	1/310	0.3	0/260	0.0	0/111	0.0
Feeling of something in the eye	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Double/ghost images	2/316	0.6	1/310	0.3	1/260	0.4	0/111	0.0
Epithelium in the interface	3/316	0.9	3/310	1.0	1/260	0.4	0/111	0.0
Sterile Interface Inflammation	2/316	0.6	2/310	0.6	0/260	0.0	0/111	0.0
Serous Macular Edema	0/316	0.0	0/310	0.0	0/260	0.0	1/111	0.9
Corneal Folds/Striae/Wrinkle	4/316	1.3	2/310	0.6	2/260	0.8	0/111	0.0
Interface debris	10/316	3.2	12/310	3.9	11/260	4.2	0/111	0.0
Interface haze/opacity	7/316	2.2	10/310	3.2	1/260	0.4	1/111	0.9
Superficial punctate keratitis (SPK)	15/316	4.7	8/310	2.6	6/260	2.3	3/111	2.7
Oil droplets/sheen	5/316	1.6	0/310	0.0	2/260	0.8	0/111	0.0
Flap distortion	1/316	0.3	0/310	0.0	0/260	0.0	0/111	0.0
Fibrotic healing at flap edge	0/316	0.0	3/310	1.0	2/260	0.8	0/111	0.0
Epithelial defect	0/316	0.0	0/310	0.0	1/260	0.4	0/111	0.0
Conjunctival injection	0/316	0.0	0/310	0.0	2/260	0.8	0/111	0.0

The following other adverse events and complications occurred at unscheduled visits at 1 month or later:

- IOP increase >10 mmHg above baseline (3 eyes): increase in the pressure in the eye
- HSV dendrite (1 eye): a branching tree-like lesion on the cornea due to herpes simplex infection
- corneal folds/striae/wrinkles (2 eyes): the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling
- interface haze/opacity (3 eyes): a cloudiness of the cornea underneath the flap, either diffuse or in localized areas
- superficial punctate keratitis (13 eyes): surface irritation in the outer layer of the cornea
- peau d' orange (2 eyes): orange peel corneal appearance that typically does not affect vision
- flap distortion (1 eye): irregular appearance of the corneal flap
- vacuoles (1 eye): small round areas of cellular debris that typically does not affect vision
- conjunctival injection (2 eyes): increased redness of the blood vessels in the front of the eye

The following ocular findings were reported at 6 months (n=260) at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters.

U.S. clinical studies of the LADARVision® system have shown the following conditions may occur after LASIK surgery. At 6 months after surgery, some patients noted these conditions were significantly worse than before surgery, as shown in the table below.

Subjective Responses	Eyes Without Astigmatism		Eyes With Astigmatism	
	n/N	%	n/N	%
Difficulty with night driving	8/140	5.7	15/101	14.9
Glare	4/141	2.8	10/101	9.9
Halos*	5/141	3.5	7/101	6.9
Light sensitivity	4/141	2.8	6/101	5.9
Dryness	6/141	4.3	3/101	3.0
Fluctuation of vision	3/141	2.1	2/101	2.0
Blurring of vision	3/141	2.1	1/101	1.0
Redness	1/141	0.7	2/101	1.0
Headache	1/141	0.7	0/101	0.0
Double vision	1/139	0.7	0/101	0.0
Pain	0/141	0.0	0/101	0.0
Excessive tearing	0/141	0.0	0/100	0.0
Burning	0/141	0.0	0/100	0.0
Feeling of something in eye	0/141	0.0	0/101	0.0

* Halos are circular flares or rings of light that may appear around a headlight or other lighted object.

I. Are You A Good Candidate For PRK or LASIK ?

If you are considering PRK or LASIK, you must:

- Be at least 21 years of age
- Have healthy eyes that are free from eye disease or corneal condition (for example, scar, infection, etc.)
- Have myopia between 0 to -10.0 diopters with no more than 4.0 diopters of astigmatism for PRK or have myopia less than –9.0D with less than –3.0D of astigmatism for LASIK
- Have documented evidence that the change in your nearsightedness is less than or equal to 0.50 diopter per year for corrections up to 7D, and less than or equal to 0.75D for corrections greater than 7D.
- at least one year prior to your pre-operative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the PRK or LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of PRK or LASIK risks and benefits as compared to other available treatments for myopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

J. What Should You Expect During PRK or LASIK Surgery?

PRK surgery is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes in the first eye without complications or adverse reactions. Laser surgery of the second eye is usually done after the first eye if needed.

LASIK surgery can be performed one eye at a time or on both eyes during the same surgical session.

Before The Surgery

First, you will need to have a pre-operative examination if you have an interest in PRK or LASIK. This exam will help to determine if your eye is healthy and suitable for PRK or LASIK. This exam will include a complete medical and eye history, and a complete evaluation of both eyes. In addition, this examination will involve mapping your cornea with a computer to determine if it is smooth and properly shaped.

> **WARNING:**
> If you wear contact lenses, it is very important to stop wearing them at least 3 weeks before the evaluation. Failure to do this will produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, talk with your doctor about eating or drinking right before the surgery. You should also arrange for transportation, since **you must not drive right after the surgery. Your doctor will inform you of when you can resume driving.**

The Day Of Surgery

Before the surgery, your doctor will ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that does not recline or move. Your doctor will instruct you to watch a blinking light. Your doctor will take a picture of your eye to aid in determining the correct placement of the treatment on the cornea. Your doctor will not apply any laser pulses at this time. Your doctor will then put drops in your operative eye to dilate (enlarge) your pupil.

About 30-40 minutes later, your doctor will place anesthetic (numbing) drops into your eye. Your doctor will escort you back into the room with the laser. You will again lie on your back and look up at a microscope that will deliver the laser light to your cornea. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye not having surgery.

PRK surgery begins with removal of the outer layer of the cornea. Your doctor will remove this layer with a small spatula or a rotary brush. LASIK surgery begins with the creation of a corneal flap with a microkeratome. Then, your doctor will reposition your head and activate the tracker. Your doctor will ask you to look directly at a blinking light. The laser in the LADARVision® system will remove small amounts of tissue from your cornea. The tracker will follow eye movements and allow the laser to continue the treatment. Still, it is important to continue looking at the blinking light throughout the treatment.

You will be under the laser for several minutes. Overall, the surgery takes about 10 minutes. After the laser surgery is complete, your doctor will place some drops into your eye. For your eye protection and comfort, your doctor will cover your eye with a bandage contact lens in PRK. In some LASIK cases, a bandage contact lens is placed in your eye as well to help heal small abrasions. The surgery is painless because of the numbing drops. The numbing drops will wear off in about 45-60 minutes. After this time, your eye may hurt for 1 to 3 days.

WARNING:

Your doctor will monitor you for any side effects if you need to use topical steroids. Possible side effects of extended 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).

The First Days After Surgery

If a bandage contact lens was applied to the eye after surgery, your doctor will remove the bandage contact lens on the day the surface of your eye has recovered. You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

DO NOT rub your eyes for the first 3 to 5 days. You may be provided with a plastic shield for eye protection after LASIK for the first few days. Your doctor can also prescribe pain medication to make you more comfortable during this time after the surgery.

Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

A haze or cloudiness of the cornea will typically occur after PRK surgery. This haze usually does not affect vision. This haze tends to decrease over time and usually disappears completely over a 3 to 6 month period.

IMPORTANT:

Use the antibiotic eye drops, anti-inflammatory eye drops and lubricants as directed by your doctor. Your results depend upon your following your doctor's directions.

K. Questions To Ask Your Doctor

You may want to ask the following questions to help you decide if PRK or LASIK 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 PRK or LASIK for my amount of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If PRK or 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 PRK or LASIK if I need them?
- How is PRK or 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 PRK or LASIK?
- Should I have PRK or 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 PRK or LASIK only on one eye?

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

L. Self-Test?

Are You An Informed And Educated Patient?

Take the test below and see if you can correctly answer these 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 when my doctor told me not to wear them.	☐	☐
4. Since the LADARVision® system tracks my eye movements, I do not have to fixate on the blinking light.	☐	☐
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	☐	☐
6. I may need reading glasses after laser surgery.	☐	☐
7. There is a risk that I may lose some vision after laser surgery.	☐	☐
8. It does not matter if I am pregnant.	☐	☐
9. If I have an autoimmune disease, I am still a good candidate for PRK or LASIK.	☐	☐

You can find the answers to Self-Test at the bottom of Page 26.

M. Summary Of Important Information?

- PRK or LASIK are permanent operations to the cornea and are irreversible.
- PRK or LASIK do not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before PRK or LASIK surgery. You will need written evidence that your nearsightedness has changed less than or equal to 0.50 Diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- 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.
- PRK or LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- PRK or LASIK are not a laser version of Radial Keratotomy (RK). These surgeries are entirely different from each other.
- Alternatives to PRK or LASIK include, but are not limited to, glasses, contact lenses and RK.
- The vision requirements of some occupations, such as military pilots, cannot be met by having RK, PRK, or LASIK.
- Before considering PRK or LASIK surgery you should:

  a. Have a complete eye examination.

  b. Talk with one or more eye care professionals about PRK or LASIK. This talk should include the potential benefits, risks, and complications of PRK or LASIK surgery. In addition, you should discuss the time needed for healing after PRK or LASIK.

Answers to Self-Test Questions:
1. False (see Risks on Page 16); 2. False (see Introduction on Page 10); 3. False (see Before the Surgery on Page 22); 4. False (see The Day of Surgery on Page 22); 5. True (see Benefits on Page 13); 6. True (see Introduction on Page 10); 7. True (see Risks on Page 16); 8. False (see Contraindications on Page 14); 9. False (see Contraindications on Page 14).

N. Patient Assistance Information?

To be completed by you or your Primary Eye Care Professional as a reference.

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

PRK DOCTOR

Name: _____

Address: _____

Phone: _____

TREATMENT LOCATION

Name: _____

Address: _____

Phone: _____

LASER MANUFACTURER

Summit Autonomous, Inc.
2501 Discovery Drive, Suite 500
Orlando, FL 32826 U.S.A.
Tel: (877)523-2784 Fax: (407) 384-1677

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