

**SUMMIT AUTONOMOUS INC.**  
**LADARVision® EXCIMER LASER SYSTEM**  
**PROFESSIONAL USE INFORMATION MANUAL FOR**  
**LASER IN-SITU KERATOMILEUSIS (LASIK)**  
**HYPEROPIA AND ASTIGMATISM**

**PHYSICIAN'S BOOKLET**

For Hyperopia with or without Astigmatism and Mixed Astigmatism  
(Sphere up to + 6.00 D and Cylinder up to -6.00D)

**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) <sup>a</sup>	0.80 - 0.90
Average fluence (mJ/cm <sup>2</sup> ) <sup>b</sup>	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<sup>®</sup> 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 Laser In-Situ Keratomileusis (LASIK) treatments for the reduction or elimination of refractive error of less than or equal +6.00D of sphere and -6.00D of cylinder at the spectacle plane (hyperopia with or without astigmatism and mixed astigmatism).
- 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 +6.00D 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

LASIK is contraindicated:

- In patients with signs of keratoconus
- In pregnant or nursing women
- 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

LASIK is 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.

The microkeratome should create a flap large enough to allow for treatment zone of 9.00 mm needed for this procedure.

### D. PRECAUTIONS

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

- In patients with 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 who are taking the medication Sumatriptin (Imitrex®)
- In patients under 21 years of age
- In patients over the long term (9 months for LASIK)
- In non-Caucasian patients
- For the treatment of astigmatism less than 0.50 Diopters
- For treatments greater than +6.0D of hyperopia or -6.0D of astigmatism
- For retreatments of hyperopia, hyperopic astigmatism or mixed 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.

Eyes with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of hyperopia.

Hyperopic astigmatism eyes with greater than 4.0D MRSE preoperatively may have lower predictability of refractive outcome and improvement in uncorrected visual acuity than eyes with lower levels of MRSE. These eyes may be more likely to experience a reduction of two lines in their best-corrected visual acuity and to require retreatment

Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity of 20/20 or better.

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.

#### **E. ADVERSE EVENTS AND COMPLICATIONS**

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

Each of the following complications was reported on the day of surgery (n=360) at a rate of 0.3%: epithelial defect and misaligned flap. The following adverse event was reported on the day of surgery at a rate of 0.8%: miscreated flap related to use of the microkeratome.

Each of the following complications was reported at the 1 week visit (n=354) at a rate of 0.6% or less: corneal folds/striae, corneal swelling, epithelium in interface, and intralamellar haze. The complication of sterile interface inflammation was reported at 1 week at a rate of 2.0%. Each of the following adverse reactions was reported at 1 week at a rate of 0.8% or less: corneal infiltrate and increase in intraocular pressure.

Each of the following complications was reported only at unscheduled visits within the first two weeks after primary treatment or retreatment: corneal swelling (4 eyes), epithelium in the interface (1 eye), and sterile interface inflammation (2 eyes). In addition, one patient with a history of heart disease experienced a myocardial infarction (heart attack) two weeks after surgery, which was not related to the LASIK procedure or to the LADARVision system.

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		3 Months		6 Months		9 Months	
	n/N	%	n/N	%	n/N	%	n/N	%
<b>ADVERSE EVENTS</b>								
Rolled flap edge with trace corneal melt	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
<b>COMPLICATIONS</b>								
Corneal abrasion	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
Corneal folds/Striae/Wrinkles	3/353	0.8	0/344	0.0	0/324	0.0	1/265	0.4
Corneal opacities	3/353	0.8	6/344	1.7	1/324	0.3	2/265	0.8
Double/ghost images	2/353	0.6	2/344	0.6	5/324	1.5	2/265	0.8
Epithelium in the interface	6/353	1.7	7/344	2.0	5/324	1.5	3/265	1.1
Feeling of something in the eye	2/353	0.6	2/344	0.6	1/324	0.3	0/265	0.0
Interface debris	10/353	2.8	7/344	2.0	5/324	1.5	1/265	0.4
Irregular epithelium	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Iron line or ring	0/353	0.0	0/344	0.0	1/324	0.3	2/265	0.8
Isolated cells in interface	0/353	0.0	1/344	0.3	2/324	0.6	1/265	0.4
Lagophthalmos	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Pain	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Sterile interface inflammation	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Superficial punctate keratitis (SPK)	20/353	5.7	17/344	4.9	10/324	3.1	14/265	5.3

The following other complications occurred at unscheduled visits at 1 month or later: superficial punctate keratitis (14 eyes); interface debris (8 eyes); corneal folds/striae/wrinkles (4 eyes); iron line/ring (3 eyes); corneal opacities (2 eyes); trichiasis (1 eye); subconjunctival hemorrhage (1 eye); conjunctival injection (1 eye); and vacuoles (1 eye).

Each of the following ocular findings was reported at 6 months (n=265) at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen.

Lens findings were reported postoperatively in 14 eyes of 8 patients. All of these patients experienced lens changes due to age (range 59 to 73 years old). These findings included nuclear sclerosis, cortical spoking, and posterior subcapsular cataract. No eyes had a loss of more than 2 lines of best spectacle corrected visual acuity (BCVA). Only one eye had a related loss of 2 lines of BSCVA. All eyes had a last-reported BSCVA of 20/32 or better.

The following other complications occurred at 1 to 6 months after retreatment: epithelium in the interface (3 eyes) and double/ghost images (4 eyes).

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

**Subjective Symptoms at 6 Months**

	Spherical Hyperopia			Hyperopic Astigmatism			Mixed Astigmatism		
		Worse	Significantly Worse		Worse	Significantly Worse		Worse	Significantly Worse
	<i>N</i>	%	%	<i>N</i>	%	%	<i>N</i>	%	%
Blurring of vision	132	9.8	1.5	111	15.3	1.8	53	7.5	3.8
Burning	133	2.3	0.8	113	8.0	1.8	53	7.5	0.0
Double vision	132	8.3	1.5	111	6.3	3.6	53	1.9	0.0
Dryness	132	16.7	3.0	113	17.7	5.3	53	24.5	1.9
Excessive tearing	132	1.5	0.0	111	1.8	0.0	52	0.0	0.0
Feeling of something in eye	133	5.3	1.5	113	5.3	2.7	53	5.7	0.0
Fluctuation of vision	133	15.8	6.0	111	20.7	1.8	53	11.3	0.0
Glare	133	21.8	0.8	113	18.6	1.8	53	22.6	0.0
Halos	132	12.9	2.3	111	20.7	4.5	53	26.4	0.0
Headache	132	3.0	0.0	110	2.7	1.8	53	3.8	0.0
Light sensitivity	133	26.3	1.5	112	21.4	1.8	53	20.8	0.0
Night driving difficulty	133	9.0	2.3	113	14.2	1.8	53	13.2	7.5
Pain	132	3.0	0.8	110	4.5	0.9	53	3.8	0.0
Redness	133	11.3	0.8	112	5.4	2.7	53	3.8	0.0

## 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 hyperopia with or without astigmatism. Eligibility criteria for patients included: being at least 18 years of age; eyes with up to +6D of hyperopia 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 0.50D 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
- severe dry eye syndrome unresolved by treatment
- previous corneal or intraocular surgery
- glaucoma
- use of systemic medications likely to affect wound healing
- risk of angle closure
- risk of developing strabismus post-treatment
- 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 have been stratified into 3 groups:

- (1) **Spherical hyperopia** – 152 eyes with up to +6D sphere and  $\leq -0.75$ D cylinder.
- (2) **Hyperopic astigmatism** – 143 eyes with +1 to 6D sphere and cylinder in the range of -0.50 to -6D.
- (3) **Mixed astigmatism** – 65 eyes with up to +5D sphere and cylinder in the range of -1.25 to -6D.

The LADARVision's treatment of eyes with a sphere of less than 2.0 D with and without hyperopic or mixed astigmatism was modified subsequent to the clinical trial in an attempt to avoid the overcorrection observed in the trial outcomes. The data reported below are from the clinical trial and do not reflect the modification that was made.

**B. SPHERICAL HYPEROPIA: LASIK**

**1. Demographics (LASIK Spherical Hyperopia)**

<b>TABLE 1</b>			
<b>DEMOGRAPHICS (LASIK SPHERICAL HYPEROPIA)</b>			
152 Eyes of 86 Enrolled Patients			
	Number	Percentage	
Gender:	Female	87	57.2
	Male	65	42.8
Race:	Caucasian	151	99.3
	Hispanic	1	0.7
Age (yrs):	Average ± SD	56.5 ± 6.9	
	Range	38 to 72	
Contact Lens History:	None	82	53.9
	Soft	69	45.4
	RGP	1	0.7
	PMMA	0	0.0

**2. Baseline Parameters (LASIK Spherical Hyperopia)**

<b>TABLE 2</b>		
<b>BASELINE PARAMETERS (LASIK SPHERICAL HYPEROPIA)</b>		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	+2.56 ± 1.16	+0.875 to +6.00
Sphere	+2.68 ± 1.18	+1.00 to +6.00
Cylinder	-0.24 ± 0.23	0.00 to -0.75
Preoperative UCVA*	n	%
20/100 or worse	74	59.2
20/50 to 20/80	42	33.6
20/25 to 20/40	8	6.4
≤20/20	1	0.8
Preoperative Manifest BSCVA	n	%
20/25 to 20/40	11	7.2
≤20/20	141	92.8

\* not including monovision

## 3. Safety and Efficacy Results (LASIK Spherical Hyperopia)

TABLE 3 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES SPHERICAL HYPEROPIA UP TO +6D					
Efficacy Variables		1 Month	3 Months	6 Months	9 Months
<b>BSCVA <math>\geq</math> 20/20 Preop*</b>					
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	45/118	57/117	57/115	49/97
	%	38.1%	48.7%	49.6%	50.5%
	CI	(29.4, 47.5)	(39.4, 58.1)	(40.1, 59.0)	(40.2, 60.8)
UCVA 20/20 or better *	n	46/124	57/123	59/121	49/103
	%	37.1%	46.3%	48.8%	47.6%
	CI	(28.6, 46.2)	(37.3, 55.6)	(39.6, 58.0)	(37.6, 57.7)
UCVA 20/25 or better*	n	74/124	85/123	83/121	73/103
	%	59.7%	69.1%	68.6%	70.9%
	CI	(50.5, 68.4)	(60.1, 77.1)	(59.5, 76.7)	(61.1, 79.4)
UCVA 20/40 or better *	n	114/124	113/123	113/121	98/103
	%	91.9%	91.9%	93.4%	95.1%
	CI	(85.7, 96.1)	(85.6, 96.0)	(87.4, 97.1)	(89.0, 98.4)
<b>MRSE <math>\pm</math>0.50D of intended</b>					
MRSE $\pm$ 1.00D of intended	n	100/149	102/149	93/143	81/120
	%	67.1%	68.5%	65.0%	67.5%
	CI	(59.0, 74.6)	(60.4, 75.8)	(56.6, 72.8)	(58.4, 75.8)
MRSE $\pm$ 2.00D of intended	n	131/149	133/149	125/143	106/120
	%	87.9%	89.3%	87.4%	88.3%
	CI	(81.6, 92.7)	(83.2, 93.7)	(80.8, 92.4)	(81.2, 93.5)
MRSE $\pm$ 2.00D of intended	n	147/149	145/149	141/143	119/120
	%	98.7%	97.3%	98.6%	99.2%
	CI	(95.2, 99.8)	(93.3, 99.3)	(95.0, 99.8)	(95.4, 100.0)
<b>Safety Variables</b>					
Loss of >2 Lines BSCVA	n	3/149	0/149	0/141	0/118
	%	2.0%	0.0%	0.0%	0.0%
	CI	(0.0, 5.8)	(0.0, 2.5)	(0.0, 2.6)	(0.0, 3.1)
Loss of 2 Lines BSCVA	n	14/149	8/149	5/141	4/118
	%	9.4%	5.4%	3.5%	3.4%
	CI	(5.2, 15.3)	(2.4, 10.3)	(1.2, 8.1)	(0.0, 8.5)
BSCVA worse than 20/40	n	0/149	0/149	0/141	0/118
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 2.5)	(0.0, 2.5)	(0.0, 2.6)	(0.0, 3.1)
Increase >1D Cylinder	n	5/149	7/149	6/143	8/120
	%	3.4%	4.7%	4.2%	6.7%
	CI	(1.1, 7.7)	(1.9, 9.4)	(1.6, 8.9)	(2.9, 12.7)
Increase >2D Cylinder	n	1/149	0/149	0/143	0/120
	%	0.7%	0.0%	0.0%	0.0%
	CI	(0.0, 3.7)	(0.0, 2.5)	(0.0, 2.6)	(0.0, 3.0)
<b>BSCVA <math>\geq</math> 20/20 Preop</b>					
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	10/138	5/138	2/132	2/109
	%	7.2%	3.6%	1.5%	1.8%
	CI	(3.5, 12.9)	(1.2, 8.3)	(0.2, 5.4)	(0.2, 6.5)

\*Not including monovision eyes

CI = 95% Confidence Interval

**TABLE 4**  
**SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES**  
**SPHERICAL HYPEROPIA UP TO +6D STRATIFIED BY DIOPTR (SPHERICAL**  
**EQUIVALENT) - 6 MONTHS**

Efficacy Variables	SE	0 to 0.99	1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.0 to 6.00	Cum Total
<b>BSCVA ≥ 20/20 Preop*</b>								
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n %	1/1 100.0%	26/41 63.4%	21/44 47.7%	5/15 33.3%	4/10 40.0%	0/4 0.0%	57/115 49.6%
UCVA 20/20* or better	n %	1/1 100.0%	27/42 64.3%	21/44 47.7%	5/15 33.3%	4/10 40.0%	1/9 11.1%	59/121 48.8%
UCVA 20/25* or better	n %	1/1 100.0%	34/42 81.0%	31/44 70.5%	8/15 53.3%	6/10 60.0%	3/9 33.3%	83/121 68.6%
UCVA 20/40* or better	n %	1/1 100.0%	42/42 100.0%	43/44 97.7%	11/15 73.3%	9/10 90.0%	7/9 77.8%	113/121 93.4%
MRSE ±0.50D of intended	n %	1/1 100.0%	38/53 71.7%	38/50 76.0%	7/18 38.9%	6/11 54.5%	3/10 30.0%	93/143 65.0%
MRSE ±1.00D of intended	n %	1/1 100.0%	50/53 94.3%	47/50 94.0%	13/18 72.2%	9/11 81.8%	5/10 50.0%	125/143 87.4%
MRSE ±2.00D of intended	n %	1/1 100.0%	52/53 98.1%	50/50 100.0%	18/18 100.0%	11/11 100.0%	9/10 90.0%	141/143 98.6%
<b>Safety Variables</b>								
Loss of >2 Lines BSCVA	n %	0/1 0.0%	0/53 0.0%	0/49 0.0%	0/17 0.0%	0/11 0.0%	0/10 0.0%	0/141 0.0%
Loss of 2 Lines BSCVA	n %	0/1 0.0%	3/53 5.7%	1/49 2.0%	0/17 0.0%	0/11 0.0%	1/10 10.0%	5/141 3.5%
BSCVA worse than 20/40	n %	0/1 0.0%	0/53 0.0%	0/49 0.0%	0/17 0.0%	0/11 0.0%	0/10 0.0%	0/141 0.0%
Increase >1D Cylinder	n %	0/1 0.0%	2/53 3.8%	1/50 2.0%	1/18 5.6%	0/11 0.0%	2/10 20.0%	6/143 4.2%
Increase >2D Cylinder	n %	0/1 0.0%	0/53 0.0%	0/50 0.0%	0/18 0.0%	0/11 0.0%	0/10 0.0%	0/143 0.0%
<b>BSCVA ≥ 20/20 Preop</b>								
BSCVA worse than 20/25 if 20/20 or better preoperatively	n %	0/1 0.0%	1/51 2.0%	1/48 2.0%	0/17 0.0%	0/10 0.0%	0/5 0.0%	2/132 1.5%

\*Not including monovision eyes

Near UCVA was J3 (20/40) or better in 2.0% of all eyes preoperatively and 37.8% of 123 eyes treated for emmetropia at 6 months. For 20 eyes targeted for monovision, near UCVA was J3 or better in 90.0% at 6 months.

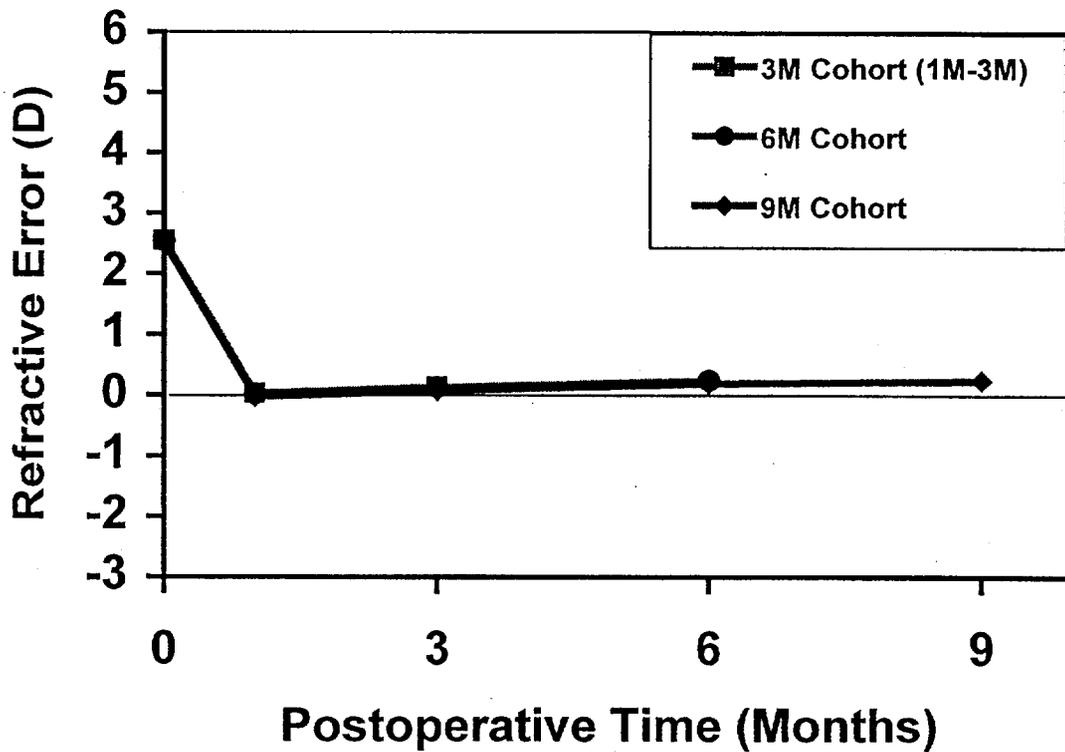


Figure 1. Manifest Refraction vs. Postop Time

Mean ± SD	n	Preop	1 Month	3 Months	6 Months	9 Months
3M Cohort (1M-3M)†	121	+2.55 ± 1.20	+0.03 ± 0.62	+0.14 ± 0.64	--	--
6M Cohort†	117	+2.55 ± 1.21	+0.02 ± 0.58	+0.13 ± 0.58	+0.24 ± 0.61	--
9M Cohort†	102	+2.51 ± 1.21	-0.03 ± 0.55	+0.07 ± 0.56	+0.19 ± 0.60	+0.24 ± 0.64
Entire Cohort (All Available Eyes)	--	+2.52 ± 1.19	+0.02 ± 0.62	+0.14 ± 0.63	+0.24 ± 0.60	+0.24 ± 0.64

\* Not including monovision

† Reflects consistent cohort at each visit.

<b>TABLE 6</b>			
<b>SPHERICAL HYPEROPIA STABILITY OF MANIFEST REFRACTION</b>			
<b>SPHERICAL EQUIVALENT: 6 MONTH COHORT</b>			
Change in Spherical Equivalent Between		1 and 3 Months (n=138)	3 and 6 Months (n=138)
≤1.00	n %	133 96.4%	130 94.2%
Mean Difference		+0.11	+0.12
SD		0.46	0.48
95% CI		(0.03, 0.19)	(0.04, 0.20)

<b>TABLE 7</b>				
<b>SPHERICAL HYPEROPIA STABILITY OF MANIFEST REFRACTION</b>				
<b>SPHERICAL EQUIVALENT: 9 MONTH COHORT</b>				
Change in Spherical Equivalent Between		1 and 3 Months (n=119)	3 and 6 Months (n=119)	6 and 9 Months (n=119)
≤1.00	n %	115 96.6%	112 94.1%	115 96.6%
Mean Difference		+0.08	+0.14	+0.03
SD		0.43	0.47	0.54
95% CI		(0.01, 0.16)	(0.06, 0.23)	(-0.07, 0.12)

#### 4. Patient Questionnaire Responses (LASIK Spherical Hyperopia)

At 6 months (n=133), subjects reported that their satisfaction with their results was as follows: 39.8% extremely satisfied, 36.1% satisfied, 12.0% not sure, 12.0% unsatisfied, and 0.0% extremely unsatisfied. Subjects reported that their quality of vision at 6 months (n=132) after surgery as compared to before surgery was as follows: 47.7% significantly better, 27.3% better, 20.5% unchanged, 4.5% worse, and 0.0% significantly worse. Postoperatively, distance correction was never used by 94.5% of subjects and near correction was not used by 30.8%.

Subjective Responses	N	Significantly Better	Better	No Change	Worse	Significantly Worse
		%	%	%	%	%
Blurring of vision	132	23.5	20.5	44.7	9.8	1.5
Burning	133	14.3	12.8	69.9	2.3	0.8
Double vision	132	14.4	10.6	65.2	8.3	1.5
Dryness	132	12.1	10.6	57.6	16.7	3.0
Excessive tearing	132	13.6	9.1	75.8	1.5	0.0
Feeling of something in eye	133	12.8	10.5	69.9	5.3	1.5
Fluctuation of vision	133	14.3	9.0	54.9	15.8	6.0
Glare	133	8.3	14.3	54.9	21.8	0.8
Halos	132	8.3	14.4	62.1	12.9	2.3
Headache	132	12.9	9.1	75.0	3.0	0.0
Light sensitivity	133	9.0	17.3	45.9	26.3	1.5
Night driving difficulty	133	14.3	20.3	54.1	9.0	2.3
Pain	132	15.2	5.3	75.8	3.0	0.8
Redness	133	12.8	9.0	66.2	11.3	0.8

**C. HYPEROPIA WITH ASTIGMATISM: LASIK**

1. Demographics (LASIK Hyperopia with Astigmatism)

<b>TABLE 9</b>			
<b>DEMOGRAPHICS (LASIK HYPEROPIA WITH ASTIGMATISM)</b>			
143 Eyes of 80 Subjects Enrolled			
		Number	Percentage
Gender:	Female	74	51.7
	Male	69	48.3
Race:	Caucasian	139	97.2
	Hispanic	4	2.8
Age (yrs):	Average ± SD	53.8 ± 11.3	
	Range	22 to 75	
Contact Lens History:	None	73	51.0
	Soft	56	39.2
	RGP	13	9.1
	PMMA	1	0.7

2. Baseline Parameters (LASIK Hyperopia with Astigmatism)

<b>TABLE 10</b>		
<b>BASELINE PARAMETERS (LASIK HYPEROPIA WITH ASTIGMATISM)</b>		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	+2.84 ± 1.26	+0.50 to +5.75
Sphere	+3.65 ± 1.45	+1.00 to +6.00
Cylinder	-1.62 ± 1.24	-0.50 to -6.00
Preoperative UCVA*	n	%
20/100 or worse	76	59.4
20/50 to 20/80	41	32.0
20/25 to 20/40	11	8.6
≤20/20	0	0.0
Preoperative Manifest BSCVA	n	%
20/25 to 20/40	23	16.4
≤20/20	117	83.6

\* not including monovision

## 3. Safety and Efficacy Results (LASIK Hyperopia with Astigmatism)

TABLE 11 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES HYPEROPIC ASTIGMATISM UP TO +6D SPH/-6D CYL					
Efficacy Variables		1 Month	3 Months	6 Months	9 Months
<b>BSCVA <math>\geq</math> 20/20 Preop*</b>					
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n % CI	33/101 32.7% (23.7, 42.7)	39/95 41.1% (31.1, 51.6)	38/88 43.2% (32.7, 54.2)	38/66 57.6% (44.8, 69.7)
UCVA 20/20 or better *	n % CI	34/124 27.4% (19.8, 36.2)	42/120 35.0% (26.5, 44.2)	41/110 37.3% (28.2, 47.0)	43/83 51.8% (40.6, 62.9)
UCVA 20/25 or better*	n % CI	52/124 41.9% (33.1, 51.1)	69/120 57.5% (48.2, 66.5)	66/110 60.0% (50.2, 69.2)	59/83 71.1% (60.1, 80.5)
UCVA 20/40 or better *	n % CI	104/124 83.9% (76.2, 89.9)	100/120 83.3% (75.4, 89.5)	100/110 90.9% (83.9, 95.6)	79/83 95.2% (88.1, 98.7)
MRSE $\pm$ 0.50D of intended	n % CI	92/138 66.7% (58.1, 74.5)	87/133 65.4% (56.7, 73.4)	75/124 60.5% (51.3, 69.1)	66/94 70.2% (59.9, 79.2)
MRSE $\pm$ 1.00D of intended	n % CI	121/138 87.7% (81.0, 92.7)	115/133 86.5% (79.5, 91.8)	110/124 88.7% (81.8, 93.7)	86/94 91.5% (83.9, 96.3)
MRSE $\pm$ 2.00D of intended	n % CI	136/138 98.6% (94.9, 99.8)	132/133 99.2% (95.9, 100.0)	123/124 99.2% (95.6, 100.0)	93/94 98.9% (94.2, 100.0)
<b>Safety Variables</b>					
Loss of >2 Lines BSCVA	n % CI	3/135 2.2% (0.5, 6.4)	0/127 0.0% (0.0, 2.9)	0/121 0.0% (0.0, 3.0)	0/90 0.0% (0.0, 4.0)
Loss of 2 Lines BSCVA	n % CI	16/135 11.9% (6.9, 18.5)	7/127 5.5% (2.2, 11.0)	7/121 5.8% (2.4, 11.6)	4/90 4.4% (1.2, 11.0)
BSCVA worse than 20/40	n % CI	1/138 0.7% (0.0, 4.0)	0/130 0.0% (0.0, 2.8)	0/124 0.0% (0.0, 2.9)	0/93 0.0% (0.0, 3.9)
Increase >1D Cylinder	n % CI	0/138 0.0% (0.0, 2.6)	0/133 0.0% (0.0, 2.7)	0/124 0.0% (0.0, 2.9)	0/94 0.0% (0.0, 3.9)
Increase >2D Cylinder	n % CI	0/138 0.0% (0.0, 2.6)	0/133 0.0% (0.0, 2.7)	0/124 0.0% (0.0, 2.9)	0/94 0.0% (0.0, 3.9)
<b>BSCVA <math>\geq</math> 20/20 Preop</b>					
BSCVA worse than 20/25 if 20/20 or better preoperatively	n % CI	8/114 7.0% (3.1, 13.4)	2/107 1.9% (0.2, 6.6)	3/101 3.0% (0.6, 8.4)	0/75 0.0% (0.0, 4.8)

\*Not including monovision eyes

CI = 95% Confidence Interval.

**TABLE 12**  
**SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES**  
**HYPEROPIC ASTIGMATISM UP TO +6D STRATIFIED BY DIOPTR**  
**(SPHERICAL EQUIVALENT) - 6 MONTHS**

Efficacy Variables	SE	0 to 0.99	1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.0 to 6.00	Cum Total
<b>BSCVA ≥ 20/20 PREOP*</b>								
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n %	1/1 100.0%	10/24 41.7%	14/29 48.3%	8/15 53.3%	3/13 23.1%	2/6 33.3%	38/88 43.2%
UCVA 20/20* or better	n %	1/1 100.0%	11/30 36.7%	15/35 42.9%	9/19 47.4%	3/17 17.6%	2/8 25.0%	41/110 37.3%
UCVA 20/25* or better	n %	1/1 100.0%	19/30 63.3%	26/35 74.3%	12/19 63.2%	5/17 29.4%	3/8 37.5%	66/110 60.0%
UCVA 20/40* or better	n %	1/1 100.0%	29/30 96.7%	33/35 94.3%	16/19 84.2%	14/17 82.4%	7/8 87.5%	100/110 90.9%
MRSE ±0.50D of intended	n %	2/4 50.0%	24/34 70.6%	27/38 71.1%	13/22 59.1%	5/18 27.8%	4/8 50.0%	75/124 60.5%
MRSE ±1.00D of intended	n %	3/4 75.0%	34/34 100.0%	35/38 92.1%	18/22 81.8%	13/18 72.2%	7/8 87.5%	110/124 88.7%
MRSE ±2.00D of intended	n %	4/4 100.0%	34/34 100.0%	38/38 100.0%	22/22 100.0%	18/18 100.0%	7/8 87.5%	123/124 99.2%
<b>Safety Variables</b>								
Loss of >2 Lines BSCVA	n %	0/4 0.0%	0/34 0.0%	0/36 0.0%	0/22 0.0%	0/18 0.0%	0/7 0.0%	0/121 0.0%
Loss of 2 Lines BSCVA	n %	0/4 0.0%	3/34 8.8%	0/36 0.0%	0/22 0.0%	3/18 16.7%	1/7 14.3%	7/121 5.8%
BSCVA worse than 20/40	n %	0/4 0.0%	0/34 0.0%	0/38 0.0%	0/22 0.0%	0/18 0.0%	0/8 0.0%	0/124 0.0%
Increase >1D Cylinder	n %	0/4 0.0%	0/34 0.0%	0/38 0.0%	0/22 0.0%	0/18 0.0%	0/8 0.0%	0/124 0.0%
Increase >2D Cylinder	n %	0/4 0.0%	0/34 0.0%	0/38 0.0%	0/22 0.0%	0/18 0.0%	0/8 0.0%	0/124 0.0%
<b>BSCVA ≥ 20/20 Preop</b>								
BSCVA worse than 20/25 if 20/20 or better preoperatively	n %	0/4 0.0%	0/27 0.0%	0/32 0.0%	0/18 0.0%	3/14** 21.4%	0/6 0.0%	3/101 3.0%

\*Not including monovision eyes

\*\* All eyes had a BSCVA of 20/32

Near UCVA was J3 (20/40) or better in 8.5% of all eyes preoperatively and 36.9% of 126 eyes treated for emmetropia at 6 months. For 14 eyes targeted for monovision, near UCVA was J3 or better in 64.3% at 6 months.

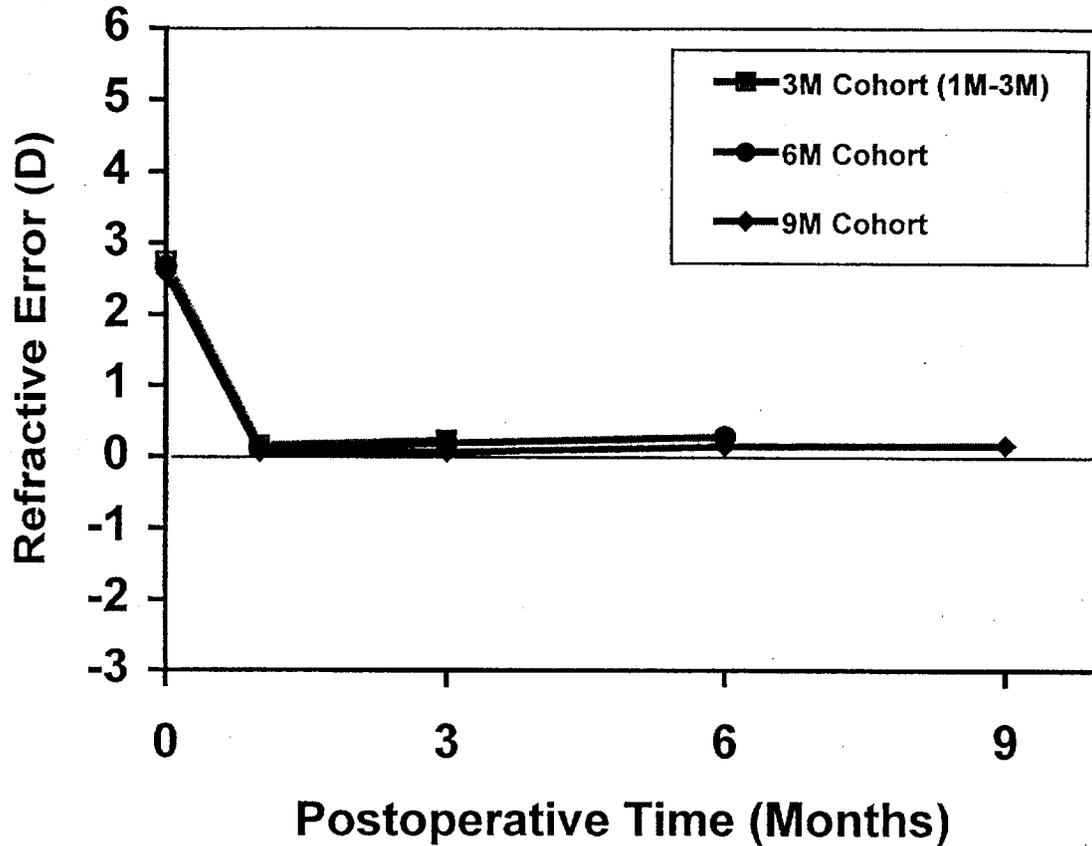


Figure 2. Manifest Refraction vs. Postop Time

Mean ± SD	n	Preop	1 Month	3 Months	6 Months	9 Months
3M Cohort (1M-3M)†	116	+2.74 ± 1.23	+0.16 ± 0.68	+0.24 ± 0.61	--	--
6M Cohort†	102	+2.67 ± 1.25	+0.12 ± 0.67	+0.20 ± 0.58	+0.29 ± 0.62	--
9M Cohort†	75	+2.58 ± 1.28	+0.07 ± 0.55	+0.07 ± 0.46	+0.15 ± 0.50	+0.17 ± 0.51
Entire Cohort (All Available Eyes)	--	+2.75 ± 1.22	+0.18 ± 0.70	+0.24 ± 0.61	+0.30 ± 0.63	+0.18 ± 0.50

\* Not including monovision

† Reflects consistent cohort at each visit.

Change in Spherical Equivalent Between		1 and 3 Months (n=115)	3 and 6 Months (n=115)
≤1.00	n %	111 96.5%	112 97.4%
Mean Difference		+0.12	+0.07
SD		0.50	0.41
95% CI		(0.03, 0.21)	(-0.01, 0.14)

Change in Spherical Equivalent Between		1 and 3 Months (n=85)	3 and 6 Months (n=85)	6 and 9 Months (n=85)
≤1.00	n %	85 100.0%	83 97.7%	83 97.7%
Mean Difference		+0.04	+0.04	+0.06
SD		0.41	0.44	0.39
95% CI		(-0.05, 0.13)	(-0.06, 0.13)	(-0.03, 0.14)

Astigmatism correction was assessed based on the magnitude of cylinder and vector analysis (Table 16). At 6 months, 60.0% of eyes had ≤0.50D and 83.1% of eyes had ≤1.00D of residual cylinder.

Absolute Magnitude		Vector Analysis	
Preoperative	1.57 ± 1.18	Intended Vector	1.57 ± 1.18
Postoperative	0.64 ± 0.64	Difference Vector	0.64 ± 0.64
Achieved Magnitude	1.02 ± 0.92	Achieved Vector	1.48 ± 0.87
% Achieved	65 ± 33	% Achieved	109 ± 50
Axis Shift*	28.2° ± 29.0°	Angle of Error	8.8 ± 12.5

\*Eyes with residual cylinder >0

#### 4. Patient Satisfaction (LASIK Hyperopia with Astigmatism)

At 6 months (n=112), subjects reported that their satisfaction with their results was as follows: 27.7% extremely satisfied, 40.2% satisfied, 19.6% not sure, 9.8% unsatisfied, and 2.7% extremely unsatisfied. Subjects reported that their quality of vision at 6 months (n=115) after surgery as compared to before surgery was as follows: 37.4% significantly better, 33.0% better, 24.3% unchanged, 5.2% worse, and 0.0% significantly worse. Postoperatively, distance correction was not required by 85.6% of subjects and near correction was not used by 33.9%.

Subjective Responses		Significantly Better	Better	No Change	Worse	Significantly Worse
	N	%	%	%	%	%
Blurring of vision	111	14.4	19.8	48.6	15.3	1.8
Burning	113	8.8	17.7	63.7	8.0	1.8
Double vision	111	14.4	13.5	62.2	6.3	3.6
Dryness	113	4.4	16.8	55.8	17.7	5.3
Excessive tearing	111	7.2	15.3	75.7	1.8	0.0
Feeling of something in eye	113	10.6	17.7	63.7	5.3	2.7
Fluctuation of vision	111	9.0	18.0	50.5	20.7	1.8
Glare	113	9.7	15.0	54.9	18.6	1.8
Halos	111	9.0	12.6	53.2	20.7	4.5
Headache	110	11.8	8.2	75.5	2.7	1.8
Light sensitivity	112	8.0	8.9	59.8	21.4	1.8
Night driving difficulty	113	17.7	13.3	53.1	14.2	1.8
Pain	110	11.8	9.1	73.6	4.5	0.9
Redness	112	10.7	12.5	68.8	5.4	2.7

**D. MIXED ASTIGMATISM: LASIK**

1. Demographics (LASIK Hyperopia with Mixed Astigmatism)

<b>TABLE 18</b>		
<b>DEMOGRAPHICS (LASIK HYPEROPIA WITH MIXED ASTIGMATISM)</b>		
65 Eyes of 35 Subjects Enrolled		
	Number	Percentage
Gender: Female	16	24.6
Male	49	75.4
Race: Caucasian	65	100.0
Age (yrs): Average ± SD	47.6 ± 9.1	
Range	32 to 67	
Contact Lens History: None	36	55.4
Soft	21	32.3
RGP	2	3.1
PMMA	6	9.2

2. Baseline Parameters (LASIK Hyperopia with Mixed Astigmatism)

<b>TABLE 19</b>		
<b>BASELINE PARAMETERS (LASIK HYPEROPIA WITH MIXED ASTIGMATISM)</b>		
Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	+0.23 ± 0.86D	-1.75 to +2.375D
Sphere	+1.85 ± 1.35D	+0.25 to +5.00D
Cylinder	-3.26 ± 1.49D	-1.25 to -6.00D
Preoperative UCVA*	n	%
20/100 or worse	26	41.9
20/50 to 20/80	26	41.9
20/25 to 20/40	10	16.1
≤20/20	0	0.0
Preoperative Manifest BSCVA	n	%
20/25 to 20/40	12	19.7
≤20/20	49	80.3

\* not including monovision eyes

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3. Safety and Efficacy Results (LASIK Hyperopia with Mixed Astigmatism)

TABLE 20 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES MIXED ASTIGMATISM UP TO +6D					
Efficacy Variables		1 Month	3 Months	6 Months	9 Months
<b>BSCVA ≥ 20/20 Preop*</b>					
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n	20/46	18/43	18/40	19/37
	%	43.5%	41.9%	45.0%	51.4%
	CI	(28.9, 58.9)	(27.0, 57.9)	(29.3, 61.5)	(34.4, 68.1)
UCVA 20/20 or better *	n	23/61	26/58	25/54	22/47
	%	37.7%	44.8%	46.3%	46.8%
	CI	(25.6, 51.0)	(31.7, 58.5)	(32.6, 60.4)	(32.1, 61.9)
UCVA 20/25 or better*	n	33/61	40/58	40/54	33/47
	%	54.1%	69.0%	74.1%	70.2%
	CI	(40.9, 66.9)	(55.5, 80.5)	(60.4, 85.0)	(55.1, 82.7)
UCVA 20/40 or better *	n	55/61	55/58	50/54	44/47
	%	90.2%	94.8%	92.6%	93.6%
	CI	(79.8, 96.3)	(85.6, 98.9)	(82.1, 97.9)	(82.5, 98.7)
<b>Safety Variables</b>					
MRSE ±0.50D of intended	n	36/64	36/61	37/57	41/50
	%	56.3%	59.0%	64.9%	82.0%
	CI	(43.3, 68.6)	(45.7, 71.5)	(51.1, 77.1)	(68.6, 91.4)
MRSE ±1.00D of intended	n	57/64	53/61	50/57	48/50
	%	89.1%	86.9%	87.7%	96.0%
	CI	(78.8, 95.5)	(75.8, 94.2)	(76.3, 94.9)	(86.3, 99.5)
MRSE ±2.00D of intended	n	63/64	60/61	57/57	50/50
	%	98.4%	98.4%	100.0%	100.0%
	CI	(91.6, 100.0)	(91.2, 100.0)	(93.7, 100.0)	(92.9, 100.0)
Loss of >2 Lines BSCVA	n	1/58	0/56	0/52	0/46
	%	1.7%	0.0%	0.0%	0.0%
	CI	(0.0, 9.2)	(0.0, 6.4)	(0.0, 6.9)	(0.0, 7.7)
Loss of 2 Lines BSCVA	n	1/58	2/56	1/52	1/46
	%	1.7%	3.6%	1.9%	2.2%
	CI	(0.0, 9.2)	(0.0, 12.3)	(0.0, 10.3)	(0.0, 11.5)
BSCVA worse than 20/40	n	0/62	0/60	0/56	0/50
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 5.8)	(0.0, 6.0)	(0.0, 6.4)	(0.0, 7.1)
Increase >1D Cylinder	n	0/64	0/61	0/57	0/50
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 5.6)	(0.0, 5.9)	(0.0, 6.3)	(0.0, 7.1)
Increase >2D Cylinder	n	0/64	0/61	0/57	0/50
	%	0.0%	0.0%	0.0%	0.0%
	CI	(0.0, 5.6)	(0.0, 5.9)	(0.0, 6.3)	(0.0, 7.1)
<b>BSCVA ≥ 20/20 Preop</b>					
BSCVA worse than 20/25 if 20/20 or better preoperatively	n	1/48	1/45	0/41	0/39
	%	2.1%	2.2%	0.0%	0.0%
	CI	(0.0, 11.1)	(10.0, 11.8)	(0.0, 8.6)	(0.0, 9.0)

\*Not including monovision eyes

CI = 95% Confidence Interval

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TABLE 21 SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES MIXED ASTIGMATISM STRATIFIED BY DIOPTR PREOPERATIVE CYLINDER** - 6 MONTHS							
Efficacy Variables	SE	1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.00 to 6.00	Cum Total
BSCVA $\geq$ 20/20 PREOP*							
UCVA 20/20 or better if BSCVA 20/20 or better Preop*	n %	7/13 53.8%	6/13 46.2%	3/7 42.9%	1/4 25.0%	1/3 33.3%	18/40 45.0%
UCVA 20/20* or better	n %	7/13 53.8%	7/15 46.7%	4/9 44.4%	3/8 37.5%	4/9 44.4%	25/54 46.3%
UCVA 20/25* or better	n %	9/13 69.2%	10/15 66.7%	8/9 88.9%	7/8 87.5%	6/9 66.7%	40/54 74.1%
UCVA 20/40* or better	n %	12/13 92.3%	14/15 93.3%	8/9 88.9%	8/8 100.0%	8/9 88.9%	50/54 92.6%
MRSE $\pm$ 0.50D of intended	n %	10/13 76.9%	10/15 66.7%	4/11 36.4%	5/8 62.5%	8/10 80.0%	37/57 64.9%
MRSE $\pm$ 1.00D of intended	n %	10/13 76.9%	15/15 100.0%	8/11 72.7%	8/8 100.0%	9/10 90.0%	50/57 87.7%
MRSE $\pm$ 2.00D of intended	n %	13/13 100.0%	15/15 100.0%	11/11 100.0%	8/8 100.0%	10/10 100.0%	57/57 100.0%
<b>Safety Variables</b>							
Loss of >2 Lines BSCVA	n %	0/13 0.0%	0/15 0.0%	0/9 0.0%	0/8 0.0%	0/7 0.0%	0/52 0.0%
Loss of 2 Lines BSCVA	n %	0/13 0.0%	0/15 0.0%	0/9 0.0%	0/8 0.0%	1/7 14.3%	1/52 1.9%
BSCVA worse than 20/40	n %	0/13 0.0%	0/15 0.0%	0/11 0.0%	0/8 0.0%	0/9 0.0%	0/56 0.0%
Increase >1D Cylinder	n %	0/13 0.0%	0/15 0.0%	0/11 0.0%	0/8 0.0%	0/10 0.0%	0/57 0.0%
Increase >2D Cylinder	n %	0/13 0.0%	0/15 0.0%	0/11 0.0%	0/8 0.0%	0/10 0.0%	0/57 0.0%
<b>BSCVA <math>\geq</math> 20/20 Preop</b>							
BSCVA worse than 20/25 if 20/20 or better preoperatively	n %	0/13 0.0%	0/13 0.0%	0/9 0.0%	0/4 0.0%	0/2 0.0%	0/41 0.0%

\*Not including monovision eyes

\*\* - The stratification by preoperative cylinder reflects the absolute amount of power difference between the two meridians

Near UCVA was J3 (20/40) or better in 30.6% of all eyes preoperatively and 75.6% of 45 eyes treated for emmetropia at 6 months. For 3 eyes targeted for monovision, near UCVA was J3 or better in 100% at 6 months.

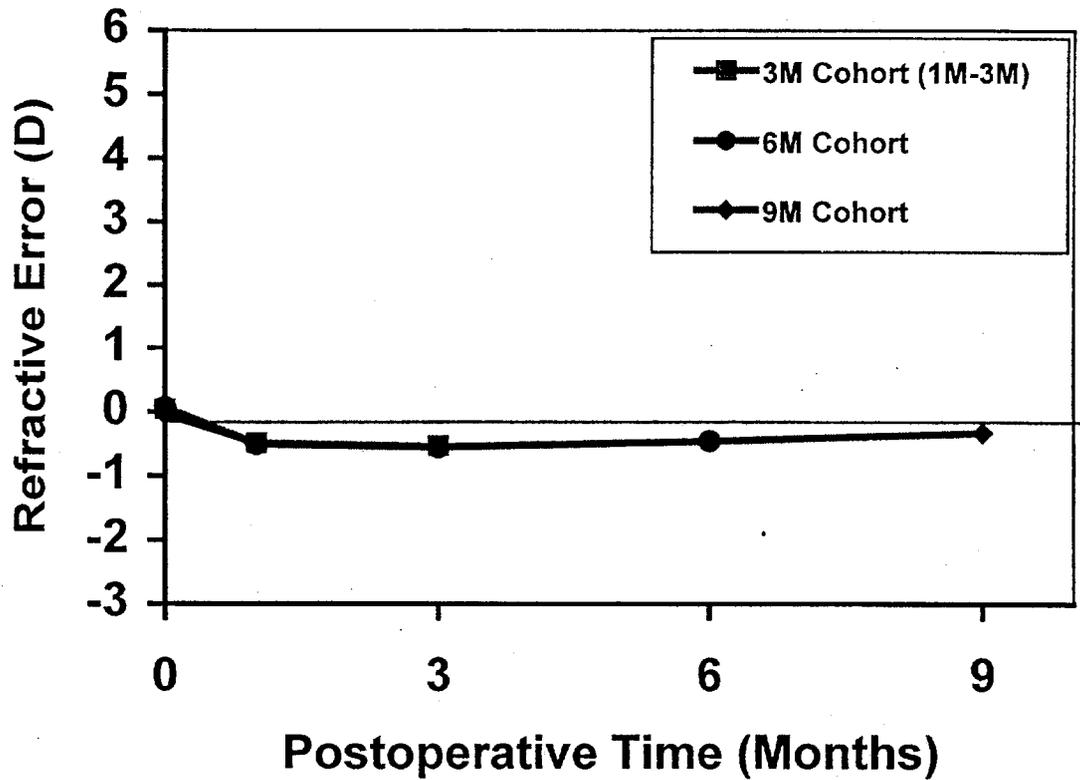


Figure 3. Manifest Refraction vs. Postop Time

Mean ± SD	n	Preop	1 Month	3 Months	6 Months	9 Months
3M Cohort (1M-3M)†	57	+0.04 ± 0.87	-0.49 ± 0.56	-0.53 ± 0.48	--	--
6M Cohort†	49	+0.07 ± 0.92	-0.50 ± 0.53	-0.55 ± 0.49	-0.46 ± 0.45	--
9M Cohort†	38	-0.04 ± 0.83	-0.49 ± 0.52	-0.54 ± 0.50	-0.46 ± 0.44	-0.33 ± 0.39
Entire Cohort (All Available Eyes)	--	-0.02 ± 0.87	-0.47 ± 0.57	-0.52 ± 0.48	-0.44 ± 0.45	-0.33 ± 0.35

\*Not including monovision

† Reflects consistent cohort at each visit

TABLE 23 MIXED ASTIGMATISM STABILITY OF MANIFEST REFRACTION CYLINDER: 6 MONTH COHORT			
Change in MR Cyl Between		1 and 3 Months (n=52)	3 and 6 Months (n=52)
≤1.00	n %	52 100.0%	52 100.0%
Mean Difference		-0.01	+0.03
SD		0.39	0.34
95% CI		(-0.12, 0.10)	(-0.06, 0.13)

TABLE 24 MIXED ASTIGMATISM STABILITY OF MANIFEST REFRACTION CYLINDER: 9 MONTH COHORT				
Change in MR Cyl Between		1 and 3 Months (n=41)	3 and 6 Months (n=41)	6 and 9 Months (n=41)
≤1.00	n %	41 100.0%	41 100.0%	40 97.6%
Mean Difference		-0.04	+0.07	-0.02
SD		0.35	0.32	0.37
95% CI		(-0.15, 0.07)	(-0.03, 0.17)	(-0.13, 0.10)

Astigmatism correction was assessed based on the magnitude of cylinder and vector analysis (Table 25). At 6 months, 57. 9% of eyes had ≤0.50D and 86. 0% of eyes had ≤1.00D of residual cylinder.

TABLE 25 SUMMARY OF CYLINDER CORRECTION: 6 MONTHS FOR MIXED ASTIGMATISM			
Absolute Magnitude		Vector Analysis	
Preoperative	3.21 ± 1.46	Intended Vector	3.21 ± 1.46
Postoperative	0.55 ± 0.49	Difference Vector	0.55 ± 0.49
Achieved Magnitude	2.66 ± 1.31	Achieved Vector	2.85 ± 1.29
% Achieved	83 ± 15	% Achieved	90 ± 14
Axis Shift*	15.5° ± 17.7°	Angle of Error	3.1 ± 3.6

\*Eyes with residual cylinder >0

#### 4. Patient Satisfaction (LASIK Hyperopia with Mixed Astigmatism)

At 6 months (n=53), subjects reported that their satisfaction with their results was as follows: 39.6% extremely satisfied, 37.7% satisfied, 11.3% not sure, 9.4% unsatisfied, and 1.9% extremely unsatisfied. Subjects reported that their quality of vision at 6 months (n=53) after surgery as compared to before surgery was as follows: 26.4% significantly better, 34.0% better, 34.0% unchanged, 1.9% worse, and 3.8% significantly worse. Postoperatively, distance correction was not required by 80.8% of patients and near correction was not used by 60.4%.

Subjective Responses	N	Significantly Better	Better	No Change	Worse	Significantly Worse
		%	%	%	%	%
Blurring of vision	53	11.3	13.2	64.2	7.5	3.8
Burning	53	3.8	15.1	73.6	7.5	0.0
Double vision	53	13.2	9.4	75.5	1.9	0.0
Dryness	53	3.8	15.1	54.7	24.5	1.9
Excessive tearing	52	9.6	5.8	84.6	0.0	0.0
Feeling of something in eye	53	7.5	17.0	69.8	5.7	0.0
Fluctuation of vision	53	3.8	15.1	69.8	11.3	0.0
Glare	53	5.7	5.7	66.0	22.6	0.0
Halos	53	3.8	5.7	64.2	26.4	0.0
Headache	53	9.4	9.4	77.4	3.8	0.0
Light sensitivity	53	7.5	15.1	56.6	20.8	0.0
Night driving difficulty	53	15.1	9.4	54.7	13.2	7.5
Pain	53	9.4	9.4	77.4	3.8	0.0
Redness	53	7.5	15.1	73.6	3.8	0.0

### **E. RETREATMENT**

Retreatment was performed in 18 (11.8%) of the spherical hyperopic eyes, 17 (26.1%) of the mixed astigmatic eyes, and 40 (28.0%) of the hyperopic astigmatic eyes. The protocol allowed for retreatment of eyes with either a UCVA worse than 20/25 or residual refractive error of 0.75D or more. Of the 66 eyes originally targeted for emmetropia, 46 eyes (70%) had a UCVA of 20/40 or better prior to retreatment. Approximately one-half of all retreated eyes had a preoperative cycloplegic sphere of +4D to +6D (prior to any treatment). Of the 57 eyes treated for hyperopic or mixed astigmatism, 24.6% had a preoperative cylinder of -4 to -6D.

Seven eyes were retreated for overcorrection of sphere and/or cylinder, all of which had low ( $\leq +2.50$ D) hyperopic sphere, including 5 mixed astigmatic eyes with less than 1D of sphere. Eleven eyes were retreated for induced cylinder with or without sphere undercorrection. The remaining 57 eyes were retreated for undercorrection of sphere and/or cylinder from the monovision or emmetropia target.

There is insufficient data for retreatments on which to base conclusions for safety and effectiveness.

## **F. 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  $0.35 \pm 0.19$  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 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 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 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 hyperopia by use of spectacles, contact lenses and other refractive surgeries such as PRK and 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 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 4). 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 hyperopic treatments with and without astigmatism, including mixed astigmatism is 9mm (optic zone 6mm with 1.5mm blend zone). Table 19 shows the ablation depth per diopter of correction at the 6mm optic zone size.

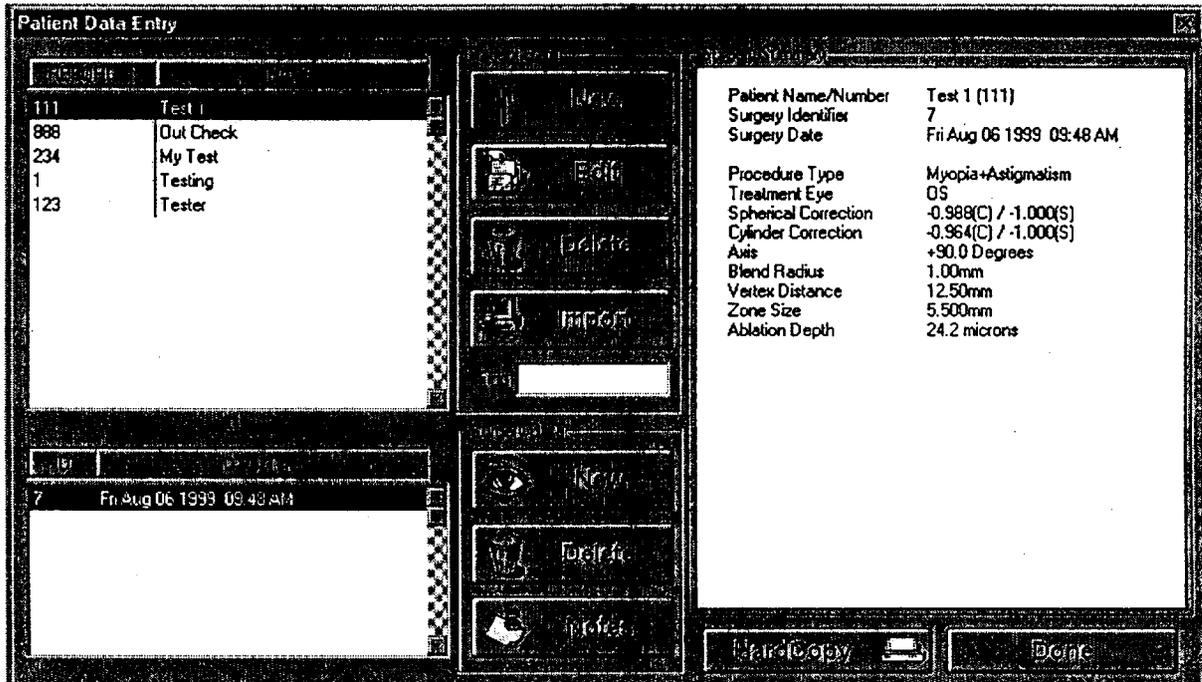


Figure 4. Patient Data Entry Screen

Corneal Plane Power (D)*	Depth in microns for OZ Diameter 6.0mm
+0.5	9
+1.0	18
+1.5	27
+2.0	36
+2.5	42
+3.0	48
+3.5	53
+4.0	59
+4.5	65
+5.0	71
+5.5	77
+6.0	83

\*For hyperopic spherical and astigmatic corrections: corneal power of the spherical component. For example, +6D sphere/-2D cylinder at the cornea has a maximum power correction of +6D

\*For mixed astigmatic corrections in minus cylinder form where the absolute value of the cylinder is greater than the absolute value of the sphere by more than 1.00D, the maximum ablation is the corneal power of the cylinder. For example, +2D sphere/-6D cylinder at the cornea is a maximum power correction of -6D. In this case, use the myopic ablation depth chart found in the physician labeling for myopia.

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 5). 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.

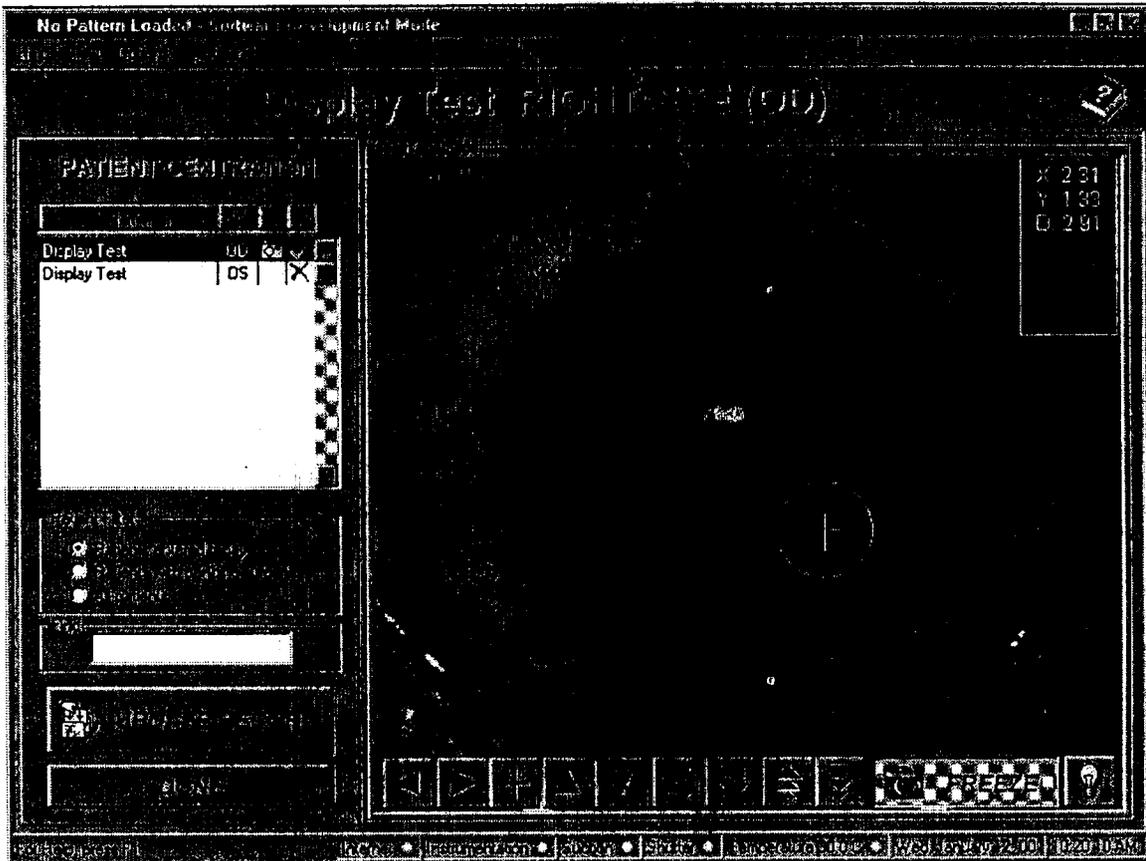


Figure 5. Undilated Pupil and Limbus Reticles

**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 flap creation 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 creation of the flap, 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.

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 6). If the ablation zone covers the hinge, the hinge protection feature is activated to prevent pulses from being fired onto the hinge. A minimum flap diameter of 9mm is required.

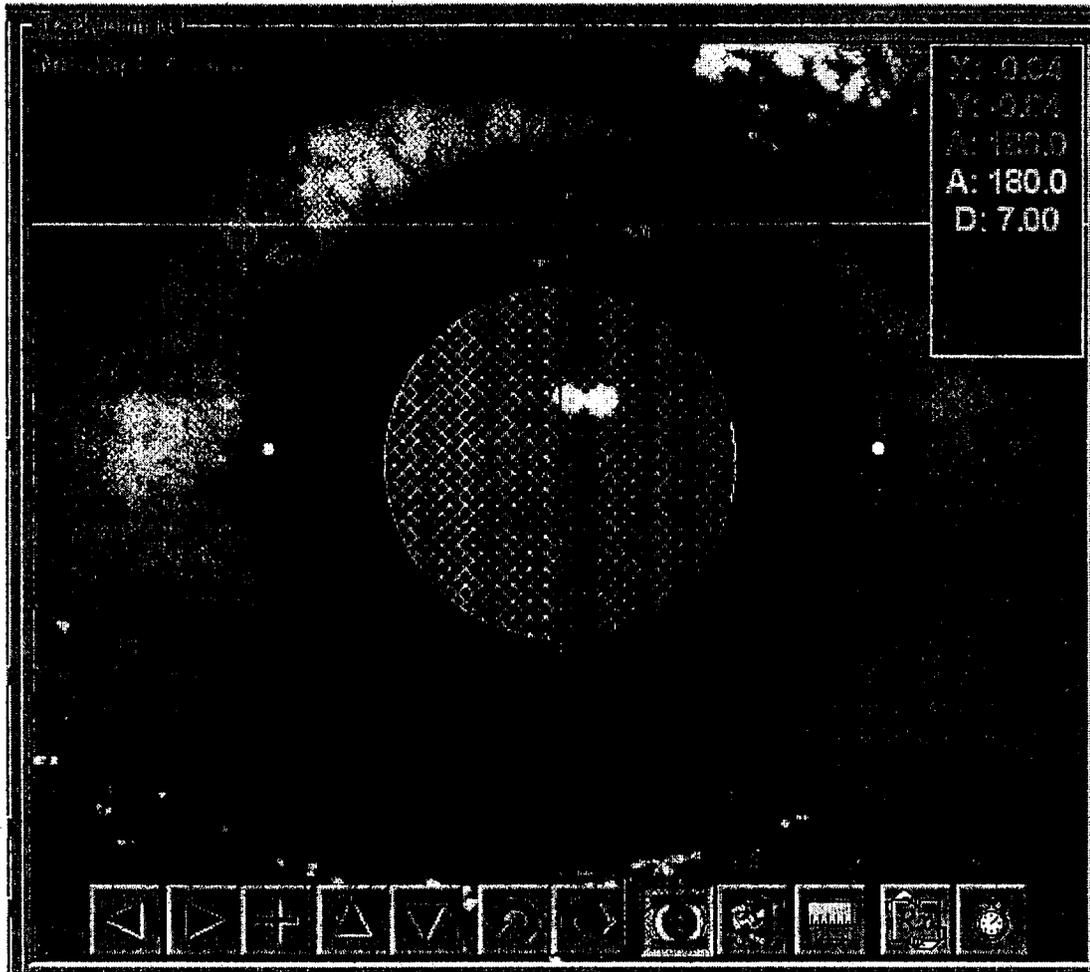


Figure 6. Showing Extent of Ablation Zone

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

Postoperative pharmaceutical treatment consists of one drop of a broad spectrum antibiotic and, if desired, a steroid and NSAID. For at least 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.

**FACTS YOU NEED TO KNOW ABOUT  
LADARVision®  
LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY**

**PATIENT INFORMATION BOOKLET**

For:  
For Farsightedness (Hyperopia) With or Without Astigmatism and Mixed Astigmatism  
(Sphere up to +6.00D and Cylinder up to -6.00D)

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.

**Allergic Conjunctivitis:** inflammation of the outer lining of the eye from an allergic reaction to the environment, such as hayfever.

**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 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 LASIK surgery.

**Bandage Contact Lens:** a soft contact lens that may be placed on the cornea after surgery to cover the eye.

**Cataract:** an opacity, or clouding, of the lens inside the eye that can cause a loss of vision. This clouding tends to develop with older age and may affect different parts of the lens, which are categorized as nuclear sclerosis, cortical spoking, and posterior subcapsular cataract.

**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 LASIK surgery.

**Conjunctiva:** the outer lining of the eye that surrounds the cornea.

**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 LASIK, PRK 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.

**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 Infiltrate:** inflammation of the cornea.

**Corneal Opacities:** cloudy areas in 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.

**Cotton Wool Spot:** a small area in the back of the eye (retina) with a cotton-like appearance that develops when there is a lack of blood supply to the area. This spot does not typically affect vision may be associated with several types of conditions, such as diabetes or high blood pressure.

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

**Drusen:** small deposits of cellular material in the back of the eye (retina), which is more common in older age. These deposits often have no affect on vision but may result in vision loss if they occur in the area responsible for central vision (macula).

**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 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 LASIK that removes tissue from the cornea.

**Farsightedness:** Another term for hyperopia. Farsightedness eyes may see better at distance than at near without glasses or contact lenses but usually require correction for both distances.

**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 LASIK 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 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 LASIK surgery.

**Hyperopia:** a condition of the eye that results in blurred distance and near vision. The cornea and lens focus light rays from distant and near objects behind the retina.

**Hyperopic Astigmatism:** a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points behind the retina.

**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.

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

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

**Intralamellar Haze:** cloudiness underneath the corneal flap.

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

**Iron Line or Ring:** a deposit of iron in the cornea that has no effect on vision.

**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 LASIK surgery.

**Lagophthalmos:** failure to close eyes completely, which may result in irritation of the front of the eye due to dryness.

**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.

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

**MRSE (Manifest Refraction Spherical Equivalent):** the amount of hyperopia and astigmatism calculated based on the glasses prescription.

**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.

**Mixed Astigmatism:** a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points with one point focused in front of the retina and the other point focused behind the retina.

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

**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.

**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.

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

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

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

**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 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.

**Trichiasis:** misdirected eyelashes that may turn inward toward the eye.

**Vacuoles:** small round areas of cellular debris in the cornea that typically has no effect on vision.

**Vitreous Floater:** a strand or spot in the fluid inside the eye that may appear as floating spot in the vision. The appearance of floaters is normal and more common with age.

## B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly? One option to see more clearly is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. A recent type of surgery that reshapes the cornea 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 Laser In-Situ Keratomileusis (LASIK). In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision<sup>®</sup> 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 LASIK with the tracker-guided LADARVision<sup>®</sup> system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about LASIK with the help of your doctor.

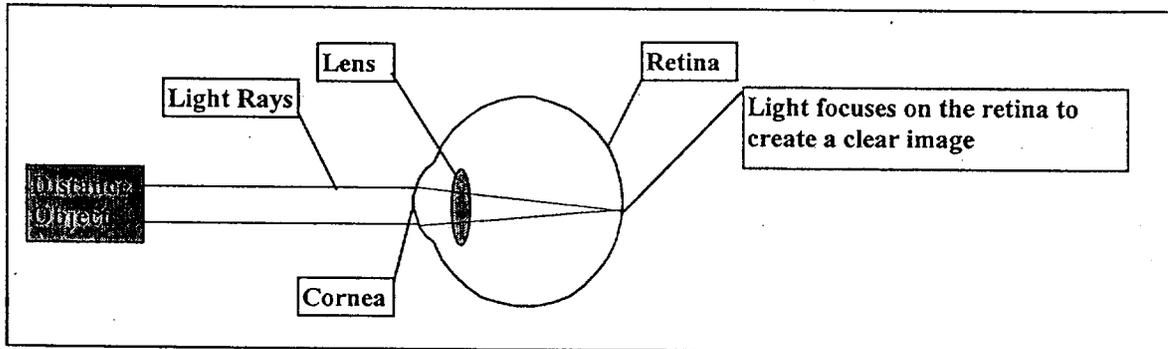
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after LASIK. LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having PRK or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

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

## C. How Does LASIK Correct Hyperopia With or Without Astigmatism or Mixed Astigmatism?

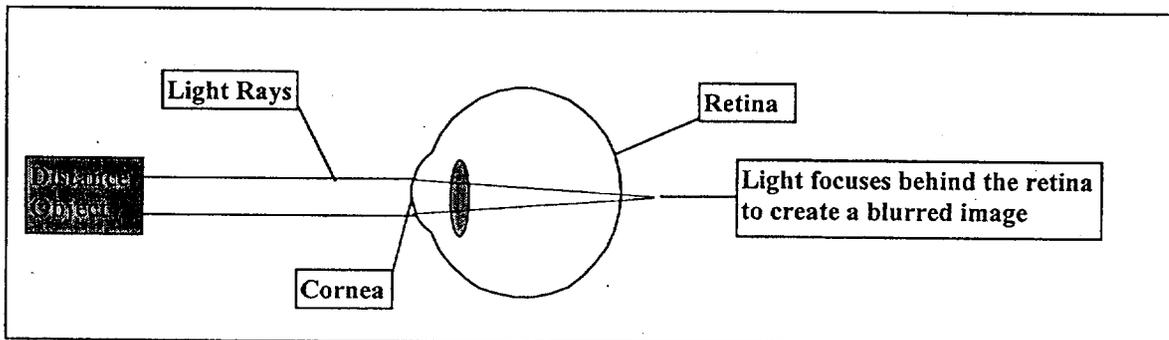
The human eye functions like a camera. The lens in a camera focuses light into images on to film. In the same way, the cornea and the lens inside the eye focus light into images on to the retina, the back surface of the eye (Diagram 1). Blurred vision occurs when the light does not focus precisely on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

DIAGRAM 1: NORMAL EYE



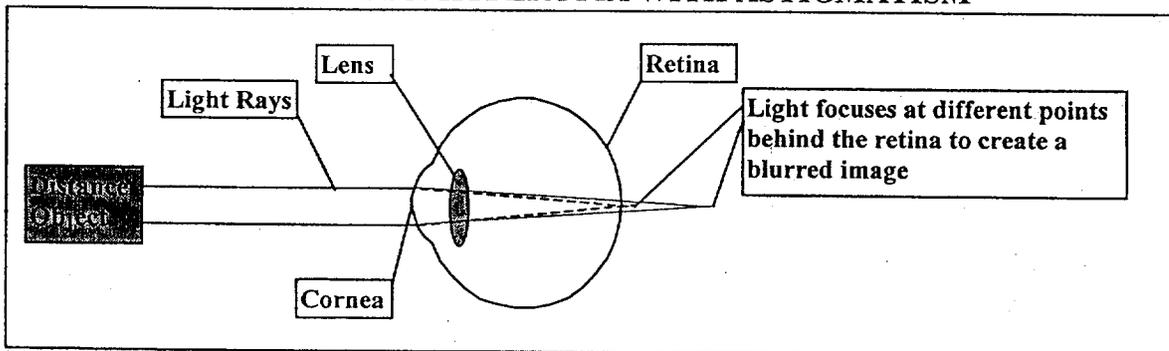
Hyperopia (farsightedness) is a condition of the eye where people usually see better in the distance than near. The cornea and lens focus light rays from a distant and near object behind the retina. Diagram 2 shows how light from a distant object focuses behind the retina to cause a blurred image.

**DIAGRAM 2: HYPEROPIA**

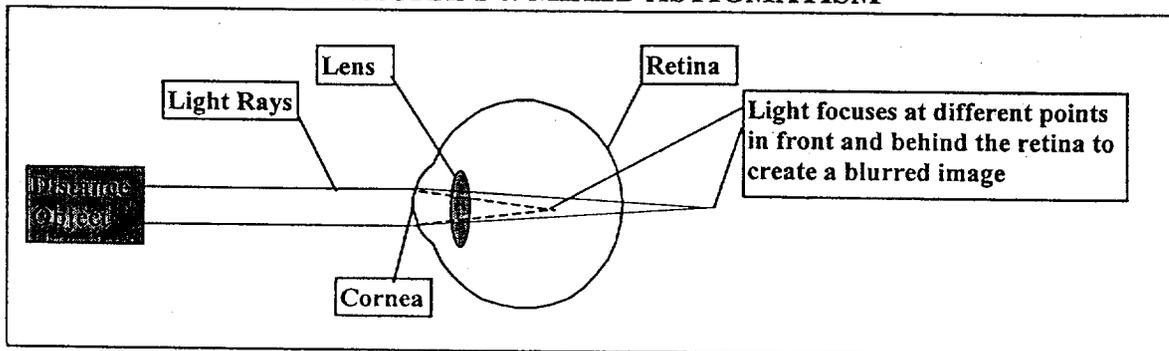


Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points. In eyes with hyperopic astigmatism, both points focus behind the retina. In eyes with mixed astigmatism, one point focuses in front of the retina and the other point focuses behind 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. Diagrams 3 and 4 show how light rays focus at different points in an eye with astigmatism causing a blurred image.

**DIAGRAM 3: HYPEROPIA WITH ASTIGMATISM**

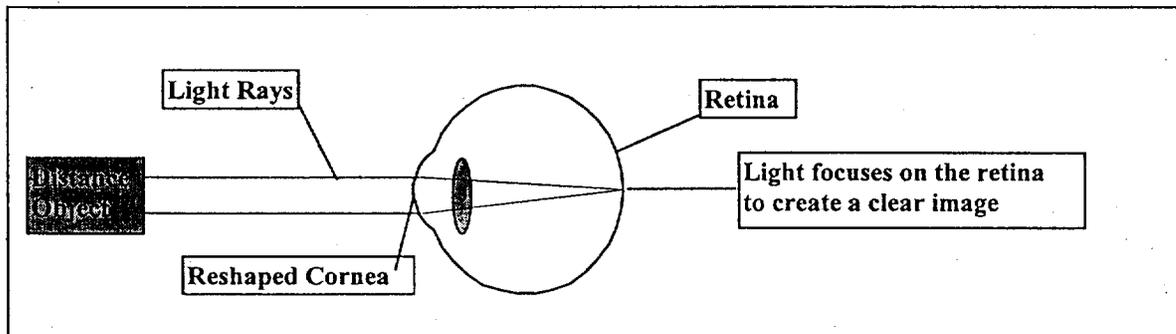


**DIAGRAM 4: MIXED ASTIGMATISM**



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 hyperopia, this is done by reshaping the periphery of the cornea. LASIK sculpts the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used 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 LASIK can reshape the cornea to provide clearer vision.

**DIAGRAM 5: CORRECTION OF VISION AFTER LASIK**



The LADARVision<sup>®</sup> 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<sup>®</sup> 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 the Benefits of LASIK?

LASIK may reduce overall farsightedness (hyperopia). LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- LASIK surgery performed with the LADARVision® system is effective in reducing hyperopia between 0 and +6.0 Diopters. The LASIK procedure is also effective in correcting up to 6 Diopters of astigmatism in eyes with hyperopic or mixed astigmatism.

The results listed in the following section are from U.S. clinical studies of the LADARVision® system for LASIK. The clinical results are arranged by the type of condition: hyperopia without astigmatism, hyperopic astigmatism, and mixed astigmatism. It is important that you know which type of condition you have to determine which results represent your condition. Please discuss which type of condition you have with your doctor prior to reading this information.

Listed in the table below are the clinical results of vision with and without glasses at 6 months after surgery, which is the time point of stability of the refractive outcome of the procedure.

U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	n/N	%	n/N	%	n/N	%
Visual Acuity 20/20 or better without glasses**	57/115	49.6	38/88	43.2	18/40	45.0
Visual Acuity 20/20 or better without glasses*	59/121	48.8	41/110	37.3	25/54	46.3
Visual Acuity 20/25 or better without glasses*	83/121	68.6	66/110	60.0	40/54	74.1
Visual Acuity 20/40 or better without glasses*	113/121	93.4	100/110	90.9	50/54	92.6
Visual Acuity 20/20 or better with glasses**	115/132	87.1	88/101	87.1	37/41	90.2
Visual Acuity 20/20 or better with glasses	121/141	85.8	94/124	75.8	47/56	83.9
Visual Acuity 20/40 or better with glasses	141/141	100	124/124	100	56/56	100
Loss of 2 lines of visual acuity with glasses	5/141	3.5	7/121	5.8	1/52	1.9
Loss of more than 2 lines of visual acuity with glasses	0/141	0.0	0/121	0.0	0/52	0.0

\*Not including eyes treated for monovision

\*\*If vision with glasses was 20/20 or better before surgery

At 6 months after surgery, patients completed a questionnaire for the following symptoms, which were rated as significantly better, better, unchanged, worse or significantly worse than before surgery. For information on the symptoms rated as worse or significantly worse, please refer to the section entitled “What are the risks of LASIK?” The table below displays the percentage of patients who rated the symptoms as unchanged, better or significantly better than before surgery. Note that this data reflects the percentage of patients who did not report worsening of these symptoms after surgery.

<b>U.S. CLINICAL STUDY PATIENT QUESTIONNAIRE RESULTS AT 6 MONTHS</b>						
Subjective responses rated as <b>unchanged, better, or significantly better</b> than before surgery						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Blurring of vision	132	88.6	111	82.9	53	88.7
Burning	133	97.0	113	90.3	53	92.5
Double vision	132	90.2	111	90.1	53	98.1
Dryness	132	80.3	113	77.0	53	73.6
Excessive tearing	132	98.5	111	98.2	52	100
Feeling of something in eye	133	93.2	113	92.0	53	94.3
Fluctuation of vision	133	78.2	111	77.5	53	88.7
Glare	133	77.5	113	79.6	53	77.4
Halos	132	84.8	111	74.8	53	73.6
Headache	132	97.0	110	95.5	53	96.2
Light sensitivity	133	72.2	112	76.8	53	79.2
Night driving difficulty	133	88.7	113	84.1	53	79.2
Pain	132	96.2	110	94.5	53	96.2
Quality of vision	132	95.5	115	94.8	53	94.3
Redness	133	88.0	112	92.0	53	96.2

Patients also reported on a questionnaire their satisfaction with their results at 6 months after surgery, which was rated as extremely satisfied, satisfied, not sure, unsatisfied or extremely unsatisfied, as shown in the table below.

<b>U.S. CLINICAL STUDY PATIENT SATISFACTION RESULTS AT 6 MONTHS</b>						
	Hyperopia without astigmatism		Hyperopic Astigmatism		Mixed Astigmatism	
	<i>N</i>	%	<i>N</i>	%	<i>n/N</i>	%
Extremely Satisfied	53/133	39.8	31/112	27.7	21/53	39.6
Satisfied	48/133	36.1	45/112	40.2	20/53	37.7
Not Sure	16/133	12.0	22/112	19.6	6/53	11.3
Unsatisfied	16/133	12.0	11/112	9.8	5/53	9.4
Extremely Unsatisfied	0/133	0.0	3/112	2.7	1/53	1.9

### **E. Contraindications**

You should **NOT** have 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<sup>®</sup>) and Amiodarone hydrochloride (Cordarone<sup>®</sup>))
- **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.

### **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.

A microkeratome, used to create the corneal flap prior to laser treatment, should create a flap large enough to allow for a treatment zone of 9.0mm needed for this procedure.

### **G. Precautions**

The safety and effectiveness of the LADARVision<sup>®</sup> system have **NOT** been established:

- In eyes with disease or corneal condition (for example, scar, infection, etc.)
- In eyes with previous surgery or injury to the center of the cornea where 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 who are taking the medication Sumatriptin (Imitrex<sup>®</sup>)

- In patients under 21 years of age
- In patients over the long term (beyond 9 months)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery)
- In non-Caucasian patients
- For the treatment of astigmatism less than 0.50 Diopters
- For treatments greater than +6.0D of hyperopia or –6.0D of astigmatism
- For retreatments of hyperopia, hyperopic astigmatism or mixed astigmatism

Eye with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of hyperopia.

Hyperopic astigmatism eyes with greater than 4.0D MRSE before surgery may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of MRSE. MRSE is the amount of hyperopic astigmatism calculated based on the glasses prescription. These eyes may be more likely to experience a reduction of two lines in their best corrected visual acuity (vision with glasses or contact lenses) and to require additional treatment (retreatment).

Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity (vision without glasses or contact lenses) of 20/20 or better.

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 to see in conditions such as very dim light, rain, snow, fog, and glare from bright lights at night.

## **H. What Are the Risks of LASIK?**

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

### On the day of LASIK Surgery

In clinical studies of the LADARVision® system for LASIK surgery, each of the following complications was reported on the day of surgery (n=360) at a rate of 0.3%: epithelial defect and misaligned flap. The following adverse event was reported on the day of surgery at a rate of 0.8%: miscreated flap related to use of the microkeratome. In the situation of a miscreated flap, 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. Best-corrected vision (vision with glasses or contact lenses) may be reduced in this early time period after surgery.
- 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, each of the following complications was reported at the 1 week visit (n=354) at a rate of 0.6% or less: corneal folds/striae, corneal swelling, epithelium in interface, and intralamellar haze. The complication of sterile interface inflammation was reported at 1 week at a rate of 2.0%. Each of the following adverse reactions was reported at 1 week at a rate of 0.8% or less: corneal infiltrate and increase in intraocular pressure.
- The following complications were reported only at unscheduled visits within the first two weeks after primary treatment or retreatment: corneal swelling (4 eyes), epithelium in the interface (1 eye), and sterile interface inflammation (2 eyes). In addition, one patient with a history of heart disease experienced a myocardial infarction (heart attack) two weeks after surgery, which was not related to the LASIK procedure or to the LADARVision system.

### 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		3 Months		6 Months		9 Months	
	n/N	%	n/N	%	n/N	%	n/N	%
<b>ADVERSE EVENTS</b>								
Rolled flap edge with trace corneal melt	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
<b>COMPLICATIONS</b>								
Corneal abrasion	0/353	0.0	0/344	0.0	1/324	0.3	0/265	0.0
Corneal folds/Striae/Wrinkles	3/353	0.8	0/344	0.0	0/324	0.0	1/265	0.4
Corneal opacities	3/353	0.8	6/344	1.7	1/324	0.3	2/265	0.8
Double/ghost images	2/353	0.6	2/344	0.6	5/324	1.5	2/265	0.8
Epithelium in the interface	6/353	1.7	7/344	2.0	5/324	1.5	3/265	1.1
Feeling of something in the eye	2/353	0.6	2/344	0.6	1/324	0.3	0/265	0.0
Interface debris	10/353	2.8	7/344	2.0	5/324	1.5	1/265	0.4
Irregular epithelium	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Iron line or ring	0/353	0.0	0/344	0.0	1/324	0.3	2/265	0.8
Isolated cells in interface	0/353	0.0	1/344	0.3	2/324	0.6	1/265	0.4
Lagophthalmos	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Pain	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Sterile Interface Inflammation	1/353	0.3	0/344	0.0	0/324	0.0	0/265	0.0
Superficial punctate keratitis (SPK)	20/353	5.7	17/344	4.9	10/324	3.1	14/265	5.3

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

- superficial punctate keratitis (14 eyes)
- interface debris (8 eyes)
- corneal folds/striae/wrinkles (4 eyes)
- iron line/ring (3 eyes)
- corneal opacities (2 eyes)
- trichiasis (1 eye)
- subconjunctival hemorrhage (1 eye)
- conjunctival injection (1 eye)
- vacuoles (1 eye)

Each of the following ocular findings was reported at 6 months (n=265) at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen.

Lens findings (cataracts) were reported postoperatively in 14 eyes of 8 patients. All of these patients experienced lens changes due to age (range 59 to 73 years old). These findings included nuclear sclerosis, cortical spoking, and posterior subcapsular cataract. No eyes had a loss of more than 2 lines of best spectacle corrected visual acuity (with glasses). Only one eye had a related loss of 2 lines of best spectacle corrected visual acuity. All eyes had a last-reported best-corrected visual acuity of 20/32 or better.

The following other adverse events and complications occurred at 1 to 6 months after retreatment: epithelium in the interface (3 eyes) and double/ghost images (4 eyes.)

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

**Subjective Symptoms at 6 Months**

Subjective Responses	Hyperopia without astigmatism			Hyperopic Astigmatism			Mixed Astigmatism		
		Worse	Significantly Worse		Worse	Significantly Worse		Worse	Significantly Worse
	<i>N</i>	%	%	<i>N</i>	%	%	<i>N</i>	%	%
Blurring of vision	132	9.8	1.5	111	15.3	1.8	53	7.5	3.8
Burning	133	2.3	0.8	113	8.0	1.8	53	7.5	0.0
Double vision	132	8.3	1.5	111	6.3	3.6	53	1.9	0.0
Dryness	132	16.7	3.0	113	17.7	5.3	53	24.5	1.9
Excessive tearing	132	1.5	0.0	111	1.8	0.0	52	0.0	0.0
Feeling of something in eye	133	5.3	1.5	113	5.3	2.7	53	5.7	0.0
Fluctuation of vision	133	15.8	6.0	111	20.7	1.8	53	11.3	0.0
Glare	133	21.8	0.8	113	18.6	1.8	53	22.6	0.0
Halos	132	12.9	2.3	111	20.7	4.5	53	26.4	0.0
Headache	132	3.0	0.0	110	2.7	1.8	53	3.8	0.0
Light sensitivity	133	26.3	1.5	112	21.4	1.8	53	20.8	0.0
Night driving difficulty	133	9.0	2.3	113	14.2	1.8	53	13.2	7.5
Pain	132	3.0	0.8	110	4.5	0.9	53	3.8	0.0
Quality of vision	132	4.5	0.0	115	5.2	0.0	53	1.9	3.8
Redness	133	11.3	0.8	112	5.4	2.7	53	3.8	0.0

### I. Are You A Good Candidate for LASIK?

If you are considering 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 hyperopia between 0 and +6.0D in combination with up to -6.0D of astigmatism
- Have documented evidence that the change in your farsightedness is less than or equal to 0.50 diopter per year for at least one year prior to your preoperative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of LASIK risks and benefits as compared to other available treatments for hyperopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

## J. What Should You Expect During LASIK Surgery?

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 LASIK. This exam will help to determine if your eye is healthy and suitable for 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.

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. In some LASIK cases, a bandage contact lens is placed in your eye as well to

help heal small abrasions. You may be provided with a plastic shield for eye protection after LASIK for the first few days. 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.

**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.

Please refer to the section entitled "What are the risks of LASIK?" for information on the complications and adverse reactions that may occur in the first few weeks after surgery.

You may also experience blurred vision with or without glasses in the first week to one month after surgery. Some patients may experience a reduction in their best-corrected vision (with glasses) in the first week to one month as compared to before surgery, which tends to improve over the time. The following table displays the vision with and without glasses at one month for patients in the U.S. clinical study.

Some patients may experience some small changes or fluctuations in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery. Your vision with and without glasses should become stable within the first few weeks after surgery. Please refer to the section entitled "What are the benefits of LASIK?" for information on visual outcomes in the clinical study at 6 months, the time point of stability of the refractive outcome of the procedure.

<b>U.S. CLINICAL STUDY RESULTS AT 1 MONTH AFTER LASIK SURGERY</b>						
	<b>Hyperopia without astigmatism</b>		<b>Hyperopic Astigmatism</b>		<b>Mixed Astigmatism</b>	
	n/N	%	n/N	%	n/N	%
Visual Acuity 20/20 or better without glasses**	45/118	38.1	33/101	32.7	20/46	43.5
Visual Acuity 20/20 or better without glasses*	46/124	37.1	34/124	27.4	23/61	37.7
Visual Acuity 20/25 or better without glasses*	74/124	59.7	52/124	41.9	33/61	54.1
Visual Acuity 20/40 or better without glasses*	114/124	91.9	104/124	83.9	55/61	90.2
Visual Acuity 20/20 or better with glasses**	104/138	75.4	82/114	71.9	37/48	77.0
Visual Acuity 20/20 or better with glasses	108/149	72.4	86/138	62.3	44/62	71.0
Visual Acuity 20/40 or better with glasses	149/149	100	137/138	99.3	62/62	100
Loss of 2 lines of visual acuity with glasses	14/149	9.4	16/135	11.9	1/58	1.7
Loss of more than 2 lines of visual acuity with glasses	3/149	2.0	3/135	2.2	1/58	1.7

\*Not including eyes treated for monovision

\*\*If vision with glasses was 20/20 or better before surgery

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## K. Questions To Ask Your Doctor

You may want to ask the following questions to help you decide if LASIK is right for you:

- Which type of refractive condition do I have: hyperopia without astigmatism, hyperopic astigmatism, or mixed astigmatism?
- What are my other options to correct my farsightedness (hyperopia)?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of farsightedness (hyperopia)?
- What vision can I expect in the first few months after surgery?
- If 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 LASIK if I need them?
- How is 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 LASIK?
- Should I have 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 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.	<input type="checkbox"/>	<input type="checkbox"/>
2. It does not matter if I wear my contact lenses when my doctor told me not to wear them.	<input type="checkbox"/>	<input type="checkbox"/>
3. Since the LADARVision® system tracks my eye movements, I do not have to fixate on the blinking light.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the surgery, there is a good chance that I will be less dependent on eyeglasses.	<input type="checkbox"/>	<input type="checkbox"/>
5. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk that I may lose some vision after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. It does not matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
8. If I have an autoimmune disease, I am still a good candidate for LASIK.	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers to Self-Test at the bottom of Page 25.

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## M. Summary Of Important Information

- LASIK is a permanent operation to the cornea and is irreversible.
- LASIK does not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least 1 year before LASIK surgery. You will need written evidence that your farsightedness has changed less than or equal to 0.50 D.
- 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.
- 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.
- Alternatives to LASIK include, but are not limited to, glasses and contact lenses.
- The vision requirements of some occupations, such as military pilots, cannot be met by having LASIK.
- Before considering LASIK surgery you should:
  - a. Have a complete eye examination.
  - b. Talk with one or more eye care professionals about LASIK. This talk should include the potential benefits, risks, and complications of LASIK surgery. In addition, you should discuss the time needed for healing after LASIK.
- If you are older or are a woman on hormone replacement therapy, you may be less likely than other patients to achieve a visual acuity of 20/20 or better without glasses or contact lenses.
- If you have hyperopia greater than 5.0D, your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses.
- If you have hyperopic astigmatism greater than 4.0D MRSE before surgery (amount of hyperopic astigmatism based on your glasses prescription), your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses. In addition, you may be more likely to experience a reduction of 2 lines of visual acuity with glasses or contact lenses. You may also be more likely to need additional treatment. The safety and effectiveness of retreatments has not yet been established.

### Answers to Self-Test Questions:

1. False (see Risks on Page 16); 2. False (see Before the Surgery on Page 20); 3. False (see The Day of Surgery on Page 20); 4. True (see Benefits on Page 13); 5. True (see Introduction on Page 10); 6. True (see Risks on Page 16; also see The First Days After Surgery on Page 21); 7. False (see Contraindications on Page 15); 8. False (see Contraindications on Page 15).

**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: \_\_\_\_\_

**LASIK 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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