AUTONOMOUS TECHNOLOGIES CORPORATION (ATC)

LADARVision® EXCIMER LASER SYSTEM

PROFESSIONAL USE INFORMATION MANUAL FOR PHOTOREFRACTIVE KERATECTOMY (PRK)

PHYSICIAN'S BOOKLET

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 *Operator's Manual*.

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

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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 ATC 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) 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 Appendix III of the OPERATION MANUAL for additional information.

ATC 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 ATC 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 ATC by telephone (1-407-384-1600)

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 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 between 40 and 100 pulses per second. The characteristics of the laser beam at the corneal treatment plane are shown below.

Treatment Plane Characteristics of the LADARVision Excimer Laser Beam

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

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

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

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

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

3. INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, PATIENT SELECTION AND PROCEDURES

A. *INDICATIONS FOR USE*

The LADARVision System is indicated for use:

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

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

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

NOTE: Refer to the preceding General Warnings section of this *Professional Use Information Manual*, in addition to the warnings and precautions found in this section.

B. *CONTRAINDICATIONS*

PRK 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)

C. WARNINGS

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

2. PRK is not recommended in patients who:

   - have a history of herpes keratitis
   - have an autoimmune disease, collagen vascular disease, clinically significant atopic syndrome, insulin dependent diabetes, or an immunocompromised status

D. PRECAUTIONS

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

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

3. The safety and effectiveness of the ATC LADARVision® Excimer Laser System have not been established:

   - In patients in whom the residual corneal thickness at the completion of ablation was less than 250 microns (see Table 13 in the section on Surgical Procedure).
   - In patients with progressive myopia, ocular disease, corneal abnormality, previous corneal surgery or trauma in the ablation zone.
   - In patients with a history of keloid formation
   - In patients with a history of glaucoma
   - For treatment of astigmatism in patients with refractive cylinder of less than 0.50D
   - In patients who are taking sumatripin (Imitrex)

- In patients under 21 years of age.
- Over the long term (more than 9 months after surgery).

4. The effects of PRK on visual performance under poor lighting conditions have not been determined. It is possible, following PRK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night.

5. There is no safety and effectiveness information for refractive treatments greater than -10.0D of myopia or greater than -4.0D of astigmatism.

E. ADVERSE EVENTS AND COMPLICATIONS

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

	Spherical Myopia* (n=467)	Myopia with Astigmatism** (n=211)
Corneal Infiltrates[1]	1.5%	1.9%
IOP increase above 25 mmHg[1]	0.2%	1.4%
Feeling of something in the eye[2]	3.0%	2.4%
Double/ghost images[2]	2.6%	6.2%
Peripheral epithelial defect[2]	1.3%	0.5%
Pain[2]	1.3%	1.9%
Halos/starbursts[2]	0.6%	0.5%

*Other findings that occurred at a rate of <0.3% included corneal ulcer, corneal erosion, corneal abrasion, scratchiness, pain, epithelial irregularity, corneal swelling, subconjunctival hemorrhage, light sensitivity, epithelial dots, iritis and ocular hypertension.

** Other findings that occurred at a rate of <0.5% included retinal vascular accident, corneal abrasion and iritis.

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

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

	Spherical Myopia (n=358)	Myopia with Astigmatism (n=187)
Difficulty with night drivfng	4.3%	9.4%
Glare	1.7%	4.4%
Halos	2.3%	6.1%
Feeling of something in eye	1.4%	0.0%
Fluctuation of vision	1.1%	3.8%
Blurring of vision	0.9%	2.2%
Light sensitivity	0.9%	0.5%
Headache	0.3%	0.5%
Double vision	0.3%	0.5%
Pain	0.3%	0.0%
Excessive tearing	0.3%	0.0%
Burning	0.3%	0.0%

F. CLINICAL STUDY

1. 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 mild to moderate myopia (up to -10D). Eligibility criteria for patients included: being at least 18 years of age; eyes with up to 10D myopia spherical equivalent at the spectacle plane with astigmatism up to 6D; best spectacle corrected visual acuity of 20/40 or better in both eyes; and a stable manifest refraction as documented by a 0.5D change or less within the previous 12 months. Contact lens wearers had to abstain from contact lens use prior to baseline examination for 3 weeks.

Patients who exhibited any of the following conditions were excluded: significant corneal abnormalities; keratoconus; active ocular disease; irregular astigmatism, herpes keratitis; use of topical ophthalmic medications; history of keloid formation; severe dry eye syndrome unresolved by treatment; corneal thickness less than 400 microns, previous corneal or intraocular surgery; glaucoma; use of systemic medications likely to affect wound healing; and patients who were immunocompromised, pregnant or who had 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.

2. SPHERICAL MYOPIA

a) Demographics (Spherical Myopia)

TABLE 1
DEMOGRAPHICS (SPHERICAL MYOPIA)

467 Eyes of 395 Enrolled Patients

		Number	Percentage
Gender:	Female	242	61.3%
	Male	153	38.7%
Race:	Caucasian	365	92.4%
	Other	7	1.8%
	Black	10	2.5%
	Asian	13	3.3%
Age (yrs):	Average ± SD	40.3 ± 9.6	
	Range	19 to 72	
Contact Lens History:	None	89	22.5%
	Soft	274	69.4%
	RGP	30	7.6%
	PMMA	1	0.3%
	Other	1	0.3%

b) Baseline Parameters (Spherical Myopia)

TABLE 2
BASELINE PARAMETERS (SPHERICAL MYOPIA)

Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-4.05 ± 1.85	-1.00 to -9.75
Sphere	-3.90 ± 1.85	-0.75 to -9.50
Cylinder	-0.30 ± 0.28	0.00 to -0.75
Preoperative UCVA	n	%
20/100 or worse	365	83.9
20/50 to 20/80	54	12.4
20/25 to 20/40	16	3.7
≤20/20	0	0.0
Preoperative BSCVA	n	%
20/25 to 20/40	22	4.7
≤20/20	445	95.3

c) Safety and Efficacy Results (Spherical Myopia)

Table 3 presents a summary of the safety and efficacy results over time for spherical myopia. Table 4 shows the same parameters stratified by diopter of spherical equivalent correction. At 6 months, uncorrected visual acuity was better than preoperative best corrected visual acuity in 19% of eyes.

TABLE 3
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL MYOPIA -1 TO -10D

EFFICACY VARIABLES	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months
	n=428	n=419	n=389	n=159	n=69	n=25
UCVA 20/20 or better*	252	290	271	108	60	23
	58.9%	69.2%	69.7%	67.9%	87.0%	92.0%
UCVA 20/25 or better*	335	349	330	133	66	24
	78.3%	83.3%	84.8%	83.6%	95.7%	96.0%
UCVA 20/40 or better*	409	404	373	155	69	24
	95.6%	96.4%	95.9%	97.5%	100%	96.0%
	n=460	n=450	n=417	n=171	n=75	n=26
MRSE ±0.50D of intended	287	336	323	139	54	22
	62.4%	74.8%	77.5%	81.3%	72.0%	84.6%
MRSE ±1.00D of intended	387	411	386	164	73	25
	84.1%	91.5%	92.6%	95.9%	97.3%	96.2%
SAFETY VARIABLES	n=460	n=450	n=417	n=171	n=75	n=26
Loss of >2 Lines BSCVA	5	4	2	0	0	0
	1.1%	0.9%	0.5%	0.0%	0.0%	0.0%
Loss of 2 Lines BSCVA	13	13	4	3	1	0
	2.8%	2.9%	1.0%	1.8%	1.3%	0.0%
BSCVA worse than 20/40	1	0	1	0	0	0
	0.2%	0.0%	0.2%	0.0%	0.0%	0.0%
Increase >2D cylinder	0	0	0	0	0	0
	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	n=438	n=428	n=396	n=161	n=74	n=26
BSCVA worse than 20/25 if 20/20 or better preop	9	8	2	0	0	0
	2.1%	1.9%	0.5%	0.0%	0.0%	0.0%

* not including monovision eyes

TABLE 4
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
SPHERICAL MYOPIA -1 TO -10D STRATIFIED BY DIOPTERS
6 MONTHS

Efficacy		1.0 to 1.99	2.0 to 2.99	3.0 to 3.99	4.0 to 4.99	5.0 to 5.99	6.0 to 6.99	Cum <7D	7.0 to 7.99	8.0 to 8.99	9.0 to 9.99	Cum ≥7D	Cum ≤10D
		n=57	n=69	n=82	n=62	n=51	n=39	n=360	n=19	n=8	n=2	n=29	n=389
UCVA 20/20 or better*	n	45	49	72	43	28	20	257	11	3	0	14	271
	%	78.9	71.0	87.8	69.4	54.9	51.3	71.4	57.9	37.5	0.0	48.3	69.7
UCVA 20/40 or better*	n	56	68	82	56	49	37	348	17	7	1	25	373
	%	98.2	98.6	100	90.3	96.1	94.9	96.7	89.5	87.5	50.0	86.2	95.9
		n=57	n=72	n=88	n=69	n=56	n=45	n=387	n=20	n=8	n=2	n=30	n=417
MRSE ±0.50D	n	51	59	78	47	39	31	305	16	1	1	18	323
	%	89.5	81.9	88.6	68.1	69.6	68.9	78.8	80.0	12.5	50.0	60.0	77.5
MRSE ±1.00D	n	57	71	87	60	48	40	362	18	4	1	23	386
	%	100	98.6	98.9	87.0	85.7	88.9	93.5	90.0	50.0	50.0	76.7	92.6
Safety		n=57	n=72	n=88	n=69	n=56	n=45	n=387	n=20	n=8	n=2	n=30	n=417
Loss of >2 Lines BSCVA	n	0	0	0	0	0	0	0	0	1	1	2	2
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.5	50.0	6.7	0.5
Loss of 2 Lines BSCVA	n	1	1	0	0	1	1	4	0	0	0	0	4
	%	1.8%	1.4%	0.0%	0.0%	1.8%	2.2%	1.0%	0.0%	0.0%	0.0%	0.0%	1.0
BSCVA worse than 20/40	n	0	0	0	0	0	0	0	0	1	0	1	1
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.5	0.0	3.3	0.2
Increase >2D cyl	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BSCVA 20/20 preop		n=57	n=64	n=87	n=69	n=52	n=40	n=369	n=18	n=8	n=1	n=27	n=396
BSCVA worse than 20/25 if 20/20 or better preop	n	0	0	0	0	0	1	1	0	1	0	1	2
	%	0.0	0.0	0.0	0.0	0.0	2.5	0.3	0.0	12.5	0.0	3.7	0.5

Stability of refractive outcome is defined as the proportion of eyes with ≤1.00D change in spherical equivalent between 2 refractions taken 3 months apart. Table 5 shows that the spherical cohort achieves stability between 3 and 6 months. Between 6 and 9 months, 98.2% (n=164) experienced ≤1.00D of change in MRSE.

TABLE 5
STABILITY OF MANIFEST REFRACTION

Change in Spherical Equivalent Between	1 and 3 Months (n=403)	3 and 6 Months (n=403)
≤1.00	362 89.8%	389 96.5%
Mean ± SD Difference	0.49 ± 0.56D	0.30 ± 0.34D
95% CI	(0.437; 0.547)	(0.269; 0.336)

d) Patient Satisfaction (Spherical Myopia)

Responses to the patient satisfaction questionnaire at 6 months indicated that in the spherical myopia cohort, the quality of vision was improved in 93.5% of eyes and 88.6% were satisfied or extremely satisfied with the results. There was no need for distance correction in 95.2% of eyes.

e) Retreatments (Spherical Myopia)

Patients were eligible for re-treatment after 3 months of follow-up. Nine eyes (1.9%) were re-treated with the laser due to undercorrection, regression and/or induced astigmatism. At the last visit, 89% of these eyes were 20/40 or better uncorrected and 78% were ±0.50D of intended correction. Corneal haze was grade 1 or less in all eyes.

3. MYOPIA WITH ASTIGMATISM

a) Demographics (Myopia with Astigmatism)

TABLE 6
DEMOGRAPHICS (MYOPIA WITH ASTIGMATISM)

211 Eyes of 194 Patients Enrolled

		Number	Percentage
Gender:	Female	111	57.2%
	Male	83	42.8%
Race:	Caucasian	179	92.3%
	Other	0	0.0%
	Black	5	2.6%
	Asian	10	5.2%
Age (yrs):	Average ± SD	42.0 ± 9.0	
	Range	20 to 64	
Contact Lens History:	None	58	29.9%
	Soft	98	50.5%
	RGP	34	17.5%
	PMMA	2	1.0%
	Other	2	1.0%

b) Baseline Parameters (Myopia with Astigmatism)

TABLE 7
BASELINE PARAMETERS (MYOPIA WITH ASTIGMATISM)

Refractive Parameters (D)	Mean ± SD	Range
Spherical Equivalent	-5.03 ± 2.05	-1.00 to -10.25
Sphere	-4.32 ± 2.06	0.00 to -9.50
Cylinder	-1.42 ± 0.73	-0.50 to -5.50
Preoperative UCVA	**n**	**%**
20/100 or worse	186	92.5
20/50 to 20/80	10	5.0
20/25 to 20/40	5	2.5
≤20/20	0	0.0
Preoperative BSCVA	**n**	**%**
20/25 to 20/40	23	10.9
≤20/20	188	89.1

c) Safety and Efficacy Results (Myopia with Astigmatism)

Table 8 presents a summary of the safety and efficacy results over time for myopia with astigmatism. Table 9 shows the same parameters stratified by diopter of spherical equivalent correction. At 6 months, uncorrected visual acuity was better than preoperative best corrected visual acuity in 23% of eyes.

Following submission of the final PMA to FDA, nine month data was acquired on 112 eyes which provided longer term safety and effectiveness results as follows: UCVA 20/20 or better 61.6%; UCVA 20/25 or better 76.8%; UCVA 20/40 or better 99.1%; MRSE ±0.50D 79.0%; MRSE ±1.00D 93.3%; Loss of >2 lines BSCVA 0.8%.

TABLE 8
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
ASTIGMATIC TREATMENTS

Efficacy Variables	**1 Month**	**3 Months**	**6 Months**
	n=200	**n=199**	**n=177**
UCVA 20/20 or better *	96 48.0%	110 55.3%	105 59.3%
UCVA 20/25 or better*	144 72.0%	153 76.9%	143 80.8%
UCVA 20/40 or better *	185 92.5%	184 92.5%	165 93.2%
	n=210	**n=208**	**n=187**
MRSE ±0.50D	122 58.1%	149 71.6%	139 74.3%
MRSE ±1.00D	181 86.2%	187 89.9%	172 92.0%
Safety Variables	**n=210**	**n=208**	**n=187**
Loss of >2 Lines BSCVA	1 0.5%	1 0.5%	0 0.0%
Loss of 2 Lines BSCVA	7 3.3%	6 2.9%	4 2.1%
BSCVA worse than 20/40	1 0.5%	0 0.0%	0 0.0%
Increase >2D Cylinder	0 0.0%	0 0.0%	0 0.0%
BSCVA 20/20 Preop	**n=187**	**n=185**	**n=168**
BSCVA worse than 20/25 if 20/20 or better Preop	2 1.1%	4 2.2%	0 0.0%

TABLE 9
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
ASTIGMATIC TREATMENTS STRATIFIED BY DIOPTERS
(SPHERICAL EQUIVALENT)
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	5.0 to 5.99	6.0 to 6.99	Cum <7D	7.0 to 7.99	8.0 to 8.99	9.0 to 9.99	Cum ≥7D	Cum ≤10D
		n=12	n=15	n=36	n=36	n=24	n=18	n=141	n=22	n=9	n=5	n=36	n=177
UCVA 20/20* or better	n	9	14	22	20	16	8	89	9	5	2	16	105
	%	75.0	93.3	61.1	55.6	66.7	44.4	63.1	40.9	55.6	40.0	44.4	59.3
UCVA 20/40* or better	n	11	15	35	33	23	16	133	20	7	5	32	165
	%	91.7	100	97.2	91.7	95.8	88.9	94.3	90.9	77.8	100	88.9	93.2
		n=12	n=15	n=36	n=36	n=28	n=20	n=147	n=24	n=10	n=6	n=40	n=187
MRSE ±0.50D	n	11	14	33	27	16	15	116	13	6	4	23	139
	%	91.7	93.3	91.7	75.0	57.1	75.0	78.9	54.2	60.0	66.7	57.5	74.4
MRSE ±1.00D	n	12	14	35	34	24	17	136	22	8	6	36	172
	%	100	93.3	97.2	94.4	85.7	85.0	92.5	91.7	80.0	100	90	92.0
Safety Variables		n=12	n=15	n=36	n=36	n=28	n=20	n=147	n=24	n=10	n=6	n=40	n=187
Loss of >2 Lines BSCVA	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Loss of 2 Lines BSCVA	n	0	0	0	0	1	1	2	2	0	0	2	4
	%	0.0	0.0	0.0	0.0	3.6	5.0	1.4	8.3	0.0	0.0	5.0	2.1
BSCVA worse than 20/40	0	0	0	0	0	0	0	0	0	0	0	0	0
	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Increase >2D Cylinder	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BSCVA 20/20 Preop		n=11	n=14	n=35	n=36	n=27	n=14	n=137	n=20	n=8	n=3	n=31	n=168
BSCVA worse than 20/25 if 20/20 or better Preop	n	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Stability of refractive outcome is defined as the proportion of eyes with ≤1.00D change in spherical equivalent between 2 refractions taken 3 months apart. Table 10 shows that the astigmatic cohort achieved stability between 3 and 6 months. Between 6 and 9 months, 98.3% (n=118) experienced ≤1.00D in MRSE.

TABLE 10
MYOPIA WITH ASTIGMATISM: STABILITY OF MANIFEST REFRACTION SPHERICAL EQUIVALENT

Change in Spherical Equivalent Between		1 and 3 Months (n=185)	3 and 6 Months (n=185)
≤1.00	n	161	180
	%	87.0	97.3
Mean ± SD Difference		0.52 ± 0.53D	0.31 ± 0.33D
95% CI		(0.439; 0.590)	(0.261, 0.357)

Astigmatism correction was assessed based on the magnitude of cylinder and vector analysis (Table 11). At 6 months, 81.3% of eyes had ≤0.50D and 94.7% of eyes had ≤1.00D of residual cylinder.

TABLE 11
SUMMARY OF CYLINDER CORRECTION
6 MONTHS

Absolute Magnitude		Vector Analysis	
Preoperative	1.42 ± 0.69	Intended Vector	1.42 ± 0.69
Postoperative	0.30 ± 0.43	Difference Vector	0.30 ± 0.43
Achieved Magnitude	1.15 ± 0.71	Achieved Vector	1.36 ± 0.72
% Achieved	79 ± 29	% Achieved	96 ± 32
Axis Shift*	31.7 ± 27.3	Angle of Error	4.9 ± 11.0

*eyes with residual cylinder >0

d) Patient Satisfaction (Myopia with Astigmatism)

In the myopia with astigmatism group, the quality of vision was improved in 93.4% of eyes and 87.4% were satisfied or extremely satisfied with the results. Distance correction was not required in 93.4% of eyes postoperatively.

e) Retreatments (Myopia with Astigmatism)

Patients were eligible for re-treatment after 3 months of follow-up. In the astigmatic cohort 8 eyes (3.8%) were re-treated with the laser due to undercorrection, regression and induced astigmatism. At the last visit, 87% of these eyes were 20/40 or better uncorrected and 87% were within 0.50D of intended correction. Corneal haze was graded as trace or less in all eyes.

4. MODERATE MYOPIA

Data has been gathered on 48 eyes to demonstrate safety and effectiveness of the laser for the moderate myopic group. This group incorporates eyes from the Primary and Continuing Cases Cohort with myopia (with and without astigmatism) with a spherical equivalent correction between -8.01 and -10.00D. Data from the Primary Cohort only has been reported in the remainder of this document and represents results of primary and fellow eyes treated prior to May 30, 1997. The Continuing Cases Cohort consists of fellow eyes of patients enrolled in the Primary Cohort and these treatments were performed after May 30, 1997. Table 12 shows the key safety and efficacy parameters for these eyes.

TABLE 12
SUMMARY OF KEY SAFETY AND EFFICACY VARIABLES
-8.01 TO -10D SE MYOPIA ± ASTIGMATISM

Efficacy Variables	**1 Month**	**3 Months**	**6 Months**	**9 Months**
	n=40	**n=39**	**n=39**	**n=27**
UCVA 20/20 or better *	12 30.0%	20 51.3%	18 46.2%	16 59.3%
UCVA 20/25 or better*	19 47.5%	28 71.8%	25 64.1%	19 70.4%
UCVA 20/40 or better *	36 90.0%	35 89.7%	32 82.1%	24 88.9%
	n=48	**n=47**	**n=47**	**n=28**
MRSE ±0.50D	11 22.9%	24 51.1%	22 46.8%	16 57.1%
MRSE ±1.00D	25 52.1%	37 78.7%	31 66.0%	23 82.1%
Safety Variables	**n=48**	**n=47**	**n=47**	**n=28**
Loss of >2 Lines BSCVA	1 2.1%	0 0.0%	3 ** 6.4%	1 3.6%
Loss of 2 Lines BSCVA	2 4.2%	3 6.4%	1 2.1%	0 0.0%
BSCVA worse than 20/40	1 2.1%	0 0.0%	1 2.1%	0 0.0%
Increase >2D Cylinder	0 0.0%	0 0.0%	0 0.0%	0 0.0%

*not including monovision eyes
** two eyes recovered to no loss of lines by 9 months

Note: 10 eyes were not 20/20 or better BSCVA preoperatively

G. PATIENT SELECTION

Consideration should be given to the following in determining the appropriate patients for PRK:

- Patients who are contact lens wearers must be requested to discontinue contact lens wear in both eyes at least 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.

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

- Baseline evaluation of patients requesting refractive surgery should be performed within 60 days of the PRK surgery.

- The patient should have the ability to tolerate local or topical anesthesia and drops to dilate the pupil.

- The patient should have the ability to lie flat without difficulty.

- The patient should be able to fixate steadily and accurately for the duration of the PRK procedure.

- The patient must be able to understand and give an informed consent.

- Patients should be clearly informed of all alternatives for the correction of their myopia by use of spectacles, contact lenses and other refractive surgeries such as radial keratotomy.

H. PROCEDURE

1. PRE-OPERATIVE (EXAMINATION OF THE PATIENT)

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

A complete examination, including cycloplegic refraction and visual acuity evaluation, must be performed. The lens must be evaluated to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery, as these opacities may adversely affect the end surgical result. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. Pre-operative corneal topography is essential on all patients to exclude abnormalities. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 60 days of PRK 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 ATC 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 1). 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 spherical treatments is 6.0mm and for astigmatic treatments is 5.5mm x 7.5mm. Table 13 shows the ablation depth per diopter of correction at the 6.0 and 5.5mm optic zone sizes.

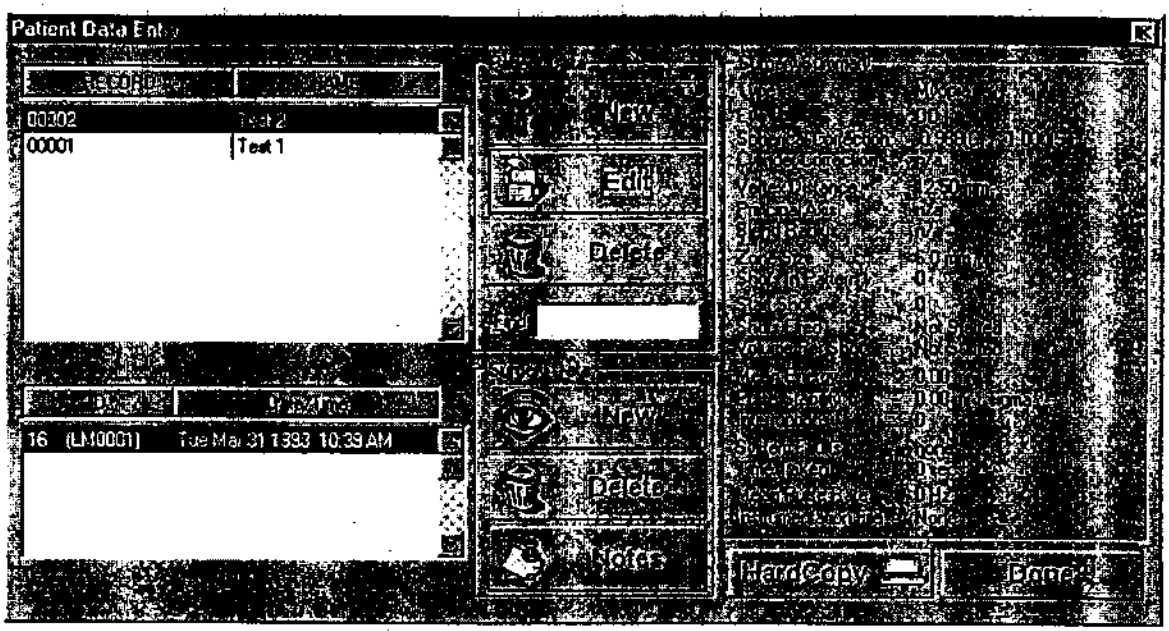

Figure 1. Surgery Database

Table 13 provides a reference with respect to the calculated ablation depth (microns) per diopter of correction for spherical (6mm) and astigmatic (5.5mm) optic zones.

TABLE 13
ABLATION DEPTH IN MICRONS AS A FUNCTION OF TREATMENT DIAMETER AND CORRECTION

	Optic Zone Diameter			Optic Zone Diameter	
Power (D)*	5.5	6.0	Power (D)*	5.5	6.0
0.5	6	8	6.5	82	100
1.0	12	15	7.0	88	107
1.5	19	23	7.5	95	115
2.0	25	30	8.0	101	123
2.5	31	38	8.5	107	131
3.0	37	45	9.0	114	139
3.5	44	53	9.5	120	147
4.0	50	61	10.0	127	155
4.5	56	68	10.5	133	163
5.0	63	76	11.0	140	171
5.5	69	84	11.5	147	179
6.0	75	92	12.0	153	187

*Power at the corneal plane; spherical equivalent for myopic spherical corrections; power of the highest dioptric meridian (spherical and cylindrical power combined) for myopic astigmatic corrections, e.g. -8.00DS/-4.00DC; maximum power correction is -12.0D in one meridian.

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

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

The LADARVision surgical procedure consists of four basic steps: (a) centration (b) pupil dilation and (c) laser calibration (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 flashing fixation LED. 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 2). 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 LED.

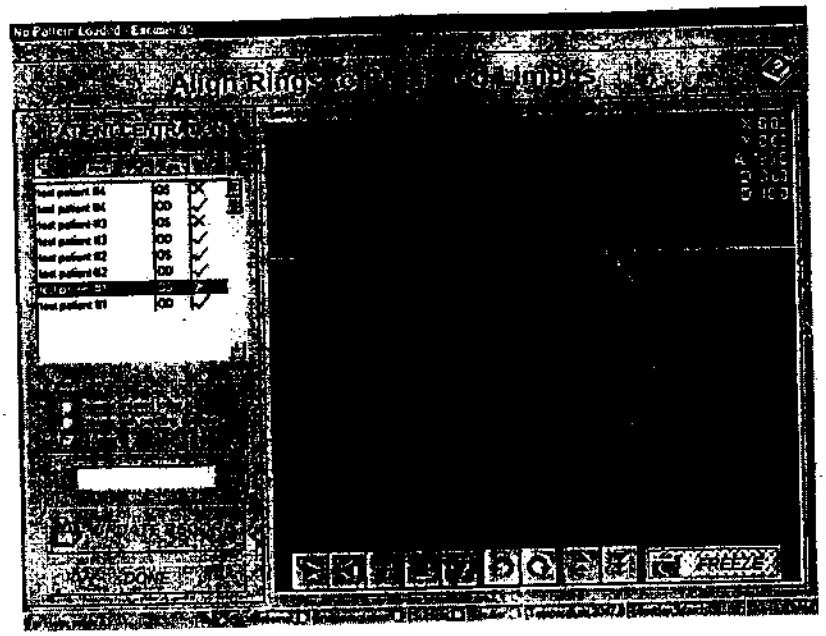

Figure 2. Undilated Pupil and Limbus Reticles

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 prior to epithelial removal 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 of the system cameras and laser beam are aligned to the same position. Finally, the Volume Per Shot step adjusts the correction algorithm based on the level of laser energy. If the laser energy changes, the number of pulses required to remove the desired tissue changes accordingly.

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

Ablation

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

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

Starting approximately 15 minutes prior to surgery, one drop of topical anesthetic is administered to the operative eye every 5 minutes. The patient is brought into the laser room, positioned under the laser and a speculum is inserted. Prior to epithelial removal, 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 the tracker is set, the epithelium is mechanically removed using a rotating brush, blunt spatula or surgical blade. The desired time between the initiation of epithelial removal and the start of ablation is standardized to two minutes to standardize corneal hydration. The software allows the surgeon to check if a sufficient zone of epithelium has been removed using a 6mm ablation zone indicator on the computer screen (Figure 3).

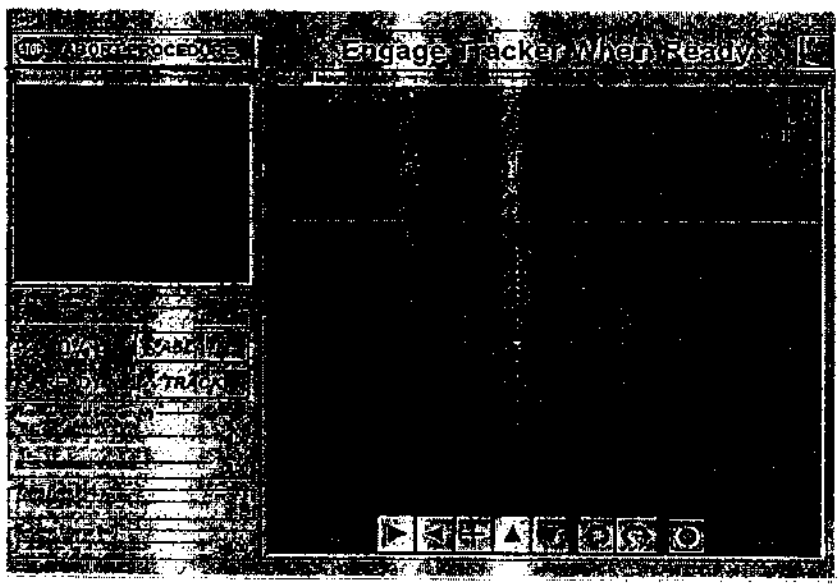

Figure 3. Showing Extent of Ablation Zone

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

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

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FACTS YOU NEED TO KNOW ABOUT LADARVision® PHOTOREFRACTIVE KERATECTOMY SURGERY FOR NEARSIGHTEDNESS

PATIENT INFORMATION BOOKLET

Mildly to Moderately Nearsighted Patients (-1.0 to -10.0 Diopters)
With Less Than or Equal to -4.0 Diopters of Astigmatism

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

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A. Glossary

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

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

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

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

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

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

Cataract: an opacity or clouding of the lens inside the eye that can cause a loss of vision.

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

Contraindications: any special condition that results in the treatment being inadvisable.

Cornea: the clear front surface of the eye. Surgery such as 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. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

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

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

Corneal Infiltrate: inflammation of the cornea.

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

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

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

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

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

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 PRK surgery.

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

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

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 PRK surgery.

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

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

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

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

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

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

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

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 PRK.

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

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

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

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the cornea using an excimer laser.

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

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

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

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

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

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 PRK to modify the healing of the cornea. If you are taking this drug for a disease condition, you should not have PRK 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.

B. Introduction

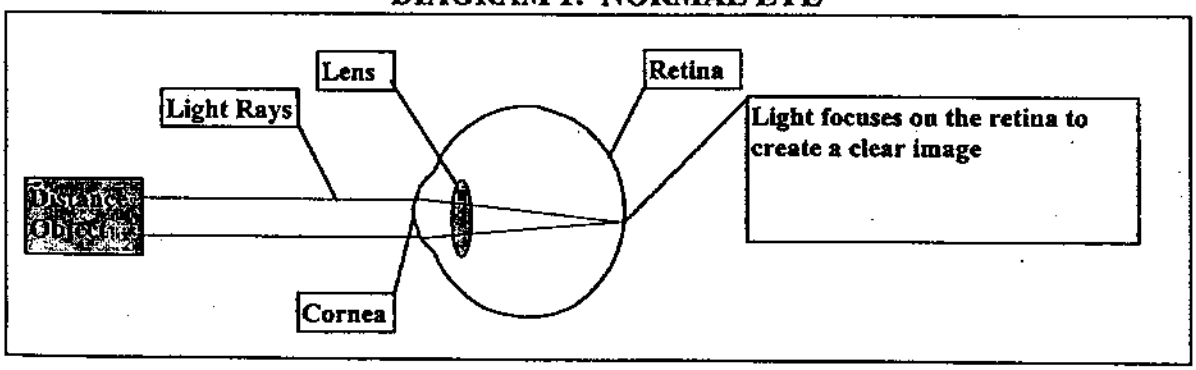
Do you need to wear glasses or contact lenses to help you to see clearly in the distance? One option to see more clearly at a distance is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. Radial Keratotomy (RK) is one type of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

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

C. How Does PRK Correct Myopia And 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. Blurred vision occurs when the light does not focus precisely on the retina.

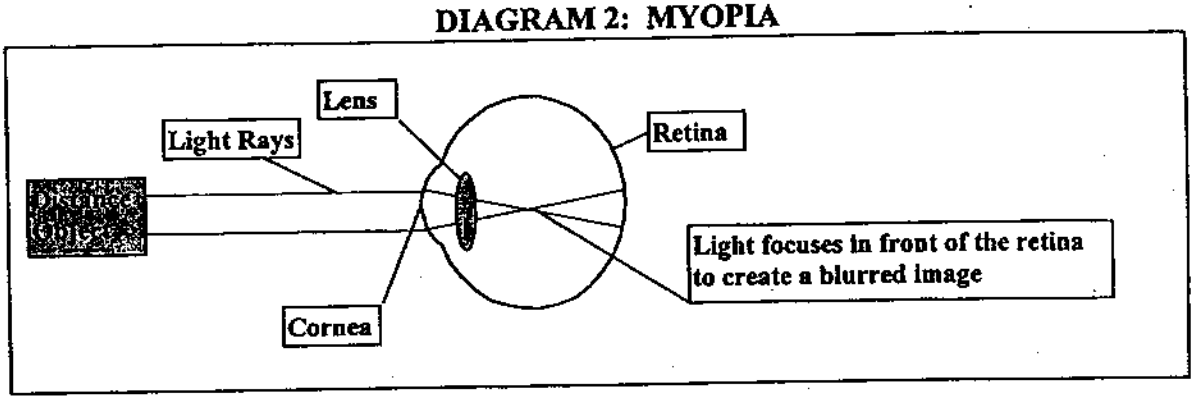
DIAGRAM 1: NORMAL EYE



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

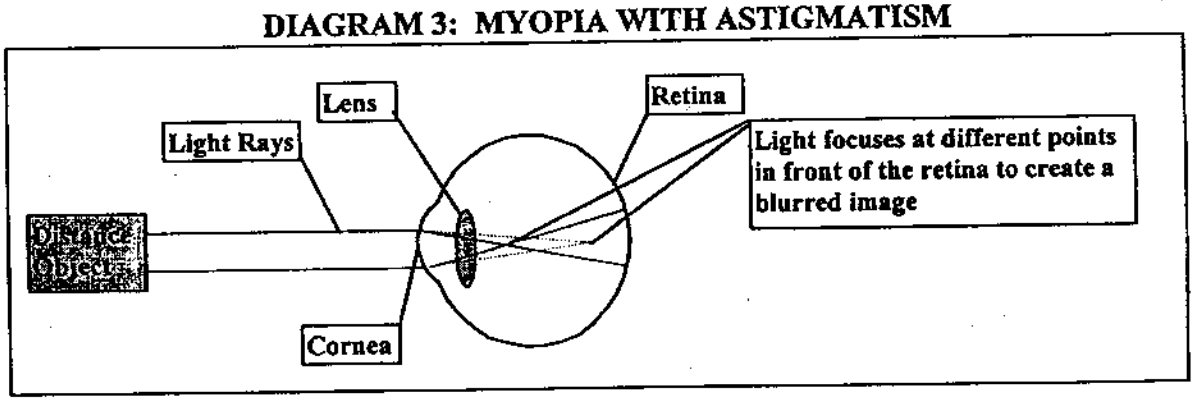
This incorrect focusing of light results in blurred images of objects at a distance. Diagram 2 shows how light focuses in front of the retina to cause a blurred image.

DIAGRAM 2: MYOPIA



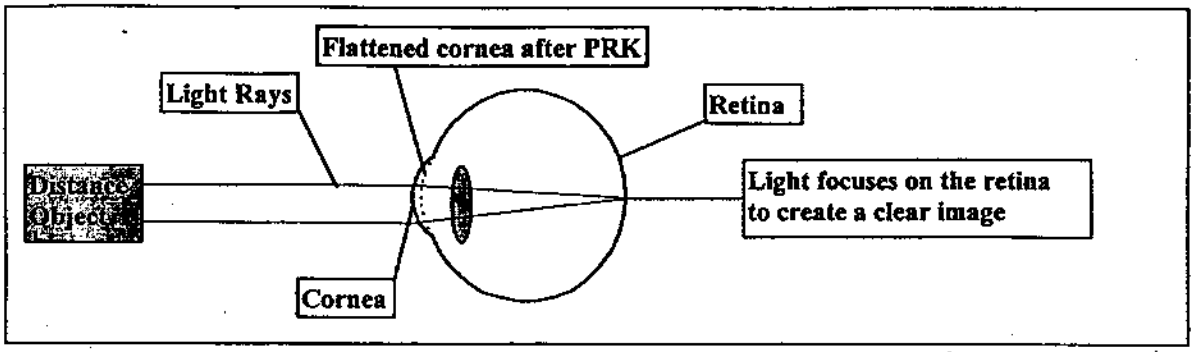
Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points in front of the retina. The different points of focus create blur of parts of the images. For example, a person with astigmatism might confuse an "R"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

DIAGRAM 3: MYOPIA WITH ASTIGMATISM



Another way to change the way the eye focuses light is to reshape the cornea. Flattening the cornea helps to focus all of the light rays on to the retina to provide clear vision. PRK flattens the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in PRK that removes tissue from the cornea. This type of laser reshapes the cornea without changing any other parts of the eye. Diagram 4 shows how PRK reshapes the cornea to provide clearer vision.

DIAGRAM 4: CORRECTION OF VISION AFTER PRK



The LADARVision® system tracks the movements of the eye during surgery. A very small laser beam is used to shape your cornea with this laser. Therefore, precise shaping of the cornea depends on accurate placement of the laser beam. Without a system to track eye movements, any movement of the eye could affect the placement of the laser beam. Your eyes are constantly making fine eye movements even though you may not be aware of the movement. Many of these movements are beyond your control. In addition, you would not be able to hold your eye perfectly still even if you tried. By tracking all eye movements, the LADARVision® system maintains accurate placement of the laser beam. The LADARVision® system corrects up to10 Diopters of myopia and up to 4 Diopters of astigmatism.

D. What Are The Benefits Of PRK?

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

- PRK may reduce overall nearsightedness. PRK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly at a distance.

E. What Are The Risks Of PRK?

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

The First Week Following Surgery

- Pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.

The First Two To Six Months Following Surgery

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

- Your cornea may become hazy or cloudy enough to affect your vision. Haze may occur as the cornea heals. The haze typically goes away over time. Some patients continue to have some haze over a longer period of time.

- You should contact your doctor if you notice any pain or change or loss of vision in the eye.

In U.S. clinical studies of the LADARVision® system, the following events related to the surgery have occurred. These events may result in a loss of vision.

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

	Eyes without Astigmatism Correction* (n=467)	Eyes with Astigmatism Correction** (n=211)
Corneal Infiltrates (inflammation)[1]	1.5%	1.9%
IOP increase above 25 mmHg[1]	0.2%	1.4%
Feeling of something in the eye[2]	3.0%	2.4%
Double/ghost images[2]	2.6%	6.2%
Peripheral epithelial defect[2]	1.3%	0.5%
Pain[2]	1.3%	1.9%
Halos/starbursts[2]	0.6%	0.5%

*Other findings that occurred at a rate of less than 0.3% included:

- corneal ulcer
- pain
- light sensitivity
- corneal swelling
- corneal erosion (a defect in the outer layer of the cornea that may recur)
- corneal abrasion (a scratch in the outer layer of the cornea often from an eye injury)
- epithelial dots (small spots in the outer layer of the cornea with no adverse effects)
- epithelial irregularity (an area of the outer layer of the cornea that is not smooth)
- scratchiness (similar to a feeling of something in the eye)
- iritis (inflammation of the inside of the eye behind the cornea)
- ocular hypertension (an increase in the pressure inside the eye)
- subconjunctival hemorrhage (an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.)

**Other findings that occurred at a rate of less than 0.5% included:

- retinal vascular accident (blockage of a blood vessel in the back of the eye unrelated to the surgery)
- corneal abrasion
- iritis

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

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

	Eyes without astigmatism correction	Eyes with astigmatism correction
Difficulty with night driving	4.3%	9.4%
Glare	1.7%	4.4%
Halos*	2.3%	6.1%
Feeling of something in eye	1.4%	0.0%
Fluctuation of vision	1.1%	3.8%
Blurring of vision	0.9%	2.2%
Light sensitivity	0.9%	0.5%
Headache	0.3%	0.5%
Double vision	0.3%	0.5%
Pain	0.3%	0.0%
Excessive tearing	0.3%	0.0%
Burning	0.3%	0.0%

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

F. Is PRK Right For You?

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

The results listed in the following section are from U.S. clinical studies of the LADARVision® system. Although vision without glasses improved for all eyes, some still needed glasses or contact lenses for some tasks after PRK. PRK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having RK or PRK.

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

U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER PRK SURGERY						
	Eyes without astigmatism			Eyes with astigmatism		
	All Eyes	<7D of myopia	≥7D of myopia	All Eyes	<7D of myopia	≥7D of myopia
Visual Acuity 20/20 or better without glasses*	69.7%	71.4%	48.3%	59.3%	63.1%	44.4%
Visual Acuity 20/25 or better without glasses*	84.8%	86.4%	65.5%	80.8%	85.1%	63.9%
Visual Acuity 20/40 or better without glasses*	95.9%	96.7%	86.2%	93.2%	94.3%	88.9%
Visual Acuity 20/20 or better with glasses	96.8%	97.6%	86.7%	93.6%	96.5%	82.5%
Visual Acuity 20/40 or better with glasses	99.8%	100%	96.7%	100%	100%	100%
Loss of more than 2 lines of visual acuity with glasses	0.5%	0.0%	6.7%	0.0%	0.0%	0.0%

*not including eyes treated for monovision

G. Contraindications

You should NOT have PRK surgery if:

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

H. Warnings

Discuss with your doctor if:

- You are an insulin dependent diabetic
- You have an autoimmune disease (a condition that affects your immune response or your body's ability to heal, e.g. aids)
- You have severe allergies
- You have a collagen vascular or autoimmune disease (These diseases are conditions that result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of these diseases are lupus, rheumatoid arthritis, multiple sclerosis and myasthenia gravis.)
- 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) before surgery to optimize the tracker operation. This effect is only temporary.

I. Precautions

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

- In eyes with unstable or worsening myopia (nearsightedness)
- In eyes with disease or corneal condition (for example, scar, infection, etc.).
- In eyes with previous surgery or injury to the center of the cornea where PRK will reshape the cornea
- In patients with a cornea that is too thin for the procedure to be completed safely
- In patients with a history of glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision)
- In patients with a tendency to form scars
- In patients who are taking the medication Sumatripin (Imitrex®)
- In patients under 21 years of age
- For the treatment of astigmatism less than 0.50 Diopters
- In patients over the long term (more than 9 months after surgery)

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

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

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

- The effects of PRK surgery on vision under poor lighting conditions have not been determined. Poor lighting conditions may include very dim light, rain, snow, fog, and glare from bright lights at night. It is possible that patients may find it more difficult to see in these conditions after PRK surgery.

- There is no safety and effectiveness information for refractive treatments greater than -10.0D of myopia or greater than -4.0D of astigmatism.

J. Are You A Good Candidate For PRK?

If you are considering PRK, you must:

- Be at least 21 years of age
- Have healthy eyes that are free from eye disease or corneal condition (for example, scar, infection, etc.)
- Have myopia between -1.0 to -10.0 diopters with no more than 4.0 diopters of astigmatism
- Have documented evidence that the change in your nearsightedness is less than or equal to 0.50 diopter per year for at least one year prior to your pre-operative exam
- Stop wearing your contact lenses in both eyes at least 3 weeks prior to your examination for surgery
- Be examined within 60 days of your surgery date
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the PRK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of PRK risks and benefits as compared to other available treatments for myopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

K. What Should You Expect During PRK Surgery?

Before The Surgery

First, you will need to have a pre-operative examination if you have an interest in PRK. This exam will help to determine if your eye is healthy and suitable for PRK. 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.

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

You will be under the laser for several minutes. Overall, the surgery takes about 10 minutes. After the laser surgery is complete, your doctor will place some drops into your eye. For your eye protection and comfort, your doctor will cover your eye with a bandage contact lens. 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. Use of the non-steroidal anti-inflammatory drops and the bandage contact lens help to diminish the pain. **DO NOT** rub your eyes for the first 3 to 5 days. Your doctor can also prescribe pain medication to make you more comfortable during this time after the surgery.

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

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.

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

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

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

L. Questions To Ask Your Doctor

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

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

M. Self-Test

Are You An Informed And Educated Patient?

Take the test below and see if you can correctly answer these questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser surgery is risk free.	☐	☐
2. Excimer laser surgery is the same as Radial Keratotomy (RK).	☐	☐
3. It does not matter if I wear my contact lenses when my doctor told me not to wear them.	☐	☐
4. Since the LADARVision® system tracks my eye movements, I do not have to fixate on the blinking light.	☐	☐
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.	☐	☐
6. I may need reading glasses after laser surgery.	☐	☐
7. There is a risk that I may lose some vision after laser surgery.	☐	☐
8. It does not matter if I am pregnant.	☐	☐
9. If I have an autoimmune disease, I am still a good candidate for PRK.	☐	☐

You can find the answers to Self-Test at the bottom of Page 19.

N. Summary Of Important Information

- PRK is a permanent operation to the cornea and is irreversible.
- PRK does not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before PRK surgery. You will need written evidence that your nearsightedness has changed less than or equal to 0.50 Diopters.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You would not be a good candidate if you have collagen vascular or autoimmune diseases. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- PRK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- PRK is not a laser version of Radial Keratotomy (RK). These surgeries are entirely different from each other.
- Alternatives to PRK include, but are not limited to, glasses, contact lenses and RK.
- The vision requirements of some occupations, such as military pilots, cannot be met by having RK or PRK.
- Before considering PRK surgery you should:
  a. Have a complete eye examination.
  b. Talk with one or more eye care professionals about PRK. This talk should include the potential benefits, risks, and complications of PRK surgery. In addition, you should discuss the time needed for healing after PRK.

Answers to Self-Test Questions:
1. False (see Risks on Page 9); 2. False (see Introduction on Page 6); 3. False (see Before the Surgery on Page 15); 4. False (see The Day of Surgery on Page 15); 5. True (see Benefits on Page 8); 6. True (see Is PRK Right For You on Page 11); 7. True (see Risks on Page 9); 8. False (see Contraindications on Page 12); 9. False (see Warnings on Page 13).

O. Patient Assistance Information

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

PRK DOCTOR

Name: _____

Address: _____

Phone: _____

TREATMENT LOCATION

Name: _____

Address: _____

Phone: _____

LASER MANUFACTURER

Autonomous Technologies Corp. (ATC)
2800 Discovery Drive
Orlando, FL 32826 U.S.A.
Tel: (407) 384-1600 Fax: (407) 384-1699

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