



ALLEGRETTO WAVE™

Scanning Spot LASIK Laser System

Procedure Manual

Information for professional use

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Using The ALLEGRETTO WAVE™ Procedure Manual

This manual provides information for the intended clinical use of the ALLEGRETTO WAVE Laser System.

Refer to the Operator Manual for the Laser Console and to the User's Manuals of the approved accessories for information regarding these components.

Carefully read and understand this manual and all related documents and instructions before using the ALLEGRETTO WAVE Laser System.

Observe all warnings, precautions and contra-indications as described in these documents.

Do not perform adjustments and procedures other than those described herein.
Failure to do so may result in harm to patient and / or user.

Consult the Table of Contents, Appendices or Indices for specific information.
If you have questions that are not addressed in this manual, contact:

**Lumenis Customer Hotline
(Business Card / Sticker)**

TYPOGRAPHICAL CONVENTIONS:

The following conventions are used in this manual for Warnings, Precautions and Notes:

WARNING

A Warning alerts the user to potential serious outcomes to the patient or the user.

CAUTION

Precautions alert the user to exercise special care necessary for the safe and effective use of the device.

NOTE

Notes provide user with helpful or supplementary information.

Notice To Users

RESTRICTIONS BY US FEDERAL LAW

CAUTION: US Federal law restricts this device to sale by or on the order by a physician or licensed eye care practitioner.

CAUTION: US Federal law restricts the use of this device to practitioners who have been trained in its operation, test and calibration and who have experience in the surgical management and treatment of refractive errors of the human eye.

RESTRICTIONS BY MANUFACTURER

There are no rightful claims to system upgrades in the event of the introduction of product improvements based on new technological developments.

CAUTION

Read and understand this Procedure Manual, the Operators Manual and all related manuals of the Laser System and its approved accessories before starting to use the ALLEGRETTO WAVE Laser System

1 Table of Contents

1 Table of Contents	6
2 Safety	8
2.1 General Warnings	8
2.2 Patient Safety	9
2.3 Laser Radiation Hazards	9
2.3.1 Eye and Skin Exposure	9
2.3.2 Laser Safety Eyewear	9
2.3.3 Additional Ocular Protection	9
2.3.4 Laser Area	10
2.3.5 Additional Safety Considerations	10
2.4 Airborne Contaminants	10
2.4.1 Laser Plume	10
2.4.2 Fluorine	10
2.4.3 Ozone	11
2.4.4 Further Information	11
2.5 Protecting Non-target Tissues	11
2.6 Electrical Hazard	11
2.7 Fire Hazards	11
2.8 Electro-Magnetic Radiation Hazards	12
3 Device Description	13
4 Indications, Contraindications, Warnings, Precautions and Adverse Events	14
4.1 Indications for Use	14
4.2 Contraindications	14
4.3 Warnings	14
4.4 Precautions	15
4.4.1 General	15
4.4.2 Patient selection	15
4.4.3 Procedure	16
4.4.4 Post Procedure	18
4.5 Adverse Events	19
5 Study data	21
5.1 Study Objectives	21
5.2 Study Design	21
5.3 Inclusion and Exclusion Criteria	21
5.4 Study Plan, Patient Assessments, and Efficacy Criteria	22
5.5 Study Period, Investigational Sites and Demographic Data	22
5.5.1 Study Period	22
5.5.2 Demographics and Baseline Characteristics	23
5.6 Data Analysis and Results	23
5.6.1 Baseline characteristics	23
5.6.2 Postoperative Characteristics and Results	24
5.6.2.1 Patient Accountability	24
5.6.2.2 Stability of Outcome	25
5.6.2.3 Effectiveness Outcomes	25
5.6.2.4 Key Safety Results	28
5.6.2.5 Retreatment	30
5.6.2.6 Patient Satisfaction	30
6 Powering Up and Laser Calibration	32

7 Preparation of Devices, Instruments and Material.....	33
8 Treatment Planning and Data Entry.....	34
8.1 Login	34
8.2 Treatment plan and Data Entry.....	34
8.2.1 Parameters determining Ablation	34
8.3 Feasibility Checks	35
8.3.1 Ablation Depth and Remaining Stromal Thickness.....	36
8.3.2 Mesopic Pupil Size	38
8.3.3 Flap Size and Hinge Location	38
8.4 Confirm, Send and Save Data	39
8.5 Additional Data Entry Information	41
8.5.1 Incorrect Data.....	41
8.5.2 Enter Treatments in a Queue.....	42
8.5.3 Open and Use Treatment Data on File	42
8.5.4 Working with short cuts	42
9 Patients preparation and surgery	44
9.1 Preoperative Medication	44
9.2 Environmental Check.....	44
9.3 Preparation.....	45
9.4 Eyetracker Calibration.....	47
9.5 Laser Ready.....	51
9.6 Centration.....	52
9.6.1 Automatic Centration Check	52
9.6.2 Changing Centration / Intended Decentration.....	52
9.7 Keratomileusis	54
9.8 Laser Ablation	55
9.8.1 Precautions and settings.....	55
9.8.2 Procedure.....	58
9.9 Management of intra-ablation events:	60
9.9.1 Bleeding	60
9.9.2 Pupil Decentered.....	60
9.9.3 Stammering Laser Sound.....	60
9.9.4 Laser Stops Before End of Treatment.....	60
9.9.5 Patient does not fixate.....	61
9.10 Post ablation procedures	61
9.11 Next treatment	61
9.12 Postoperative Medication.....	62
9.13 Retreatment procedures	62
10 Appendix.....	63
10.1 Table Effective Ablation Zone and Treatment Time	64
10.1.1 Optical Zone 6.0 mm.....	64
10.1.2 Optical Zone 6.5 mm.....	65
10.2 List of Optical and Ablation Zones	66
10.3 Ablation Profiles	67
10.4 Patients Views	68
10.4.1 Focused View.....	68
10.4.2 Blurry Views	69
10.4.3 Blurry View with Distance Diode Light	69

2 Safety

2.1 General Warnings and Precautions

The ALLEGRETTO WAVE Laser System is a medical device currently designed for use in ophthalmology for the photorefractive treatments with the Laser In-Situ Keratomileusis ("LASIK") procedure. It is intended for use solely by the physicians trained in the use of this Laser System.

WaveLight medical lasers and accessories are intended solely for use by the physicians trained in the use of these instruments.

The system user alone is responsible for having sufficient medical knowledge for carrying out all surgical procedures. The user must be well versed in the therapeutic effects and possible dangers of the device and must possess the necessary skills to use it in conformity with the operating instructions contained in this manual.

Ensure that you have complied with all local, regional and governmental regulations pertaining to the use of Class IV lasers prior to using this device.

Only ALLEGRETTO WAVE Service Representatives or Service Representatives who have been specifically authorized by WaveLight Laser Technologie AG may service the Laser System. Servicing or any form of manipulation of the system by non-authorized personnel will result in a termination of the warranty and nullification of any liability on the part of WaveLight Laser Technologie AG.

The ALLEGRETTO WAVE Laser System may only be operated with accessories or components that are approved, delivered or provided by WaveLight Laser Technologie AG specifically for the use with the ALLEGRETTO WAVE Laser System.

Do not operate the Laser System if any of the screens are dark or the display is distorted.

The ALLEGRETTO WAVE Laser System is a stationary device that must not be moved by the user.

After turning on the Laser System carefully go through the calibration tests and record the results in the laser logbook. The system has to be tested successfully before use. Failure to do so may result in harm to the patient (under - or over correction or de-centered ablation).

Call the ALLEGRETTO WAVE Service Representative to check the Laser System after exposure to any kind of shock that could have caused a misalignment of the optical elements. Misalignment after a shock exposure could result in non-satisfactory treatments.

Precautionary measures are to be employed in the handling and use of all accessories, disposable articles and agents that come into contact with patients to avoid exposure to pathogens.

Do not operate the laser system outside the environmental specifications provided in the Operators Manual.

Do not eat drink or smoke in the laser room.

During surgery, carefully monitor the laser ablation through the microscope. Stop depressing the Laser Foot Pedal immediately if the laser spots seem to fall only in one location or debris or liquid is visible on the ablated surface.

2.2 Patient Safety

All patients must be given the opportunity to read and understand the Patient Booklet and all of their questions must have been answered to the patients' satisfaction before giving the consent for Laser In-Situ Keratomileusis surgery (LASIK).

2.3 Laser Radiation Hazards

2.3.1 Eye and Skin Exposure

The ALLEGRETTO WAVE Laser System contains a Class IV laser. The integrated Excimer laser creates invisible UV laser radiation with 193nm wavelength. The emission is pulsed with a repetition rate of 200Hz. Each pulse has a pulse length of 10-20ns. The average power is < 0.8W.

This radiation is potentially hazardous to skin and to surface layers of the cornea. This radiation will not enter the eye and is not hazardous to posterior segment of the eye or to the crystalline lens.

Hazardous laser radiation will occur during the test procedures, treatment and service procedures. During user test procedures and treatments, the radiation leaves the Laser Aperture under the Microscope arm towards the headrest or the floor. The area of potential hazard is called the Nominal Hazard Zone (NHZ). As reflections may occur from instruments or devices brought into the laser beam, the entire laser room is considered to be the NHZ. The floor, ceiling, walls, closed doors and closed windows bound the hazard zone.

All personnel in the laser room should avoid direct laser radiation exposure to skin or eyes.

2.3.2 Laser Safety Eyewear

All personnel who are within the NHZ shall wear eye protection with a minimum optical density (OD) of 8.23 at 193nm wavelength.

2.3.3 Additional Ocular Protection

Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light onto the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage. Laser safety eyewear must be worn in addition to prescription eyewear.

Never look directly into laser aperture while the laser is powered. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.

2.3.4 Laser Area

In addition to providing the required laser safety eyewear, take the following steps to secure the treatment room, or the controlled area:

To alert personnel before they enter the controlled area, place a warning sign on the outside of all treatment room doors when the laser is in use.

Close the treatment room doors during operation of the laser.

External door interlocks that automatically disable the laser when the treatment room door is opened may be installed.

2.3.5 Additional Safety Considerations

Laser light can be reflected off smooth metallic surfaces, even though they may be blackened.

CAUTION

Plastic instrumentation such as speculums or eye shields may melt when exposed to the laser beam, possibly resulting in chemical burns or noxious gases. Therefore, only surgical instruments approved for the use with lasers should be used.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

For further information regarding Laser Safety refer to the Operators Manual.

2.4 Airborne Contaminants

2.4.1 Laser Plume

Laser plume may contain viable tissue particulates.

The Laser Plume may be noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be evacuated.

Plume Evacuation has to be applied during every treatment.

2.4.2 Fluorine

The ALLEGRETTO WAVE Laser System is equipped with pressurized cylinder of ArF-Premix-Gas. Fluorine is one of the ingredients of the ArF-Premix-Gas mixture necessary for operating the excimer laser. The ALLEGRETTO WAVE ArF-Premix-Gas includes < 0.2 Vol. % Fluorine gas. Fluorine gas is hazardous. Inhalation as well as eye and skin contact with fluorine should be avoided.

Keep the ArF Premix Gas Cylinder closed when the system prompts you to do so or when powering down the Laser Console. Fluorine can be detected by its pungent odor.

For further information regarding gas safety refer to the Operators Manual.

2.4.3 Ozone

A further potential danger consists due to the formation of ozone, which arises from the interaction of oxygen and either ultraviolet radiation or high voltage. Ozone can also be detected by its pungent odor. Purging the beam path with nitrogen reduces the formation of ozone in the laser system.

2.4.4 Further Information

For further information regarding safety against airborne contaminants, refer to the Operators Manual.

2.5 Protecting Non-target Tissues

Except during actual treatment and test procedures, the Laser Console must always be in Standby Mode. Maintaining the Laser Console in Standby Mode prevents accidental laser exposure if the Laser Foot Pedal is inadvertently depressed.

Only the person performing the surgery should have access to the Laser Foot Pedal. Use caution depressing the Laser Foot Pedal when it is in proximity to footswitches for other equipment. To avoid accidental laser exposure make sure the footswitch about to be depressed is the correct one.

2.6 Electrical Hazard

Never open the protective covers of Laser Console and accessories. Opening the covers can expose the user to high voltage components, the laser resonator and possible laser radiation. Only WaveLight-certified ALLEGRETTO WAVE Service Representatives shall work inside the Laser Console and inside the accessories.

The area around the Laser Console, Foot Pedal Unit and any of the accessories should be kept dry. Do not operate the laser if any of the cords are faulty or burned. The laser should undergo routine inspection and maintenance per WaveLight manufacturer's recommendations and institutional standards.

2.7 Fire Hazards

Do not use this device in the presence of flammables or explosives, such as, but not limited to, volatile anesthetics and alcohol. An explosion and/or fire could occur.

2.8 Electro-Magnetic Radiation Hazards

The device has been successfully tested for electromagnetic conformity according to IEC 601 standard (International standard for medical laser systems).

Despite adherence to all applicable EMC requirements, collateral influence of laser system and other electronic devices cannot be ruled out entirely. The use of any kind of cellular device in the laser room and in the vicinity of the laser during test and treatments is not allowed.

Effects of the device on implantable medical devices are unknown.

On account of possible risk of interference while the laser is in operation, persons with implanted devices such as, but not limited to pacemakers or defibrillators may not be present in the laser room during operation.

Effects on embryos are unknown. Pregnant women may not be present in the laser room while the laser is in operation.

3 Device Description

The ALLEGRETTO WAVE is a scanning spot Excimer Laser System used in refractive surgery for photorefractive treatments with the Laser In-Situ Keratomileusis (LASIK) technique.

The excimer laser creates a radiation of 193nm wavelength. This radiation is able to ablate corneal tissue in very thin layers without damage or thermal alteration of collateral tissue. The ablation effect is threshold dependent - the energy per irradiated area, known as Fluence, has to be above a certain threshold to ablate corneal tissue. Below the threshold the radiation will cause heating instead of ablation.

The laser radiation is used to change the front shape of the corneal lens by ablating tissue. This sculpting has to be done with very high precision in order to achieve a new corneal lens shape with the desired smoothness of surface and precision of optical power. Every single laser pulse (spot) has to meet very high requirements regarding precision of ablated depth, volume and spot position.

The ALLEGRETTO WAVE Laser System consists of a combination of features including several internal energy control mechanisms and external test procedures to provide the right energy and fluence per laser pulse. The fast Eyetracker for determining eye position and a precise scanner motor for positioning the laser spot enable precise placement of every laser spot even when the eye is moving or having saccades. In addition, the Eyetracker offers an automatic centration of the ablation to avoid unintended decentration of the correction zone.

The Gaussian shaped energy distribution within the laser beam and a small ablation spot of approximately 1 mm assure the desired contour precision and high surface smoothness of the newly shaped corneal curvature. Refer to section 10.3 for detailed information about ablation profiles.

Due to the small spot diameter used in the ALLEGRETTO WAVE, the excimer laser beam source is compact with low laser gas volume and minimal laser gas consumption.

During the treatment thousands of laser pulses have to be delivered to the cornea in a complex pattern. As the excimer laser is operated with a high repetition rate of 200 pulses per second, treatment times are short.

For treatments at least the following components of the system have to be operated:

Laser Console	- containing operating elements, laser head, optical transmission system, energy and system controls, eyetracker, scanner motors, gas supply, focusing and fixation lights, system software and ablation profiles with scanning spot patterns, operating microscope with illumination and test systems.
Patient Bed	- with moving motors and bed control
Eyetracker Monitor	- showing the tracked pupil / eye
Notebook Computer	- containing software for programming treatment parameters
Plume Evacuator	- to remove ablation plume during treatment

Optional accessories, such as slit lamp, may be applied for higher comfort.

A microkeratome of the physician's choice is utilized to create the flap before the laser portion of the treatment can be conducted.

4 Indications, Contraindications, Warnings, Precautions and Adverse Events

4.1 Indications for Use

The ALLEGRETTO WAVE Laser System is indicated for use in Laser In-Situ Keratomileusis (LASIK) treatments for:

- the reduction or elimination of myopia of up to –12.0 diopters (D) of sphere and up to –6.0 D of astigmatism at the spectacle plane;
- patients who are 18 years of age or older; and
- patients with documentation of a stable manifest refraction defined as ≤ 0.5 D preoperative spherical equivalent shift over one year prior to surgery.

4.2 Contraindications

LASIK treatments are contraindicated in:

- pregnant or nursing women;
- patients with a diagnosed collagen vascular, autoimmune or immunodeficiency disease;
- patients with diagnosed keratoconus or any clinical pictures suggestive to keratoconus; and
- patients who are taking one or both of the following medications: isotretinoin (Accutane®¹); amiodarone hydrochlorid (Cordarone®²).

4.3 Warnings

LASIK treatment is not recommended in patients who have :

- systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status;
- a history of Herpes simplex or Herpes zoster keratitis;
- significant dry eye that is unresponsive to treatment; and
- severe allergies.

¹ Accutane® is a registered trademark of Hoffmann-La Roche Inc.

² Cordarone® is a registered trademark of Sanofi-Synthelabo Inc.

4.4 Precautions

4.4.1 General

Safety and effectiveness of the ALLEGRETTO WAVE Laser System has not been established for patients:

- with progressive myopia and/or astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone;
- with corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage;
- with residual corneal thickness after ablation of less than 250 microns due to an increased risk for corneal ectasia;
- with history of glaucoma or ocular hypertension of > 23 mmHg;
- taking the medication sumatriptan succinate (Imitrex^{®3});
- under 18 years of age;
- over the long term (more than 12 months after surgery);
- with media problems, corneal, lens and/or vitreous opacities including, but not limited to, cataract;
- with iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eyetracking;
- taking medications likely to affect wound healing including, but not limited to, antimetabolites;
- for treatments with an optical zone below 6.0 millimeters and above 6.5 millimeters in diameter. While the ALLEGRETTO WAVE has the potential for additional ranges of optical and ablation zones, no information is available regarding their level of safety and/or effectiveness; and
- your nearsightedness is worse than -12 **Diopters** or **astigmatism** is worse than 6 **Diopters**, because it is unknown whether **LASIK** is safe and effective for you. ✓

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see such in conditions as very dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently in the presence of residual refractive error and perhaps in patients with pupil sizes larger than the optical zone size.

The refraction is determined in the spectacle plane, but treated in the corneal plane. In order to determine the right treatment program to achieve the right correction, assessment of the vertex distance during refraction test is recommended.

Preoperative evaluation for dry eyes should be performed. Patients should be advised of the potential for dry eyes post LASIK surgery.

4.4.2 Patient selection

In addition to contraindications, warnings and general precautions the following should be considered in order to find good candidates for LASIK and to get sufficient information for the treatment plan:

- A complete baseline exam including, but not limited to, cycloplegic refraction within 60 days prior to surgery is necessary. A slit lamp exam has to be performed. The status of

³ Imitrex[®] is a registered trademark GlaxoSmithKline Inc.

the lens has to be evaluated to ensure that neither nuclear sclerosis nor other lens opacities are present. These opacities may adversely affect final visual result. Dilated fundus exam by indirect ophthalmoscopy has to be performed, as retinal pathology is more likely in patients with myopia.

- The pupil size should be obtained under low light conditions so that the maximum dilated size of the patient's pupil can be estimated. This will allow for the selection of appropriate optical zone sizes that can limit the potential for night time driving problems with glare, haloes, etc. Patients with very large mesopic pupil should be advised of potential for negative effects on vision after surgery, such as glare, halos and nighttime driving difficulty.
- Preoperative evaluation of dry eye should be performed. Patients should be advised of the potential for dry eye post-LASIK surgery.
- Optical nerve and intraocular pressure have to be examined as glaucoma is more common in myopic than emmetropic subjects. If elevated pressure or signs of glaucomatous damage are found, topical steroids should be used only under careful medical supervision or the patient should not be treated.
- In order to exclude corneal abnormalities careful videokeratography (topography) is essential.
- Contact lens wearers must discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 3 days **prior to preoperative evaluation**.
- Contact lens wearers must also discontinue wearing hard or gas permeable lenses for at least 3 weeks and soft lenses for at least 3 days **prior to surgery**.
- The patient must be able to lie flat in a supine position
- Topical or local anesthesia must be tolerated.
- The patient must be able to fixate steadily.
- The patient must be able to understand and give the informed consent and sign the informed consent form.
- All alternatives to the LASIK procedure for correcting myopia by spectacles, contact lenses and other surgical procedures such as radial keratotomy, automated lamellar keratoplasty or clear lens exchange should be clearly communicated and understood by the patient.

4.4.3 Procedure

The determined patient and eye data have to match with the patient presenting and with the eye prepared for surgery. Make sure that treatment parameters are precisely transferred from the files to the laser system. A double check with the patient and assisting personnel is recommended. It is the sole responsibility of the operating surgeon to ensure that all data is accurate.

Carefully clean and prepare the microkeratome according to its manuals. Make sure that the blade is free of burrs and nicks. Check if the chosen plate thickness matches with the intended flap thickness.

Instruct patients not to wear makeup as this poses risk for contamination of the stromal interface. Patients must not use perfumes, After Shave, Eau de Cologne or other substances applied to the skin containing alcohol.

Aromatic substances and solvents including, but not limited to alcohol, fresh glue and paint should not be noticeable at the laser aperture, because these substances may absorb energy of the laser pulses and therefore may cause undercorrections.

Strong disturbances of the air between the laser aperture and the patient's head during laser ablation must be avoided. Switch off any ventilation device causing a noticeable airflow during ablation, with exception of the Plume Evacuator of the Laser System. Instruct personnel not to move around and keep doors and windows closed during ablation. Uncontrolled airflow may have an effect on the quality of the ablation.

Potentially noisy devices such as telephones that may cause a sudden sound during the procedure should be switched off. Sudden noise may distract surgeon and / or patient.

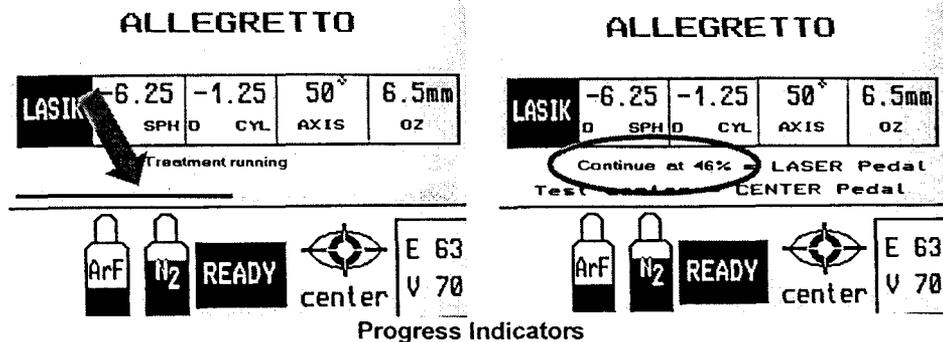
Medications likely to dilate or constrict the pupil should not be given during the last 6 hours prior to surgery as the Eyetracker will not be able to track pupils of less than 1.5mm and more than 8.0mm diameter.

Check that the patient is able to see the green blinking fixation light and to discern it from other light sources around the laser aperture.

Perform an External Energy Check according to the Operators Manual prior to treating a new patient. Repeat the test if more than 30 minutes have elapsed before the treatment is begun.

Head alignment in order to apply cylinder treatment in the right axis is essential.

If laser ablation is interrupted, the parameters remain in the system and the system will proceed with the ablation pattern exactly at that point, at which the treatment was interrupted. The progress of the ablation procedure is indicated in the LCD Display of the Laser Console.

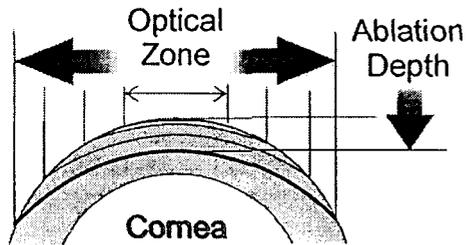


If for any reason a treatment has to be terminated before ablation was completed, the percentage of treatment accomplished has to be recorded and kept in the patient files.

CAUTION
Aborted treatment

If the treatment is aborted, treatment parameters and progress information are lost. Reasons may include power loss or manual abortion. The system offers no procedure to finish the treatment at a later time.

During ablation spherical and astigmatic error are treated separately. The spherical portion of the refractive treatment is applied first; the astigmatic portion follows immediately without an interruption. Both ablation portions are enrolled by creating the full amount of intended correction



already after the first few seconds, but in a diameter smaller than the full Optical Zone. During the course of the ablation the zone already corrected is enlarged to the programmed Optical Zone diameter. The currently achieved diameter with full correction is not indicated.

Evolution of Ablation

Do not perform a laser ablative treatment on a stromal surface compromised due to cutting problems with the microkeratome, such as buttonhole, step profile or severe incomplete cut smaller than the intended Optical Zone.

Keep the stromal surface dry and clean during ablation. Prevent liquid or blood from running towards the Ablation Zone. Liquid and debris will shield the stromal surface against ablation. Irregular ablations will most likely result. If liquid or blood reaches the Optical Zone, irregular ablations may lead to deviation of the best possible clinical results.

Myopic Spherocylinder

Treatment Data			
Surgeon:	Kevin Miller, MD		
	SPH	CYL	Axis
Correction:	-6.25	-1.25	50
Optical Zone:	6.5	mm	
Ablation zone:	7.2x9.0	mm	Outer diameter
Central depth:	118	µm	Maximum
Peripheral depth:	18	µm	Maximum
Flap thickness:	160	µm	Nominal value (see Setup)
Remaining:	282	µm	stromal thickness

Optical and Ablation Zone

Do not move instruments across or in the area of the intended Optical Zone during laser ablation. The instrument may shield stroma partially against ablation. Resulting irregular ablations may lead to a deviation of the best possible clinical result. Optical and Ablation Zone diameters are indicated in the Notebook Computer screen. The LCD display of the Laser Console shows the Optical Zone diameter only.

4.4.4 Post Procedure

The following post-operative examinations are recommended on day 1 or 2 and at 1, 3 and 6 months:

- Slit Lamp Examination
- Uncorrected Visual Acuity (UCVA or VA sc)

Best Spectacle-Corrected Visual Acuity (BSCVA or VA cc)
 Manifest Refraction

Intraocular Pressure at 3 months or at any postop date later than 2 weeks after surgery, if patient's vision has deteriorated significantly within days
 Keratometry and Videokeratography at 1, 3 and 6 months.

4.5 Adverse Events

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

Table 1 presents the adverse events that actually occurred during the postoperative period following LASIK.

Table 1 Adverse Events								
Adverse Event	1 Month		3 Months		6 Months		1 Year	
	%	n	%	n	%	n	%	n
	N=876		N=844		N=818		N=813	
Corneal infiltrate or ulcer requiring treatment	0.0	0	0.0	0	0.0	0	0.0	0
Lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month	0.2	2	0.0	0	0.0	0	0.0	0
Corneal edema at 1 month or later visible in the slit lamp exam	0.0	0	0.0	0	0.0	0	0.0	0
Any complication leading to intraocular surgery	0.0	0	0.0	0	0.0	0	0.0	0
Melting of the flap of >1 mm sq	0.0	0	0.0	0	0.0	0	0.0	0
Epithelium of > 1 mm ² in the interface with loss of 2 lines or more of BSCVA	0.0	0	0.0	0	0.0	0	0.0	0
Uncontrolled IOP rise with increase of > 5 mm Hg or any reading above 25 mm Hg	0.0	0	0.0	0	0.0	0	0.0	0
Retinal detachment or retinal vascular accident	0.0	0	0.0	0	0.0	0	0.0	0
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction	0.0	0	0.0	0	0.0	0	0.0	0

Table 2 lists complications that occurred at the time of surgery. Overall, 1.2% (11/901) of eyes experienced some operative event which was reported as a complication. The most common complication (0.9%, 8/901) was a flap relift and irrigation for debris. Epithelial defect occurred in 0.1% (1/901) – this did not prevent surgery from proceeding.

In 1 case (0.1%), another complication occurred. In this case, on the first attempt to perform the keratectomy the investigator was unable to obtain adequate suction. The patient was rescheduled for later in the day and used Lotomax drops q 10 min x 5. On the second attempt suction was adequate and the keratectomy was successfully performed.

Table 2 Operative Complications N=901		
Complication	%	n
18% Treatment	0.1	1
Epithelial Defect	0.1	1
Flap relift/irrigate debris	0.9	8
Other	0.1	1
Total Eyes Affected	1.2	11

Table 3 list complications that occurred during the follow-up period.

Table 3 Complications Summary Table								
Complications	1 Month		3 Months		6 Months		1 Year	
	%	n	%	n	%	n	%	n
	N=876		N=844		N=818		N=813	
Corneal edema between 1 week and 1 month after the procedure	0.0	0	0.0	0	0.0	0	0.0	0
Corneal epithelial defect at 1 month or later	0.7	6	0.8	7	0.1	1	0.3	2
Any epithelium in the interface	0.2	2	0.1	1	0.0	0	0.0	0
Foreign body sensations at 1 month or later	0.5	4	0.1	1	0.0	0	0.0	0
Pain at 1 month or later	0.0	0	0.2	2	0.0	0	0.0	0
Ghosting or double images in the operative eye at stability or beyond			0.7	6	0.9	7	0.3	2
Need for lifting and/or reseating of the flap/cap prior to 1 month	0.0	0	0.0	0	0.0	0	0.0	0

5 Study data

The Sponsor performed a clinical study of the WaveLight ALLEGRETTO WAVE Excimer Laser System at eleven U.S. clinical sites under the auspices of an Investigational Device Exemption (IDE) G990317. The data from this study served as the basis for the approval decision. Specifically, safety and effectiveness outcomes at 3 months postoperatively were assessed, as stability was reached at that time. Outcomes at 6 and 12 months postoperatively were also evaluated for confirmation of stability. The IDE study is described in detail as follows.

5.1 Study Objectives

The objectives of the study were to determine the safety and effectiveness of the WaveLight ALLEGRETTO WAVE Excimer Laser System for LASIK treatment of myopic refractive errors up to -14.0 D with and without astigmatic refractive errors up to -6.0 D.

5.2 Study Design

The study was a prospective, non-randomized, 11 center, 11 surgeon study where the primary control was the preoperative status of the treated eye (i.e., comparison of pretreatment and post-treatment visual parameters in the same eye).

5.3 Inclusion and Exclusion Criteria

Subjects in the LASIK for myopia and myopic astigmatism study must have met all of the following inclusion criteria to qualify for enrollment:

- Subjects must have been undergoing LASIK surgery for the correction of myopia.
- Intended treatment from 0 to -14 D of spherical equivalent myopia or myopia with astigmatism, with up to -14 D of spherical component and up to -6.0 D of astigmatic component. (All refractions measured at the spectacle plane).
- Subjects must have had bilateral physiologic myopia.
- BSCVA of 20/40 or better in each eye.
- Subjects must have had a stable refraction (0.5 D or less change in MRSE) for the last 12 months, objectively documented (by previous clinical records, eyeglass prescriptions, etc.).
- Subjects who are contact lens wearers must have had hard or gas permeable lenses discontinued for 3 weeks and soft lenses discontinued for 3 days prior to the preoperative evaluation.
- Subjects must have been at least 18 years of age.
- Corneal topography must have been normal, as judged by the operating investigator.
- Subjects must have signed a written Informed Consent form acknowledging their awareness of their participation in this study, the alternative treatments available, the risks involved, and the investigative nature of LASIK, and other issues that conform to the standard of care for Informed Consent practices.
- Subjects must have been able to return for scheduled follow-up examinations for 12 months after surgery.

Subjects with the following conditions were not eligible for enrollment in the LASIK for myopia and myopic astigmatism study:

- Subjects with anterior segment pathology
- Subjects with residual, recurrent or active ocular disease
- Subjects who had undergone previous intraocular or corneal surgery involving the stroma in the eye to be operated.
- Subjects who had a history of herpes keratitis
- Subjects with diagnosed autoimmune disease, systemic connective tissue diseases or atopic syndrome, diabetes mellitus, or taking systemic medications (i.e., corticosteroids or antimetabolites) likely to affect wound healing
- Subjects with unstable central keratometry/topography readings with irregular topography patterns or keratometry mires, including signs of keratoconus.
- Subjects with known sensitivity to study medications.
- Subjects with intraocular pressure of > 23 mm Hg by Goldmann applanation tonometry, a history of glaucoma, or glaucoma suspect.
- Women who are pregnant or nursing or who planned to become pregnant over the course of their participation in this investigation.
- Participation in other ophthalmic clinical trials during this clinical investigation
- Subjects with colobomas of the iris or other irregularities of the pupil margin.

5.4 Study Plan, Patient Assessments, and Efficacy Criteria

Subjects were evaluated preoperatively and postoperatively at 1 day, 1 month, 3 months, 6 months, and 1 year. Preoperative objective measurements included: uncorrected distance and near visual acuity, manifest refraction, distance best spectacle corrected visual acuity, cycloplegic refraction, applanation tonometry, slit lamp examination, pupil size measurement in photopic and scotopic conditions, central keratometry, computerized corneal topography, pachymetry, dilated fundus examination, and patient questionnaire.

Postoperatively, objective measurements included: uncorrected distance and near visual acuity, manifest refraction, distance best spectacle corrected visual acuity, cycloplegic refraction, applanation tonometry, slit lamp examination, central keratometry, computerized corneal topography, dilated fundus examination, and patient questionnaire.

Subjects were permitted to have second eyes (fellow eyes) treated at the same time as the first eye (primary treatment). Subjects were eligible for retreatment no sooner than 3 months after surgery. Subjects were eligible for retreatment if the manifest refractive myopia (spherical equivalent) was 0.5 D or greater, the manifest myopic astigmatism was 0.5 D or more, the distance visual acuity was 20/30 or less, or due to any subjective complaints by the patient with treatable cause as determined by the investigator.

Effectiveness was evaluated based on improvement in uncorrected visual acuity and predictability of the manifest refraction spherical equivalent (MRSE).

5.5 Study Period, Investigational Sites and Demographic Data

5.5.1 Study Period

A total of 901 eyes in 459 subjects were treated between 2/20/01 and 10/11/02. All follow-up received by SurgiVision prior to March 24, 2003 was included in this PMA.

5.5.2 Demographics and Baseline Characteristics

The demographics for this study are very typical of a contemporary refractive surgery trial performed in the U.S. Gender of subjects treated was almost equally split with 51.6% (465/901) of the cases being female and 48.4% (436/901) being male. Overall, 92.6% (834/901) of eyes treated were in Caucasian subjects, 2.9% (26/901) in Hispanics, 1.8% (16/901) in Asians, 1.3% (12/901) were in Black subjects, and 1.2% (11/901) were categorized as "other" races. The mean age of the patients treated was 38.07 ± 9.7 years with a range from 18 to 67.

Category	Classification	%	n
Gender	Female	51.6	465
	Male	48.4	436
Race	Caucasian	92.6	834
	Black	1.3	12
	Asian	1.8	16
	Hispanic	2.9	26
	Other	1.2	11
	Not Reported	0.2	2
Eyes	OD	50.1	451
	OS	49.9	450
CL History	Soft	55.6	500
	RGP	8.3	75
	PMMA	1.0	9
	Glasses	34.8	313
	Unknown	0.2	2
Age (in Years)	Average	38.07	
	Standard Deviation	9.7	
	Minimum	18.0	
	Maximum	67.0	

5.6 Data Analysis and Results

5.6.1 Baseline characteristics

Table 5 contains a summary of the preoperative refractive errors of the entire cohort.

Table 5 Baseline Characteristics All Eyes (n=901)		
Spherical Equivalent Refraction	%	n
0.00 to 1.00 D	2.0	18
1.01 to 2.00 D	13.2	119
2.01 to 3.00 D	15.4	139
3.01 to 4.00 D	16.6	150
4.01 to 5.00 D	16.4	148
5.01 to 6.00 D	12.8	115
6.01 to 7.00 D	9.8	88
7.01 to 8.00 D	4.7	42
8.01 to 9.00 D	4.7	42
9.01 to 10.00 D	2.6	23
10.01 to 11.00 D	0.4	4
11.01 to 12.00 D	1.2	11
12.01 to 13.00 D	0.2	2
>13.00 D	0.0	0
Cylinder		
0.00 D	19.4	175
0.25 D	13.5	122
0.50 D	17.1	154
0.75 D	14.4	130
1.00 D	9.5	86
1.25 D	6.6	59
1.50 D	4.1	37
1.75 D	3.3	30
2.00 D	3.3	30
2.25 D	1.7	15
2.50 D	1.8	16
2.75 D	1.6	14
3.00 D	1.3	12
3.25 D	0.4	4
3.50 D	0.7	6
3.75 D	0.3	3
4.00 D	0.3	3
4.25 D	0.1	1
4.50 D	0.0	0
4.75 D	0.1	1
>5.00 D	0.3	3

5.6.2 Postoperative Characteristics and Results

5.6.2.1 Patient Accountability

There were 901 eyes treated. Accountability for All Eyes treated was 97.2% (876/901) at 1-month, 93.8% (844/900) at 3-months, 91.9% (818/890) at 6-months, and 93.9% (813/866) at 1-year. The following cohorts were used for analysis:

- Safety-all eyes (901)
- Effectiveness-all eyes (901)
- Stability-subset of all eyes seen at any two consecutive visits, and subset of all eyes seen at 1, 3 and 6-months (765 and 833)

5.6.2.2 Stability of Outcome

In the 1-3 month window, greater than 95% of eyes experienced a change of MRSE not exceeding 1.0 D. Furthermore, the mean of the paired difference of MRSE was -0.01 D in the 1 to 3-month time period. Thus, stability was demonstrated at 3-months postoperatively.

Table 6 Refractive Stability (Eyes with 1, 3 and 6 Month Visits (n=765))				
Change in MRSE	1 and 3 Months		3 and 6 Months	
	%	n	%	n
<1.00 D	97.6	747	99.0%	757
95% CI for %	97.1%, 98.2%		98.6%, 99.4%	
MRSE (D)				
Mean	-0.01 D		-0.05 D	
SD	0.34		0.30	
95% CI for Mean	-0.03, 0.01		-0.07, -0.02	

Please note that the confidence interval gives an estimated range of values which is likely to include an unknown population parameter, the estimated range being calculated from a given set of data. The width of the confidence interval gives us some idea about how uncertain we are about the parameter.

5.6.2.3 Effectiveness Outcomes

The analysis of effectiveness was based on the 844 eyes evaluable at the 3-month stability time point. Key efficacy outcomes over the course of the study and at the point of stability stratified by diopter of MRSE are presented in Tables 7 and 8.

Table 7 Summary of Key Efficacy Variables Over Time								
	1 Month		3 Months		6 Months		1 Year	
	%	n	%	n	%	n	%	n
	95% CI		95% CI		95% CI		95% CI	
Efficacy Variables	N=841		N=813		N=782		N=780	
UCVA 20/20 or better*	82.8	696	84.4	686	87.7	686	87.4	682
	81.5%, 84.1%		83.1%, 85.7%		86.6%, 88.9%		86.3%, 88.6%	
UCVA 20/40 or better*	97.6	821	98.0%	797	98.3%	769	99.0	772
	97.1%, 98.2%		97.5%, 98.5%		97.9%, 98.8%		98.6%, 99.3%	
	N=876		N=844		N=818		N=813	
MRSE \pm 0.50 D	85.6	750	84.8	716	85.3	698	85.1	692
	84.4%, 86.8%		83.6%, 86.1%		84.1%, 86.6%		83.9%, 86.4%	
MRSE \pm 1.00 D	96.8	848	96.7	816	97.3	796	97.7	794
	96.2%, 97.4%		96.1%, 97.3%		96.7%, 97.9%		97.1%, 98.2%	
MRSE \pm 2.00 D	99.4	871	99.5	840	99.6	815	99.5	809
	99.2%, 99.7%		99.3%, 99.8%		99.4%, 99.8%		99.3%, 99.8%	

*For all eyes minus those intentionally treated for monovision.

Table 8
Summary of Key Efficacy Variables
at 3 Months (Stratified by Preoperative MRSE)

	0 to 1 D	>1 to 2 D	>2 to 3 D	>3 to 4 D	>4 to 5 D	>5 to 6 D	>6 to 7 D	Total ≤7 D
	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI
Efficacy Variables	N=17	N=110	N=126	N=138	N=130	N=101	N=82	N=704
UCVA 20/20 or better*	94.1 16 88.4%, 99.8%	87.3 96 84.1%, 90.5%	92.9 117 90.6%, 95.2%	92.0 127 89.7%, 94.3%	83.1 108 79.8%, 86.4%	79.2 80 75.2%, 83.3%	79.3 65 74.8%, 83.8%	86.5 609 85.2%, 87.8%
UCVA 20/40 or better*	100 17 100%, 100%	97.3 107 95.7%, 98.8%	98.4 124 97.3%, 99.5%	99.3 137 98.6%, 100%	98.5 128 97.4%, 99.5%	97.0 98 95.3%, 98.7%	97.6 80 95.9%, 99.3%	98.2 691 97.7%, 98.7%
MRSE ±	N=17	N=114	N=131	N=141	N=135	N=106	N=84	N=728
0.50 D	94.1 16 88.4%, 99.8%	91.2 104 88.6%, 93.9%	84.7 111 81.6%, 87.9%	95.0 134 93.2%, 96.9%	84.4 114 81.3%, 87.6%	84.0 89 80.4%, 87.5%	78.6 66 74.1%, 83.1%	87.1 634 85.9%, 88.3%
1.00 D	100 17 100%, 100%	98.3 112 97.0%, 99.5%	98.5 129 97.4%, 99.5%	99.3 140 98.6%, 100%	98.5 133 97.5%, 99.6%	96.2 102 94.4%, 98.1%	96.4 81 94.4%, 98.5%	98.1 714 97.6%, 98.6%
2.00 D	100 17 100%, 100%	100 114 100%, 100%	100 131 100%, 100%	100 141 100%, 100%	100 135 100%, 100%	100 106 100%, 100%	100 84 100%, 100%	100 728 100%, 100%

	>7 to 8 D	>8 to 9 D	>9 to 10 D	>10 to 11 D	>11 to 12 D	>12 to 13 D	Cum Total >7 D
	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI	% n 95% CI
Efficacy Variables	N=34	N=38	N=22	N=4	N=10	N=1	N=109
UCVA 20/20 or better*	70.6 24 62.8%, 78.4%	73.7 28 66.5%, 80.8%	68.2 15 58.3%, 78.1%	50.0 2 25.0%, 75.0%	70.0 7 55.5%, 85.5%	100 1 100%, 100%	70.6 77 66.3%, 75.0%
UCVA 20/40 or better*	100 34 100%, 100%	100 38 100%, 100%	95.5 21 100%, 100%	100 4 100%, 100%	80.0 8 67.4%, 92.7%	100 1 100%, 100%	97.3 106 95.7%, 98.8%
MRSE ± 0.50 D	N=37	N=40	N=22	N=4	N=11	N=2	N=116
MRSE ± 0.50 D	86.5 32 80.9%, 92.1%	72.5 29 65.4%, 79.6%	59.1 13 48.6%, 69.6%	75.0 3 53.4%, 96.7%	45.5 5 30.4%, 60.5%	0.0 0 0.0%, 0.0%	70.7 82 66.5%, 74.9%
MRSE ± 1.00 D	94.6 35 90.9%, 98.3%	87.5 35 82.3%, 92.7%	86.4 19 79.1%, 93.7%	100 4 100%, 100%	72.7 8 59.3%, 86.2%	50.0 1 14.6%, 85.4%	87.9% 102 84.9%, 91.0%
MRSE ± 2.00 D	97.3 36 94.6%, 100%	100 40 100%, 100%	100 22 100%, 100%	100 4 100%, 100%	81.8 9 70.2%, 93.5%	50.0 1 14.6%, 85.4%	96.6% 112 94.9%, 98.3%

*For all eyes minus those intentionally treated for monovision.

Analysis of the correction of the cylindrical component of the astigmatic eyes is presented in Tables 9 and 10.

Table 9		
Cylinder Correction Efficacy Stratified by Preoperative Cylinder		
Preoperative Cylinder	3 Months	
	Reduction of Absolute Cylinder	
	% Reduction Mean ¹	Ratio Mean ²
< 1.00 D	76.9%	0.56
> 1.00 to < 2.00 D	79.6%	0.21
> 2.00 to < 3.00 D	83.1%	0.17
> 3.00 to < 4.00 D	82.1%	0.18
> 4.00 to < 5.00 D	92.1%	0.08
> 5.00 to < 6.00 D	93.9%	0.06
Total	78.2%	0.44

¹ [(Postoperative cylinder – Preoperative cylinder) / Preoperative cylinder] x 100

² Postoperative cylinder / Preoperative cylinder]

Looking at the intended versus achieved vector magnitude cylinder, the Intended Refractive Correction (“IRC”) had a mean of -1.02 ± 0.76 D. The Surgically Induced Refractive Correction (“SIRC”) had a mean of -1.14 ± 0.86 D. The vector magnitude ratio (SIRC/IRC) was 1.18 at 3-months. The Panel has found 0.82 acceptable for correction efficacy (SIRC/IRC) at stability.

Table 10	
Cylinder Correction Efficacy Stratified by Preoperative Cylinder	
Preoperative Cylinder	3 Months
	Achieved vs. Intended Vector Magnitude Ratio (Achieved/Intended) Mean
ALL	1.18
0 to 0.50 D	1.36
>0.50 to < 1.00 D	1.13
>1.00 to < 2.00 D	1.09
>2.00 to < 3.00 D	1.11
>3.00 to < 4.00 D	1.08
>4.00 to < 5.00 D	1.07
>5.00 to < 6.00 D	0.90

5.6.2.4 Key Safety Results

The analysis of safety was based on the 844 eyes that have had the 3-month examination. The key safety results for this study are presented in Tables 11 and 12. Overall the device was deemed reasonably safe.

Table 11								
Summary of Key Safety Variables Over Time								
	1 Month		3 Months		6 Months		1 Year	
	%	n	%	n	%	n	%	n
	95% CI		95% CI		95% CI		95% CI	
Safety Variables	N=876		N=844		N=818		N=813	
Loss of ≥ 2 lines BSCVA	0.9	8	0.6	5	0.7	6	0.5	4
	0.6%,1.2%		0.3%,0.9%		0.4%,1.0%		0.3%,0.7%	
BSCVA worse than 20/40	0.1	1	0.0	0	0.0	0	0.0	0
	0.0%,0.2%		0.0%,0.0%		0.0%,0.0%		0.0%,0.0%	
	N=263		N=251		N=242		N=249	
Increase > 2 D Cylinder#	0.4	1	0.4	1	0.0	0	0.4	1
	0.0%,0.8%		0.0%,0.8%		0.0%,0.0%		0.0%,0.8%	
	N=833		N=800		N=779		N=771	
BSCVA worse than 20/25 if 20/20 or better preoperatively	0.2	2	0.1	1	0.3	2	0.1	1
	0.1%,0.4%		0.0%,0.3%		0.1%,0.4%		0.0%,0.3%	

#For eyes treated for spherical correction only.

Table 12
Summary of Key Safety Variables
at 3 Months (Stratified by Preoperative MRSE)

	0 to 1 D	>1 to 2 D	>2 to 3 D	>3 to 4 D	>4 to 5 D	>5 to 6 D	>6 to 7 D	Total ≤7 D
	% n 95% CI							
Safety Variables	N=17	N=114	N=131	N=141	N=135	N=106	N=84	N=728
Loss of ≥ 2 lines BSCVA	0.0 0 0.0%,0.0%	0.9 1 0.0%,1.8%	0.0 0 0.0%,0.0%	0.7 1 0.0%,1.4%	2.2 3 1.0%,3.5%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%	0.7 5 0.4%,1.0%
BSCVA worse than 20/40	0.0 0 0.0%,0.0%							
Increase >2 D cylinder#	0.0 0 0.0%,0.0%	2.4 1 0.0%,4.9%	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%	0.4 1 0.0%,0.9%
BSCVA worse than 20/25 if 20/20 or better preoperatively	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%	0.8 1 0.0%,1.5%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%	0.1 1 0.0%,0.3%

	>7 to 8 D	>8 to 9 D	>9 to 10 D	>10 to 11 D	>11 to 12 D	>12 to 13 D	Cum Total >7 D
	% n 95% CI						
Safety Variables	N=37	N=40	N=22	N=4	N=11	N=2	N=116
Loss of ≥ 2 lines BSCVA	0.0 0 0.0%,0.0%						
BSCVA worse than 20/40	0.0 0 0.0%,0.0%						
Increase >2 D cylinder#	0.0 0 0.0%,0.0%						
BSCVA worse than 20/25 if 20/20 or better preoperatively	0.0 0 0.0%,0.0%						

#For eyes treated for spherical correction only.

5.6.2.5 Retreatment

A total of 33 eyes were retreated with the study laser due primarily to undercorrection. One eye was retreated for overcorrection. Table 13 contains the outcomes for retreated eyes.

Table 13								
Summary of Key Safety and Efficacy Variables Over Time for Retreated Eyes								
	1 Month		3 Months		6 Months		1 Year	
	%	n	%	n	%	n	%	n
	95% CI		95% CI		95% CI		95% CI	
Efficacy Variables	N=25		N=16		N=21		N=1	
UCVA 20/20 or better*	56.0	14	87.5	14	66.7	14	100	1
	46.1%, 65.9%		79.2%, 95.8%		56.4%, 77.0%		100%, 100%	
UCVA 20/40 or better*	96.0	24	100	16	100	21	100	1
	92.1%, 99.9%		100%, 100%		100%, 100%		100%, 100%	
	N=25		N=15		N=21		N=1	
MRSE \pm 0.50 D	64.0	16	100	15	85.7	18	100	1
	54.4%, 73.6%		100%, 100%		78.1%, 93.4%		100%, 100%	
MRSE \pm 1.00 D	96.0	24	100	15	100	21	100	1
	92.1%, 99.9%		100%, 100%		100%, 100%		100%, 100%	
MRSE \pm 2.00 D	100	25	100	15	100	21	100	1
	100%, 100%		100%, 100%		100%, 100%		100%, 100%	
Safety Variables	N=25		N=16		N=21		N=1	
Loss of \geq 2 lines BSCVA	4.0	1	0.0	0	4.8	1	0.0	0
	0.1%, 7.9%		0.0%, 0.0%		0.1%, 9.4%		0.0%, 0.0%	
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%	
BSCVA worse than 20/25 if 20/20 or better preoperatively	0.0	0	0.0	0	4.8	1	0.0	0
	0.0%, 0.0%		0.0%, 0.0%		0.1%, 9.4%		0.0%, 0.0%	
	N=7		N=5		N=6		N=0	
Increase >2 D cylinder#	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%	

*For all eyes minus those intentionally treated for monovision.

#For eyes treated for spherical correction only.

5.6.2.6 Patient Satisfaction

Subjects were asked to complete a patient questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively. Responses were made by placing a mark or an "x" through the provided line. Each end of the line was marked with opposing answers such as "Never" versus "All the Time". A mark on either end of the bar represented an extreme answer (never on one end, all the time on the other end) and a mark in the middle indicated a scaled response between the extremes.

Patient reports of glare from bright lights, light sensitivity, night driving glare and visual fluctuations all improved after LASIK. The percent of subjects reporting "none" or "mild" of these symptoms improved after treatment.

**Table 14
Patient Symptoms**

	Preoperative (N=892)						3 Months (N=832)					
	None-Mild		Moderate		Marked-Severe		None-Mild		Moderate		Marked-Severe	
	%	n	%	n	%	n	%	n	%	n	%	n
Glare from Bright Lights	48.1	429	34.5	308	17.4	155	61.4	511	26.2	218	12.4	103
Halos	71.0	635	15.8	141	13.2	118	67.9	565	13.2	110	9.1	76
Light Sensitivity	61.8	552	26.0	232	12.3	110	73.2	609	18.5	154	8.3	69
Night Driving Glare	50.5	450	32.2	287	17.4	155	64.1	533	24.0	200	11.9	99
Visual Fluctuations	87.3	780	10.3	92	2.5	22	71.4	594	22.5	187	6.1	51