LABELING

WaveLight
Laser Technologie AG

ALLEGRETTO WAVE™

Scanning Spot LASIK Laser System

Patient Information Booklet

Information for patients considering Laser Assisted In-Situ Keratomileusis (LASIK) Surgery

Information for patients considering LASIK surgery for the elimination or reduction of myopia (nearsightedness) of up to –12.00 D of sphere and up to –6.00 D of astigmatism at spectacle plane, who are 18 years of age or older, and who have documented evidence that their refraction did not change by more than 0.5 Diopter during the year before the preoperative examination

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1 INTRODUCTION

This booklet has important information about **LASIK** surgery with the **ALLEGRETTO WAVE™ Laser System.**

Read this booklet carefully and completely. All terms printed in bold can be found in the glossary at the end of the booklet. The Glossary defines each of these terms for you.

2 THE NEARSIGHTED AND ASTIGMATIC EYE

The human eye is very much like a camera. As shown in Figure 1, the camera lens focuses light to form clear images onto film. Similarly, the **cornea** and lens in the eye focus light onto the back surface of the eye, called the **retina**.

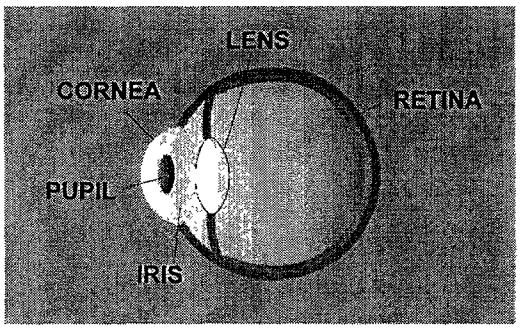


Figure 1: The Human Eye

However, in some people this focusing of light doesn't occur perfectly. There are three main types of errors that can occur: **nearsightedness, farsightedness** and **astigmatism**. In all types, the eye is not able to focus images perfectly on the **retina**.

Nearsightedness is a type of focusing error that results in blurry distant vision. Light from a distant object focuses in front of the **retina**, rather than on the **retina**. Figure 2 shows that distant vision is blurry when light focuses incorrectly in **nearsighted** eyes.

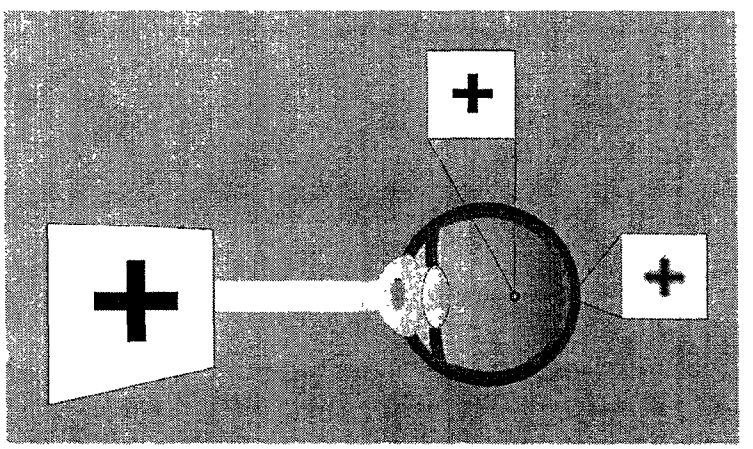


Figure 2: Nearsighted Eye Looking at a Black Cross

Nearsightedness is not a disease; it is a variation of the human eye that tends to be genetic. It occurs quite frequently all around the world, e.g. 25% of all North Americans are **nearsighted**. This condition starts developing usually during childhood and stabilizes in the late teens or early adulthood. Reasons for the **nearsighted** condition are too much distance between the **lens** and **retina** or too much **optical power** of the **lens** and **cornea.**

Farsightedness is a condition of the human eye where people may see distant objects clear while near objects appear blurry. The image is focused beyond the retina. The focal point, which is where a sharp image appears, would be outside the eye. Farsightedness commonly gets evident later in life. Eyes of young people are often able to compensate for this condition. As we age, we loose this ability.

Astigmatism may occur along with **nearsightedness (Myopic astigmatism)**, **farsightedness (hyperopic astigmatism)**, or a combination of **nearsightedness** and **farsightedness (mixed astigmatism)**.The **astigmatism** creates blurry images on the **retina**. If you look at objects with various edges, some edges may look less blurry than other edges.

The reason for this condition is that the **optical power** of the eye differs, depending on the direction. This leads to different focal points in the eye. The image on the **retina** is blurry and distorted.

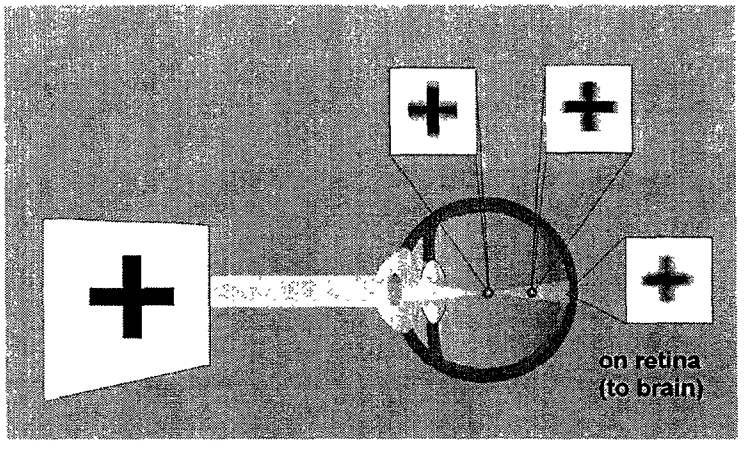


Figure 3: Nearsighted Eye with Astigmatism Looking at a Black Cross

Usually wearing glasses or contact lenses helps your eye focus light properly on the retina. **LASIK** surgery is another way to focus light on the **retina**. It uses an **Excimer** laser to remove tiny amounts of tissue from the **cornea**. This type of laser does not change any other parts of the eye.

3 WHAT IS THE ALLEGRETTO WAVE LASER SYSTEM?

The **ALLEGRETTO WAVE Laser System** consists of the laser console, which includes the laser and all control systems necessary for the surgeon to perform **LASIK**, such as control panels, monitors and a microscope. The **ALLEGRETTO WAVE Laser System** uses a very small laser beam to reshape the **cornea**. The system uses an **eyetracker** to help assure that it places the laser pulses in the correct position on the eye. The **eyetracker** will interrupt the treatment if your eye moves too much. The laser beam has a specially shaped profile and a small spot diameter to achieve the desired contour of the treated surface. When you are prepared for **LASIK**, you will lie down on a bed. This bed is then moved under the laser and the **LASIK** treatment can begin.

The **ALLEGRETTO WAVE Laser System** is approved for treating patients who have up to –12 **Diopters** of **nearsightedness** with or without **astigmatism** of up to 6.0 **Diopters**, who are 18 years of age or older, and who have documented evidence that their refraction did not change by more than 0.5 Diopter during the year before the preoperative examination.

Discuss the content of this booklet and any questions you may have with your doctor. Your doctor can help you decide if a **LASIK** treatment is for you. Make sure your doctor answers all your questions to your satisfaction before you agree to have **LASIK** treatment.

4 HOW DOES LASIK CORRECT NEARSIGHTEDNESS AND / OR ASTIGMATISM?

For the correction of **nearsightedness**, the **optical power** of the eye must be decreased. Therefore, the surface of the **cornea** is flattened by removing tissue mainly from the center of the **cornea**.

Surgical procedure

- Numbing **eye drops** are given before surgery.
- The **ALLEGRETTO WAVE Laser System** does not require your doctor to dilate your **pupil** before treatment.
- As shown in Figure 4, your doctor will use an instrument called a **microkeratome** to create a **flap** of tissue from the upper layer of your **cornea**. You will feel slight pressure on your eye and your vision will get dark. Vision will reappear when your doctor removes the **microkeratome**.

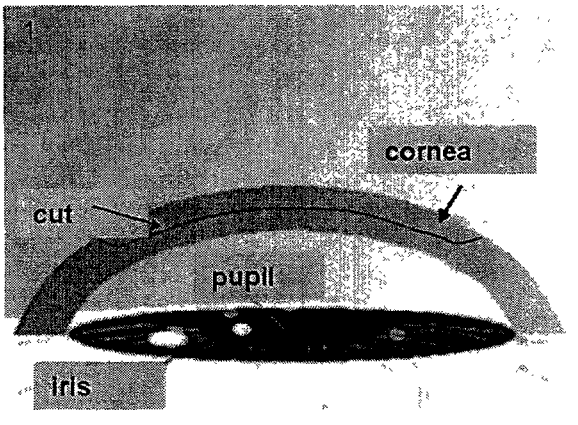


Figure 4: Cross Section of Cornea

- Your doctor will fold the **flap** back to expose the inner layers of your **cornea**. See Figure 5.

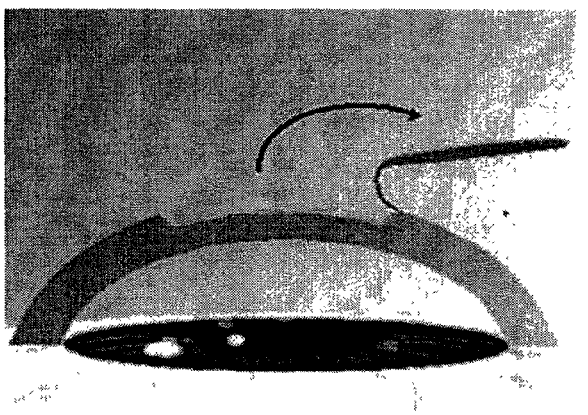


Figure 5: Flap Being Opened

- Your vision will be blurry at that time, but you should try to keep your eye locked on the green blinking light during the **LASIK** procedure.

  Your doctor will use the **ALLEGRETTO WAVE Laser System** to shape your **cornea**. The system will remove tissue from the inner layers of the **cornea** under the **flap**. Usually the system will remove **corneal** tissue only about 1/100 of an inch thick in the treated area. See Figure 6.

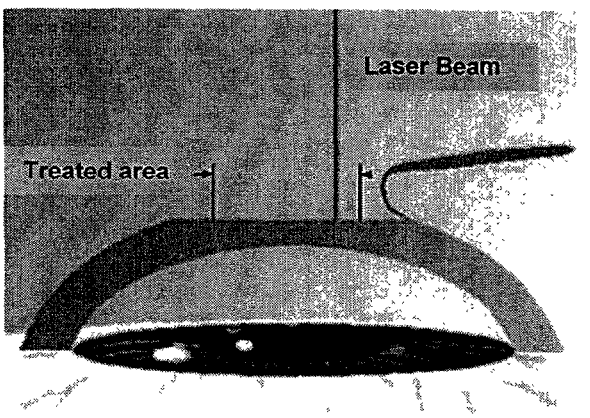


Figure 6: Cornea Being Shaped by Laser

The shaping procedure uses an **Excimer laser**. The light of this laser is invisible ultraviolet (UV) light. This light precisely removes small amounts of tissue each time the laser is activated, which is called a pulse. The laser pulses will not harm the surrounding or underlying **corneal** tissue.

The system applies very short laser pulses to create very precise and smooth shapes on the **cornea**. Each pulse removes tissue in a diameter of less than 1 millimeter (0.04 inch). In order to keep treatment times short, the laser has to deliver many pulses in a short time. The **ALLEGRETTO WAVE Laser System** delivers 200 pulses per second.

Every laser pulse has to be directed precisely onto your **cornea**. However, eye movements can occur, even when you are trying to keep your eye steady. Therefore, a built in **eyetracker** detects the current position of your eye and aligns the laser pulse with your **cornea**, prior to the release of each laser pulse.

After the laser treatment is finished, the surgeon will fold back the **flap**, and check to be sure that it is in the correct position (Figure 7). Your vision will improve immediately, but it will be blurry or cloudy.

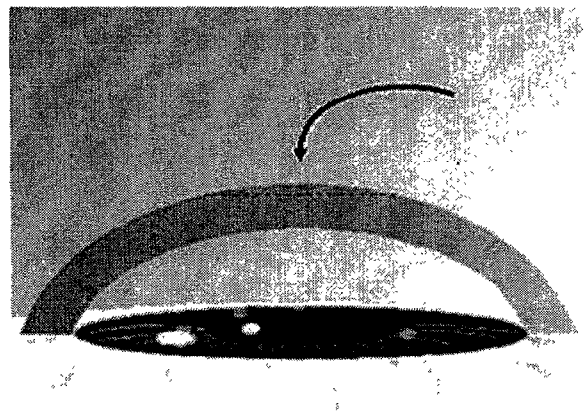


Figure 7: Flap Being Folded Back Into Position

The whole surgical procedure usually takes less than ten minutes per eye.

If you are going to have both your eyes treated, your doctor may operate on your other eye immediately. Even if you have agreed to have both eyes treated on the same day, your doctor may decide to treat your other eye at a later date.

Surgical alternatives to **LASIK** surgery, for example **RK (Radial Keratotomy)** and **PRK (Photorefractive Keratectomy)** are different procedures. **RK** applies a knife to make fine cuts in the **cornea**. **PRK** like **LASIK** uses an **Excimer laser** to shape the **cornea**. However **PRK** removes the upper tissue layer mechanically prior to laser surgery instead of creating a **flap**.

5 CONTRAINDICATIONS, WARNINGS, PRECAUTIONS

Contraindications-When Can't You Have LASIK?

If you have any of the following situations or conditions you should not have **LASIK** because the risk is greater than the benefit:

- you are pregnant or nursing, because these conditions may cause temporary and unpredictable changes in your **cornea** and a **LASIK** treatment would improperly change the shape of your **cornea**;
- you have a **collagen vascular, autoimmune** or **immunodeficiency disease**, such as rheumatoid arthritis, multiple sclerosis, lupus or AIDS, because these conditions affect the body's ability to heal;
- you show signs of **keratoconus** or any other condition that causes a thinning of your **cornea**. This condition can lead to serious corneal problems during and after **LASIK** surgery. It may result in need for additional surgery and may result in poor vision after **LASIK**;
- you are taking medications with ocular side effects, e.g. Isotretinoin (Accutane®[1]) for acne treatment or Amoidarone hydrochloride (Cordarone®[2]) for normalizing heart rhythm, because they may affect the accuracy of the **LASIK** treatment or the way your cornea heals after **LASIK**. This may result in poor vision after **LASIK**.

[1] Accutane® is a registered trademark of Hoffmann-La Roche Inc.
[2] Cordarone® is a registered trademark of Sanofi-Synthelabo Inc.

What Warnings and Other Information Do You Need to Know About?

If you have any of the following conditions, you may have **LASIK** if your doctor evaluates the seriousness of your condition and believes the benefit of having **LASIK** is greater than the risk.

- Systemic diseases likely to affect wound healing. If you have a systemic disease such as a connective tissue disease, severe atopic disease or are immunocompromised, **LASIK** may be risky for you because it may affect the ability of your eyes to heal.

- Diabetes. If you have diabetes and depend on insulin, **LASIK** may be risky for you because your diabetes may interfere with the healing of your eyes.

- History of **Herpes simplex** or **Herpes zoster** infection that has affected your eyes. If you have had a **Herpes simplex** or a **Herpes zoster** infection that affected your eyes, or have an infection now, **LASIK** is more risky for you.

- Symptoms of significant dry eye. If you have severely dry eyes, **LASIK** may increase dryness. This may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.

- Severe allergies. If you have severe allergies and take medicines for them, **LASIK** is more risky for you.

Precautions

It is unknown whether **LASIK** is safe and effective for the following conditions. You should discuss these issues with your doctor.

- Unstable eyes that have changed by more than 0.5 **diopter** in **nearsightedness** or **astigmatism** in the last 12 months, and your **nearsightedness** or **astigmatism** is getting better or worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after **LASIK**.

- If you have an eye disease, it is unknown whether **LASIK** is safe and effective under this condition.

- History of injury or surgery to the center of the **cornea** (for example, surgery to correct vision such as **RK, PRK, LASIK**), or other surgery on the eye. If your eyes are injured or you have had surgery, it is unknown whether **LASIK** will weaken the **cornea** too much. This may result in poor vision after **LASIK**.

- **Corneal** abnormality (e.g., scar, irregular astigmatism, infection, etc.). If you have an abnormal **corneal** condition, such as **corneal** scars, because it may affect the accuracy of the **LASIK** treatment or the way your **cornea** heals after **LASIK**. This may result in poor vision after **LASIK**.

- Your **corneas** are too thin. If your **corneas** are too thin to allow your doctor to cut a proper flap during the **LASIK** procedure, you can't have **LASIK** because it is necessary to have a flap.

- History of **glaucoma** or have had pressure greater than 23 mmHg inside your eyes, because it is unknown whether **LASIK** is safe and effective for you.

- You take medicines that might make it harder for wounds to heal, such as Sumatriptan succinate (Imitrex®[3]) used for migraine headaches, because it is unknown whether **LASIK** is safe and effective for this condition.

- Younger than 18 years of age, because it is unknown whether **LASIK** is safe and effective for you.

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

- Over the long term (more than 12 months), because it is unknown whether **LASIK** is safe and effective for periods longer than 12 months.

- If you have a **cataract** or other problem with the lens or vitreous of your eye, it is unknown whether **LASIK** is safe and effective under this condition.

- If you have any problems with the iris (colored part) of your eye or have had previous surgery on this part of your eye, then the eyetracker on the laser may not work properly and **LASIK** may not be safe effective for you.

- Any other medications you are taking. Let your doctor know if you are taking prescription medicines or any medications you bought without a prescription because certain medications including antimetabolites may affect the ability of your eye to heal after surgery.

- For a treatment zone with the laser below 6.0 millimeters and above 6.5 millimeters in diameter because it is unknown whether **LASIK** with these treatment zones is safe and effective for you.

- 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.

- Large pupils. Before surgery your doctor should measure your pupil size under dim lighting conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery. Some patients may find it more difficult to see in conditions such as dim light, rain, fog, snow and glare from bright lights. This has been shown to occur more frequently when the entire prescription has not been fully corrected and perhaps in patients with pupil sizes larger than the treatment area.

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

6 WHAT ARE ITS BENEFITS?

By using the **ALLEGRETTO WAVE Laser System**, your doctor can help eliminate or reduce your **nearsightedness** and **astigmatism** and, therefore, your need to wear glasses or contact lenses.

Clinical Study

A clinical study was done to evaluate the benefits and risks of the ALLEGRETTO WAVE Laser System for LASIK. The study included 901 eyes treated for nearsightedness with or without astigmatism. The study results are shown below and in Section 9 "Frequently Asked Questions".

Study Patient Demographics for Nearsightedness

Most patients were Caucasian. No patients were over 69 years old. **Table 1** shows the age, race, gender and contact lens history of patients in the study.

Table 1
Demographics of 901 Eyes of 459 Subjects

Age		Race		Gender		Contact Lens History	
Average:	38 ± 10 years	Asian	1.8%	Female	51.6%	Soft	55.6%
Range:	18 to 67 years	Black	1.3%	Male	48.4%	RGP[1]	8.3%
		Caucasian	92.6%			PMMA[2]	1.0%
		Hispanic	2.9%			Glasses	34.8%
		Other	1.2%				

[1]Rigid Gas Permeable
[2]Polymethylmethacrylate

Visual Acuity *without* Glasses After Surgery for Nearsightedness
Visual Acuity measures the sharpness of vision using a letter chart. **Table 2** shows that at least 98% of study cases saw 20/40 or better **without** glasses after surgery. Most states require that your vision be 20/40 or better if you drive **without** any glasses or contact lenses.

Table 2
Visual Acuity without Glasses After Surgery for Nearsightedness

Time after Surgery	1 Month (N=841)	3 Months (N=813)	6 Months (N=782)	1 Year (N=780)
% of eyes with 20/20 or better	83%	84%	88%	87%
% of eyes with 20/40 or better	98%	98%	98%	99%

In the clinical study on **LASIK**, vision **without** glasses improved for all eyes. Some people still needed glasses or contact lenses after surgery.

Visual Acuity *without* Glasses After Surgery and With Glasses Before Surgery
Table 3 shows that at 3 months after surgery, 75.6% saw as well or better without glasses as they did with glasses before surgery.

Table 3
Change in Eyes' Visual Acuity *without* Glasses After Surgery Compared to *with* Glasses Before Surgery

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)			
	1 Month (N=841)	3 Months (N=813)	6 Months (N=782)	1 Year (N=780)
Gain of more than 2 lines[1]	1.0%	0.2%	0.7%	0.2%
Gain of 2 lines[1]	5.5%	8.4%	8.3%	9.3%
Gain of 1 line[1]	27.2%	32.4%	33.3%	34.2%
No change	40.0%	34.6%	36.1%	32.2%
Loss of 1 line[2]	14.7%	13.4%	12.7%	14.0%
Loss of 2 lines[2]	5.9%	5.0%	3.9%	4.8%
Loss of more than 2 lines[2]	5.7%	6.0%	5.0%	5.4%

[1] Gain of lines means the patient could read one or more lines of letters on the eye chart (visual acuity chart) that they could not read before surgery
[2]Loss of lines means the patient could not read one or more lines of letters on the eye chart (visual acuity chart) that they could read before surgery

7 WHAT ARE ITS RISKS?

Clinical Study

Visual Acuity *with* Glasses After Surgery for Nearsightedness

Best vision with glasses was measured before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 4** shows the percent of patient's eyes that achieved 20/20 or better and 20/40 or better visual acuity after LASIK surgery while wearing glasses.

Table 4
Visual Acuity with Glasses After Surgery

Time after Surgery	Preop (N=901)	1 Month (N=876)	3 Months (N=844)	6 Months (N=818)	1 Year (N=813)
% of eyes with 20/20 or better	94.9%	96.1%	98.3%	98.8%	98.7%
% of eyes with 20/40 or better	100%	99.9%	100%	100%	100%

Change in Visual Acuity with Glasses After Surgery for Nearsightedness

Best vision with glasses was measured before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 5** shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses.

Table 5
Change in Eyes' Visual Acuity *with* Glasses After Surgery Compared with Before Surgery for Nearsightedness

Change in Visual Acuity with Glasses	Time After Surgery (Number of Eyes Examined)			
	1 Month (N=876)	3 Months (N=844)	6 Months (N=818)	1 Year (N=813)
Gain of more than 2 lines[1]	2.1%	2.5%	1.2%	0.9%
Gain of 2 lines[1]	8.7%	11.4%	14.3%	17.3%
Gain of 1 line[1]	40.5%	43.6%	41.6%	42.9%
No change	40.5%	36.3%	36.8%	32.4%
Loss of 1 line[2]	7.3%	5.7%	5.4%	6.0%
Loss of 2 lines[2]	0.6%	0.6%	0.7%	0.5%
Loss of more than 2 lines[2]	0.3%	0.0%	0.0%	0.0%

[1] Gain of lines means the patient could read one or more lines of letters on the eye chart (visual acuity chart) that they could not read before surgery
[2]Loss of lines means the patient could not read one or more lines of letters on the eye chart (visual acuity chart) that they could read before surgery

Adverse Events and Complications for Nearsightedness
Certain adverse events and complications occurred after the **LASIK** surgery. Two adverse events occurred during the postoperative period of the clinical study; 0.2% (2/876) had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following adverse events did **not** occur: corneal infiltrate or ulcer requiring treatment; corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of >1 mm sq; epithelium of > 1 mm2 in the interface with loss of 2 lines or more of BSCVA; uncontrolled IOP rise with increase of > 5 mm Hg or any reading above 25 mm Hg; retinal detachment or retinal vascular accident; and decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction.

The following complications occurred 3 months after LASIK during this clinical trial: 0.8% (7/844) of eyes had a corneal epithelial defect, 0.1% (1/844) had any epitheliuim in the interface, 0.1% (1/844) had foreign body sensation, 0.2% (2/844) had pain, and 0.7% (6/844) had ghosting or double images in the operative eye.

The following complications did **not** occur 3 months following LASIK in this clinical trial: corneal edema and need for lifting and/or reseating the flap/cap.

Subjective Results for Nearsightedness
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. The results can be found in **Table 6**.

Table 6

Patient Symptoms for Nearsightedness

	Preoperative (N=892)			3 Months (N=832)		
	None-Mild %	Moderate %	Marked-Severe %	None-Mild %	Moderate %	Marked-Severe %
Glare from Bright Lights	48.1%	34.5%	17.4%	61.4%	26.2%	12.4%
Halos	71.0%	15.8%	13.2%	67.9%	13.2%	9.1%
Light Sensitivity	61.8%	26.0%	12.3%	73.2%	18.5%	8.3%
Night Driving Glare	50.5%	32.2%	17.4%	64.1%	24.0%	11.9%
Visual Fluctuations	87.3%	10.3%	2.5%	71.4%	22.5%	6.1%

8 WHAT WILL HAPPEN BEFORE, DURING AND AFTER LASIK?

The following section lists all issues you need to know about pre-operative, operative and postoperative procedures and care.

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

Before Surgery:
If you are interested in having **LASIK** surgery, you will have a complete examination of your eyes before surgery. This will determine if your eyes are healthy and suitable for **LASIK** surgery. The examination will include your complete medical history and computerized mapping of your **corneal** surface to determine the smoothness and shape of the **cornea**.

IMPORTANT

Stop wearing your contact lenses several days before your LASIK examination. If you wear contact lenses, it is very important to **stop** wearing them before the pre-operative examination. Patients wearing soft contact lenses must stop wearing them 3 days before the preoperative examination and patients wearing gas permeable or hard contact lenses must stop wearing them 3 weeks before the preoperative examination. Failure to do so might produce poor results after surgery, as your treatment parameters cannot be determined precisely.

IMPORTANT

Tell your doctor about medications you take. Medications you take could affect the outcome of your treatment.

IMPORTANT

Tell your doctor about your allergies. If you have any allergies tell your doctor, so you will not receive any treatment that could cause you problems with your allergies.

You should arrange for transportation since you must not drive immediately after surgery. You may resume driving only after receiving permission to do so from your doctor.

Day of Surgery:
Eat and drink according to your doctor's recommendation.

IMPORTANT

Don't wear makeup at and around your eyes during the surgery since your eye area should be as clean as possible during the surgery to help avoid infection or irritation.

IMPORTANT

Do not wear perfume or cologne during the surgery, it may interfere with the laser and result in poor vision.

At the clinic, numbing (anesthetic) drops will be placed into the eye that will be treated. You will be asked to lie flat on your back on a cushioned bed. This bed has a special headrest with a ring cushion. The back of your head should lie properly in the ring to minimize movement of your head. If your head is properly seated in the headrest, head movement will be difficult.

You will be moved with the bed under the laser. Look up to the lights. There are red and white lights, which your doctor uses. You must stare at the green blinking light in the center of the black opening in the white cover above your head.

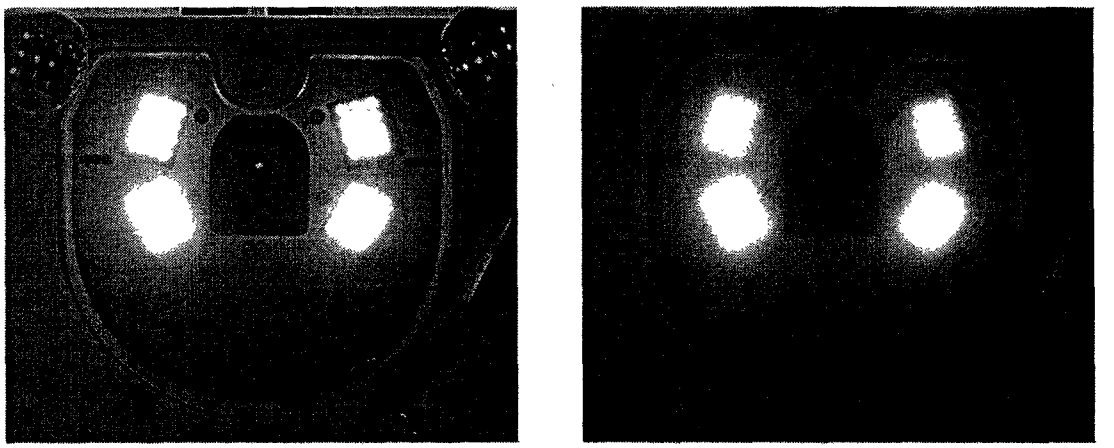


Figure 8: Patients view under the laser (crisp and blurred)

IMPORTANT

Do not let the red and white lights distract you during **LASIK**. Stare at the green blinking light only to ensure that the treatment occurs in the correct location on your eye. The doctor may change the brightness of the white lights for different steps of the procedure. This is normal and should not distract you.

The doctor will place an instrument between your eyelids to hold them open during surgery. A temporary cover will be placed over the other eye for your comfort. Relax and try to keep your eye open without squinting for the whole procedure.

IMPORTANT

Do not move your head during the surgery to ensure that the treatment occurs in the correct location on your eye.

The **LASIK** surgery begins with the placement of a suction ring on your eye. You will feel a large amount of pressure on your eye and your vision might turn black. Your doctor uses a **microkeratome** to cut a thin **flap** of tissue while moving forward over the front of the **cornea**. This instrument usually makes a weak buzzing sound. The suction will be released and your vision will reappear, but it will be very blurry. Your doctor then folds the **flap** back to expose your inner **cornea**.

The **eyetracker** will be started and your doctor will put your head under a microscope for the laser treatment. Your doctor will ask you to look steadily at the green blinking light. A bright red light will flash and the laser pulses will begin. The laser will remove tiny amounts of tissue from your **cornea**. You will hear the buzzing sound of the laser **ablation** on your **cornea** and a suction noise above your head. This is created by a suction device, used to remove the **corneal** tissue that has been removed. Although the **eyetracker** will follow movements of your eye you should stare at the blinking green light throughout the treatment. If you moved your eye too far, the tracker will interrupt the **ablation** procedure and your doctor will remind you to stare at the green blinking light. Your doctor will use the laser for about one minute. The whole **LASIK** will take about 10 minutes.

After the **ablation** is completed, your doctor puts the **flap** back and rinses your eye. Your doctor then waits a few minutes to allow the **flap** to stick on the shaped surface and then removes the device holding your eyelid. Your doctor may add some eye drops on your eye before moving you out from under the laser. Your doctor may apply a lubricant and eye patch to your eye before you leave the clinic.

Some doctors may choose to treat the second eye right away. In this case the same procedure is performed on your other eye.

The surgery is usually painless due to the use of numbing (anesthetic) drops. 45 to 60 minutes after the surgery the numbing effect will fade. The eye may hurt for 1 to 3 days. Your doctor may prescribe pain medication to make you feel more comfortable during this time.

IMPORTANT

Don't rub your eye during the first 3 to 5 days after surgery even if it feels itchy because rubbing the eye could unseat the flap and cause your vision to worsen. Your doctor may provide a plastic shield to protect your eye during this period. If so, you should wear the shield.

IMPORTANT

If you need to use topical **steroids** for you, you may have side effects from them. Some possible side effects are ocular hypertension, **glaucoma** or **cataract**. Read the patient information that comes with your medication to learn more about it.

First Days after Surgery:
If your doctor put an eye patch on your eye, your doctor or his/her staff will remove it the next day. If your doctor applied a **bandage contact lens**, your doctor will remove it when the surface of your eye has healed.

Your treated eye(s) will be mildly sensitive to light and you may have the feeling that something is in your eye for the first few days. Wearing sunglasses should make you feel more comfortable during this time.

Your vision should become stable within the first few weeks after surgery. However, you may experience small improvement or deterioration of your vision over time. This is quite normal and may occur for up to 6 months or more after surgery. A **haze** or cloudiness of the **cornea** rarely occurs after **LASIK**.

CAUTION

Use the **antibiotic eye drops**, anti-inflammatory eye drops and lubricants, as your doctor directed you. Your results depend upon following your doctor's directions. Not following your doctor's directions might lead to poor treatment results.

9 FREQUENTLY ASKED QUESTIONS

- **Is LASIK treatment permanent?**

  - The part of your **cornea** that is removed by the **LASIK** treatment cannot be put back on your **cornea** because it is destroyed by the laser.
  - The change in your ability to see after you have **LASIK** may or may not be permanent. The study using **ALLEGRETTO WAVE** for treatment showed that the treatment was unchanged at 12 months after **LASIK**. However, it is unknown what will happen to you after that, because the study did not look at patients' conditions beyond 12 months after they had **LASIK**.
  - You might have permanent difficulty seeing in dim lighting, rain, snow, fog, or bright glare. How difficult it might be for you to see under these conditions after you have **LASIK** has not been studied and so it is impossible to predict.

- **Will I be able to see sharply at a distance (visual acuity) without glasses after LASIK?**

  In the clinical study of the **ALLEGRETTO WAVE** device for **myopia** and **myopic astigmatism**, there were various defects in patients' corrections:

  - 0.4% (1/251) of eyes had a worsening of their **astigmatism** (increase of 2 or more **diopters** in their refractive **cylinder**) when they were treated for **nearsightedness** (spherical **myopia**).
  - 0.6% (5/844) of eyes had a worsening of their visual acuity, in that they could no longer read 2 lines on the eye chart that they could previously read.
  - 0.5% (4/844) of eyes after the **LASIK** procedure had too much of their **cornea** removed or too little, leaving them with an error in correction of 2 **diopters** or more.

- **Will I need reading glasses after LASIK?**
  You may need to wear reading glasses, even though you did not need to before **LASIK**. From the clinical study with the **ALLEGRETTO WAVE** device, it is hard to say how likely it is that you will need reading glasses, but it is possible.

- **Will my vision be perfect after LASIK surgery?**

  As with any surgical procedure there are risks associated with **LASIK** surgery. It is important to discuss all risks with your doctor before making the decision to have the surgery:

  - It is not possible to predict how your eyes will respond to the treatment. Your eye may be either undercorrected or overcorrected after the surgery. A mild degree of either may be perfectly well tolerated. Under- or overcorrection for **astigmatism** is also possible. If the result of the surgery is not satisfactory, you may need to wear glasses or contact lenses or have an additional **LASIK** surgery in the same eye for enhancement of the result.

  - A special type of **astigmatism** – known as irregular **astigmatism** – may occur after **LASIK**. In this condition, the **cornea** does not heal smoothly and may require wearing of hard gas permeable contact lenses to achieve best vision. Irregular **astigmatism** may lessen over several weeks or months.

  - You may need reading glasses, even if you did not wear them before the surgery. This will occur due to an age-related phenomenon called presbyopia. If you are in the presbyopic age range, any method to correct your **nearsightedness** will likely necessitate the need for reading glasses.

  - Mild glare and **halos** at nighttime are not uncommon after **LASIK**. In most patients, these symptoms are mild and will lessen over time. In rare cases they may be severe and last long enough to require the use of eye drops to reduce the size of the eye's **pupil**. Glare and **halos** may interfere with night driving.

  - Infection of the eye is a potential complication following **LASIK** surgery. A potentially lengthy course of treatment may be necessary. Potential consequences of **corneal** infections include **corneal** scarring, **corneal** perforation and spread of the infection inside the eye. Any of these conditions, if severe enough, may result in partial loss of vision or even blindness.

  - Diffuse haziness (Lamellar Keratitis) in the **flap** bed that typically shows up 1 to 3 days after surgery in 1 of 1000 eyes. Treatment of diffuse lamellar keratitis will involve application of cortisone-type drops. In some cases the surgeon might have to lift the flap again.

  - Intraocular pressure of the eye may rise in the treated eye(s), possibly due to the prescribed medication to reduce swelling (inflammation) or diffuse lamellar keratitis. The increased pressure usually does not cause any noticeable symptoms. A severe increase in pressure may cause pain or nausea.

- **LASIK** has not been proven to cause problems inside the eye such as **cataract** or **retinal** detachment. If it is necessary for you to take medications after surgery for a long time this can possibly increase the risk of **cataract** formation.

o **What risks are associated with the surgical procedure?**

- Many patients feel more comfortable with a mild degree of oral sedation before the **LASIK** procedure. If you receive sedation you should not drive or operate machinery for 24 to 48 hours after surgery.

- Application of the **microkeratome** will increase the pressure inside the eye. It is very common for patients to have the vision in the eye become dim or even temporarily completely disappear. It is felt that this is due to the pressure closing small blood vessels inside the eye. Once the **microkeratome** is removed and the pressure is normalized, the vessels re-open and vision fully returns. There is a concern among refractive surgeons that blood vessel closure in the eye may be permanent although this has never occurred. Should this occur, the result could be a permanent partial or even total loss of vision, which would be apparent at the time of surgery.

- Unsatisfactory **flap** cut related to the use of the **microkeratome**. In this case the surgeon will not perform **LASIK** at that time. A new **flap** can usually be created 3 months after the first attempt and the surgery can be completed then.

- Patients with very large **pupils** (larger than 6 mm) are advised of the potential for negative effects of vision after **LASIK** surgery including glare, **halos**, and nighttime driving difficulties.

- The effects of the laser device on implantable medical devices are unknown.

o **Should I have both eyes treated during the same session?**

You and your surgeon must decide whether to treat the second eye immediately after the first eye or at a later date. Even if you decide to have both eyes treated at the same time, it is the doctor's decision at the time of surgery whether this will actually occur.

- If there is an infection or problem with healing after the surgery, it is more likely that both eyes are affected if they are both treated at the same session.

- If only one eye is treated the difference in vision between the treated eye and the one without treatment might make vision difficult. In such a case you might not have functional vision unless the second eye is treated with **LASIK** or by wearing glasses or contact lenses that compensate for the difference.

- **What side effects could follow after having LASIK surgery?**

  You may experience the following side effects, which are part of the normal healing process. These symptoms are temporary and occur in many patients:

- The effects of **LASIK** on vision under poor light conditions such as very dim light, rain, snow, fog or bright glare have not been determined. You might find it more difficult to see under such poor light conditions than under normal light conditions. This effect may be permanent. If you have very large **pupils** you may be at a higher risk for this effect.

- You might experience eye irritation related to drying of the **corneal** surface following **LASIK** surgery. The symptoms may be temporary or, in rare cases permanent, and may require frequent application of artificial tears.

- You might feel moderate pain, discomfort and feeling of something in the eye for several days after surgery. Analgesic (pain reducing) medications may be necessary.

- Tearing, usually limited to the first 72 hours after surgery. In rare cases tearing can be so bad as to blur vision and interfere with functions such as driving.

- Blurry or double vision as the **cornea** heals, particularly in the first 72 hours. Double vision can also occur as a long-term complication of the surgery.

- Glare and increased sensitivity to bright light. Light sensitivity is usually most intense for the first 48 hours after surgery, although it may persist for prolonged periods after **LASIK**. Your eyes may remain slightly more sensitive to light than they were before surgery. You may have difficulties with night driving.

- Swelling of the eye or **cornea**. Swelling usually resolves within 48 hours after surgery.

- Ptosis or drooping of the upper eyelid has been noted as an uncommon occurrence following **LASIK**. The cause is not yet fully understood. Generally, post-**LASIK** ptosis is mild in degree and will resolve by itself over several months

- **Corneal** scarring (or **haze**) may occur after **LASIK** surgery, although it is rare. Scarring or **haze** may cause partial vision loss or in cloudiness of vision.

- Epithelial ingrowth has been reported with **LASIK** and may first be noted within the first few weeks after surgery. **LASIK** involves cutting between two layers of **corneal** tissue. It has been observed, that surface cells can grow into the space between the two layers. Although not uncommon, epithelial ingrowth is generally mild and not progressive. In most cases it is something the surgeon will observe but will not be noticeable to the patient nor will it affect their vision. In rare cases cells will continue to grow and affect vision. This will require re-opening of the **flap** and mechanical removal of the epithelial cells. If it is not treated epithelial ingrowth can lead to loss of the **flap**.

- Prolonged abnormal surface healing may occur. During the process of using the **microkeratome**, defects on the **flap** surface may be created. These generally respond well to patching of the eye and/or the use of a soft contact lens. The defects may take several days or weeks to fully heal and could – while active – reduce visual acuity.
- Movement of the **flap** may occur due to rubbing of the eye. Do not rub the eye, even if the eye is itchy. If the **flap** has moved, you may notice a sudden deterioration of your quality of vision. You should contact your doctor immediately.
- The development of dry eye symptoms may be a potential effect after having had **LASIK** surgery.

o What other side effects were found in the US clinical study?

During the first year after treatment, the following events were reported in patients included in US clinical studies:

- 0.8% (7/844) of cases had a defect in the top layer of the **cornea** (**Corneal epithelial defect**).
- 0.2% (2/876) of cases had an ingrowth of surface cells in the **interface** (Epithelial ingrowth).
- 0.5% (4/876) of cases experienced a foreign body sensation in their eye after **LASIK** surgery.
- 0.2% (2/844) of cases had pain in their eye after a long-term period after **LASIK** surgery.
- 0.9% (7/818) of cases had ghost or double images
- 1.4% (10/743) of cases showed a trace level of **Corneal haze** (cloudiness of **cornea**).
- 0.2% (2/876) of cases had a problem with the **flap** or cap that required the doctor to intervene with a surgery.
- 1.4% (3/212) of cases had an increased intraocular pressure of >5 mm Hg.

10 HOW CAN LASIK AFFECT YOUR CAREER CHOICE?

Some occupations may have certain vision requirements that cannot be met with a refractive surgical procedure. Please check details before making the decision to have surgery.

11 WHAT SHOULD YOU ASK YOUR DOCTOR?

You may want to ask your doctor the following questions to help you decide if **LASIK** surgery is the best option for you:

- What other options are available to correct my vision?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of **LASIK** for my amount of **nearsightedness** and/or **astigmatism**?
- What vision can I expect the first few months after surgery?
- If **LASIK** does not correct my vision, what is the possibility that my glasses will be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after **LASIK** if I need them?
- Is it likely that I will need reading glasses, as I get older?
- Will my **cornea** heal differently, if injured after having **LASIK**?
- Should I have **LASIK** in both eyes?
- How long will I have to wait till I get **LASIK** on the second eye?
- What vision problems may I experience, if I have **LASIK** only on one eye?

You should discuss the cost of surgery and follow-up care with your doctor. Most health insurance policies do not cover **refractive surgery**.

12 SUMMARY OF IMPORTANT INFORMATION

- **LASIK** is a permanent operation to the **cornea** and cannot be reversed.
- **LASIK** may not eliminate the need for glasses or contact lenses. In addition, you may need reading glasses, even if you did not wear them prior to the **LASIK** surgery.
- Your vision must be stable at least one year before the pre-op examination. You will need written evidence that your **nearsightedness** and **astigmatism** have changed only 0.5 **Diopter** or less.
- Pregnant or nursing women do not qualify for **LASIK** surgery.
- You are not a good candidate for **LASIK** surgery if you have a **collagen vascular disease** or **autoimmune disease** or have a condition that makes wound healing difficult.
- **LASIK** surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery.
- **LASIK** is not a laser version of **RK**, these surgeries are completely different from each other.
- Alternatives to **LASIK** include, but are not limited to glasses, contact lenses, **PRK** and **RK**.
- Some professions prohibit refractive surgery including **LASIK**.
- Before considering **LASIK** surgery, you should
  a) Have a complete eye exam.
  b) Talk with one or more eye care professionals about the potential benefits, risk and complications of **LASIK**. You should also discuss the time needed for healing and the discomfort you may experience or problems that may occur during this time.

13 SELF TEST

Are you an informed and educated patient?

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

	TRUE	FALSE
a) **LASIK** is a permanent procedure	☐	☐
b) **LASIK** is free of risks	☐	☐
c) **LASIK** is the same as **RK**	☐	☐
d) It doesn't matter if I wear my contact lenses when my doctor told me not to wear them	☐	☐
e) I may need reading glasses after **LASIK**	☐	☐
f) There is a risk that I may lose some vision after **LASIK**	☐	☐
g) It's ok to have **LASIK** if I am pregnant	☐	☐
h) It matters if I take medication with ocular or healing side effects like Cordarone, Imitrex or Accutane	☐	☐
i) After surgery there is a very good chance that I am less dependent on eye glasses	☐	☐
j) Since the **ALLEGRETTO WAVE Laser System** uses an **eyetracker**, I do not have to fixate the blinking light during laser treatment	☐	☐
k) Even if my refraction was changing a lot over the last year, I am still a good candidate for **LASIK**	☐	☐

You can find the answers in section 15.

14 WHERE CAN YOU GET MORE INFORMATION?

Primary Eye Care Professional
Name:
Address:
Phone:
Email:

LASIK Doctor
Name:
Address:
Phone:
Email:

Treatment Location
Name:
Address:
Phone:

Laser Manufacturer:
WaveLight Laser Technologie AG
Am Wolfsmantel 5
91058 Erlangen
Germany
www.WaveLight-Laser.com

Distribution and Support in the US:
Lumenis Inc.
2400 Condensa Street
Santa Clara, CA 95051
U.S.A.
Phone: 1-408 764 3000
Toll free: 1-800-LUMENIS
www.lumenis.com

15 ANSWERS TO SELF-TEST QUESTIONS

a) True (see pages 26 and 33; b) False (see pages 17, 18, 19, 27 and 28); c) False (see page 10 and 33; d) False (see page 20); e) True (see pages 26 and 27); f) True (see pages 16, 17, 26 and 27); g) False (see pages 11 and 33; h) True (see pages 11 and 13); i) True (see pages 16 and 17); j) False (see pages 7, 10 and 24); k) False (see pages 13 and 33.

16 GLOSSARY

Ablation, Ablate	Removal of tissue with an **Excimer Laser**
ALLEGRETTO WAVE™ Laser System	Modern high speed laser system with **eyetracker** for treatment of **nearsightedness**, **farsightedness** and **astigmatism**, manufactured by WaveLight Laser Technologie AG in Germany
Anesthetic Eye Drops	Drops used to numb the eye
Antibiotic Eye Drops	Drops used to prevent or treat infection
Anti-inflammatory Eye Drops	Drops used to prevent or treat swelling
Astigmatism	Refractive condition creating focused images at two different distances from the **retina**. Astigmatism may create ghost or double images. The **cornea** or the **lens** is too flat or too steep in one direction (much like the shape of a football). The amount of **astigmatism** is measured in **diopters.**
Autoimmune Disease	Condition in which the body attacks itself that may lead to inflammation or swelling of parts of the body. Examples are Multiple sclerosis and Myasthenia gravis. Patients with this type of disease should not have **LASIK** surgery
Bandage Contact Lens	Soft contact lens temporarily used to cover the **cornea** after surgery
BSCVA	Abbreviation of Best spectacle corrected visual acuity. Best visual acuity with glasses
Cataract	Opacity of the **lens** usually caused by aging of the lens that may cause loss of vision.
Collagen Vascular Disease	Condition that alters the way the body creates or metabolizes connective tissue like collagen. The **cornea** is made up of collagen. Examples are Lupus or Rheumatoid arthritis. Patients with this type of disease should not have **LASIK** surgery

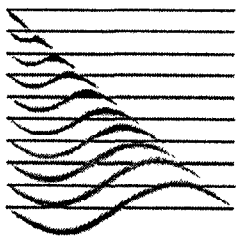
Cornea	Clear front surface of the eye. Acts like a lens and provides about 70% of the eyes refractive power. The cornea is approximately 550 **microns** thick. Normal variations range from 450 to 600 **microns**
Corneal Epithelium	Surface cells, forming the top layer of the **cornea**
Corneal epithelial defect	Damage in the top layer of the **cornea** that may result in pain or discomfort. The damage is temporary and usually heals quickly.
Cylinder	Value that describes the amount of **astigmatism**
Diopter	Unit used to measure the amount of **nearsightedness**, **farsightedness** and **astigmatism. Nearsightedness** is measured in terms of negative **diopters**, **farsightedness** is measured in terms of positive **diopters**
Excimer laser	Type of laser emitting UV light. This Laser is used in **PRK** or **LASIK** to **ablate corneal** tissue precisely and without collateral damage or influence
Eyetracker	Device that detects and tracks the position of the eye or **pupil**. Such a tracker may enable laser systems to follow the eye with the laser beam.
Farsightedness	Refractive condition creating focused images in front of the **retina**. Near objects seem blurry, distant objects may be seen clearly. The **cornea** is too flat or the eye is too short. The amount of farsightedness is measured in **diopters**.
FDA	Food and Drug Administration, governmental agency that approves medical technology in the U.S.A.
Flap	Thin slice of **corneal** tissue created on the surface of the **cornea** with a **microkeratome**. Tissue will be removed under the flap
Floaters	Cloudy structures in the fluid in the center of the eyeball causing "floating" structures in the image
Glaucoma	Condition, usually associated with elevated pressure in the eye. Condition may result in damage of the optical nerve, leading to loss of vision.

Halo	Circular flares of light around bright lights in dim conditions. This symptom may occur after surgery
Haze	Cloudiness of the **cornea**. This symptom may occur after surgery
Herpes simplex	Type of infection caused by a virus that causes cold sores or vesicles in different parts of the body. This virus may be recurrent. Patients with history of this condition should discuss this with their doctor before having **LASIK** surgery
Herpes zoster	Type of infection caused by a virus that causes vesicles on one side of the body. This virus may be recurrent. Patients with history of this condition should discuss this with their doctor before having **LASIK** surgery
Hyperopia	Medical term for **farsightedness**
Immunodeficiency Disease	Condition that alters the body's ability to heal. An example is AIDS. Patients with this type of disease should not have **LASIK** surgery
Iris	Colored ring tissue between **cornea** and lens. The circular opening in the center of the eye is the **pupil**. Acts like a variable diaphragm to adjust light intensity on the **retina**
Interface	Interface layer between the **flap** and the remaining **corneal** tissue
Keratoconus	Condition of the **cornea** that results in thinning
Keratomileusis	Sculpting of the **cornea** by removing tissue
Keratotomy	Cutting the **cornea**
LASIK	Acronym for **Laser in-situ keratomileusis**. **Refractive surgery** that **ablates** corneal tissue after creating a **flap**. "In situ" is a Latin term meaning "without removal" (of the upper tissue layer)
Laser in-situ keratomileusis	**Refractive surgery** that removes corneal tissue after creating a **flap**.
Lens	Flexible **lens** behind the **iris** that helps to focus images on the **retina**

Microkeratome	Precision instrument, similar to a carpenters plane, used to create the **flap** during **LASIK** surgery
Micron	1/1000 of a millimeter or 4/10000 inch. The symbol is "µm"
Myopia	Medical term for **nearsightedness**
Nearsightedness	Refractive condition creating focused images in front of the **retina**. Distant objects seem blurry, near objects may be seen clearly. The **cornea** is too steep or the eye is too long. The amount of **nearsightedness** is measured in **diopters**
Optical Power	Ability of an object such as the eye to bend light rays as they pass through
Optical Zone	Part of the treatment area in which the refractive laser treatment shall be effective
Photorefractive Keratectomy	**Refractive surgery** that **ablates** corneal tissue without making a **flap**.
PRK	Acronym for **photorefractive keratectomy**. Refractive surgery that removes corneal tissue without making a **flap**. The upper layer of tissue is removed prior to surgery.
Pupil	An opening in the center of the **iris** that changes its size in response to changes in light brightness
Radial Keratotomy	**Refractive surgery** that uses a knife to make radial cuts in the **cornea**
Refractive Error	Condition of the eye that creates blurry images. **Nearsightedness, farsightedness** and **astigmatism** are refractive errors.
Refractive Surgery	Surgery on or in the eye performed in order to reduce or eliminate the dependence on glasses or contact lenses.
Retina	Light and color sensitive membrane inside the eye. Transforms images into nerve signals
RK	Acronym for **radial keratotomy**. **Refractive surgery** that uses a knife to make radial cuts in the **cornea**
Steroids	Drugs used to reduce inflammation or the body's healing response after injury or disease.
Vitreous, Vitreous body	Gel-like fluid that fills the center of the eyeball behind the **lens**

17 INDEX

- End -



ALLEGRETTO WAVE™

Scanning Spot LASIK Laser System

Procedure Manual

Information for professional use

WaveLight Laser Technologie AG
Am Wolfsmantel 5
91058 Erlangen, Germany

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

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.

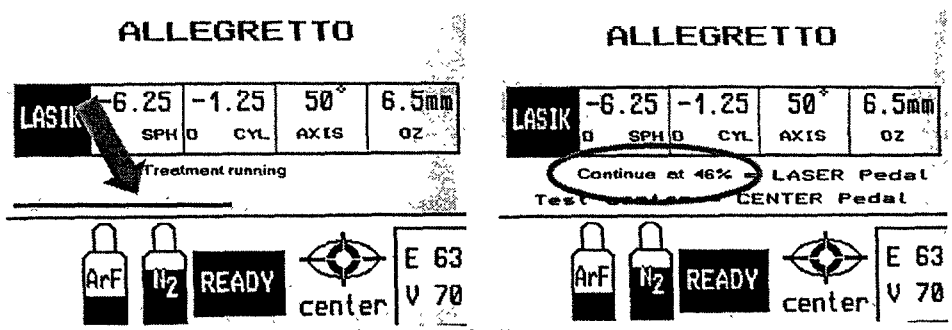
Medications likely to dilate or constrict the pupil should not be given during the last 6 hours prior to surgery as the Eyetracker will not be able to track pupils of less than 1.5mm and more than 8.0mm diameter.

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.

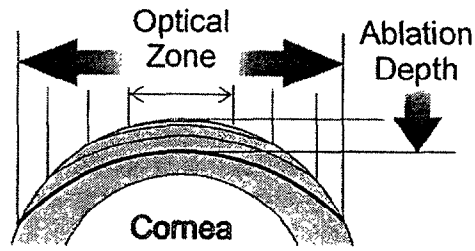


Progress Indicators

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

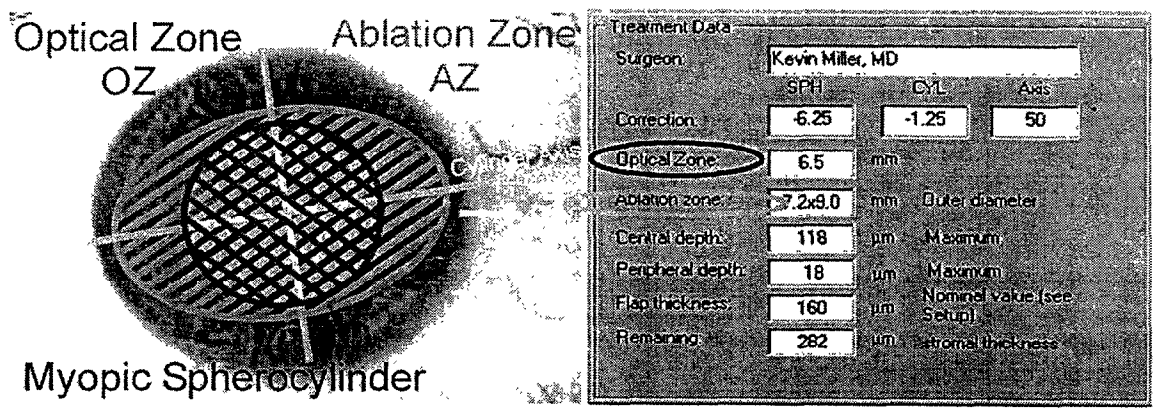


already after the first few seconds, but in a diameter smaller than the full Optical Zone. During the course of the ablation the zone already corrected is enlarged to the programmed Optical Zone diameter. The currently achieved diameter with full correction is not indicated.

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.



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=876	%	n N=844	%	n N=818	%	n 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 mm2 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 % N=876	1 Month n N=876	3 Months % N=844	3 Months n N=844	6 Months % N=818	6 Months n N=818	1 Year % N=813	1 Year n 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.

Table 4
Demographic Characteristics
(N=901)

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 95% CI	% n 95% CI
≤1.00 D 95% CI for %	97.6 747 97.1%, 98.2%	99.0% 757 98.6%, 99.4%
MRSE (D) Mean SD 95% CI for Mean	 -0.01 D 0.34 -0.03, 0.01	 -0.05 D 0.30 -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 % n 95% CI	3 Months % n 95% CI	6 Months % n 95% CI	1 Year % n 95% CI
Efficacy Variables	N=841	N=813	N=782	N=780
UCVA 20/20 or better*	82.8 696 81.5%, 84.1%	84.4 686 83.1%,85.7%	87.7 686 86.6%,88.9%	87.4 682 86.3%,88.6%
UCVA 20/40 or better*	97.6 821 97.1%, 98.2%	98.0% 797 97.5%,98.5%	98.3% 769 97.9%,98.8%	99.0 772 98.6%,99.3%
	N=876	N=844	N=818	N=813
MRSE ± 0.50 D	85.6 750 84.4%,86.8%	84.8 716 83.6%,86.1%	85.3 698 84.1%,86.6%	85.1 692 83.9%,86.4%
MRSE ± 1.00 D	96.8 848 96.2%,97.4%	96.7 816 96.1%,97.3%	97.3 796 96.7%,97.9%	97.7 794 97.1%,98.2%
MRSE ± 2.00 D	99.4 871 99.2%,99.7%	99.5 840 99.3%,99.8%	99.6 815 99.4%,99.8%	99.5 809 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 % n 95% CI	>1 to 2 D % n 95% CI	>2 to 3 D % n 95% CI	>3 to 4 D % n 95% CI	>4 to 5 D % n 95% CI	>5 to 6 D % n 95% CI	>6 to 7 D % n 95% CI	Total ≤7 D % 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%
	N=17	**N=114**	**N=131**	**N=141**	**N=135**	**N=106**	**N=84**	**N=728**
MRSE ± 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%
MRSE ± 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%
MRSE ± 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 % n 95% CI	>8 to 9 D % n 95% CI	>9 to 10 D % n 95% CI	>10 to 11 D % n 95% CI	>11 to 12 D % n 95% CI	>12 to 13 D % n 95% CI	Cum Total >7 D % 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%
	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

	3 Months	
Preoperative Cylinder	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

	3 Months
Preoperative Cylinder	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 % n 95% CI	3 Months % n 95% CI	6 Months % n 95% CI	1 Year % n 95% CI
Safety Variables	**N=876**	**N=844**	**N=818**	**N=813**
Loss of ≥ 2 lines BSCVA	0.9 8 0.6%,1.2%	0.6 5 0.3%,0.9%	0.7 6 0.4%,1.0%	0.5 4 0.3%,0.7%
BSCVA worse than 20/40	0.1 1 0.0%,0.2%	0.0 0 0.0%,0.0%	0.0 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 0.0%,0.8%	0.4 1 0.0%,0.8%	0.0 0 0.0%,0.0%	0.4 1 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%,0.4%	0.1 1 0.0%,0.3%	0.3 2 0.1%,0.4%	0.1 1 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 % n 95% CI	>1 to 2 D % n 95% CI	>2 to 3 D % n 95% CI	>3 to 4 D % n 95% CI	>4 to 5 D % n 95% CI	>5 to 6 D % n 95% CI	>6 to 7 D % n 95% CI	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%	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 0.0%,0.0%	0.0 0 0.0%,0.0%
	N=2	**N=41**	**N=49**	**N=46**	**N=38**	**N=29**	**N=22**	**N=227**
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%
	N=17	**N=114**	**N=130**	**N=138**	**N=130**	**N=96**	**N=77**	**N=702**
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 % n 95% CI	>8 to 9 D % n 95% CI	>9 to 10 D % n 95% CI	>10 to 11 D % n 95% CI	>11 to 12 D % n 95% CI	>12 to 13 D % n 95% CI	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%	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 0.0%,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%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%
	N=10	**N=6**	**N=4**	**N=2**	**N=2**	**N=0**	**N=24**
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%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%
	N=32	**N=34**	**N=19**	**N=3**	**N=9**	**N=1**	**N=98**
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%	0.0 0 0.0%,0.0%	0.0 0 0.0%,0.0%	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 % n 95% CI	3 Months % n 95% CI	6 Months % n 95% CI	1 Year % n 95% CI
Efficacy Variables	N=25	N=16	N=21	N=1
UCVA 20/20 or better*	56.0 14 46.1%, 65.9%	87.5 14 79.2%, 95.8%	66.7 14 56.4%, 77.0%	100 1 100%, 100%
UCVA 20/40 or better*	96.0 24 92.1%, 99.9%	100 16 100%, 100%	100 21 100%, 100%	100 1 100%, 100%
	N=25	N=15	N=21	N=1
MRSE ± 0.50 D	64.0 16 54.4%, 73.6%	100 15 100%, 100%	85.7 18 78.1%, 93.4%	100 1 100%, 100%
MRSE ± 1.00 D	96.0 24 92.1%, 99.9%	100 15 100%, 100%	100 21 100%, 100%	100 1 100%, 100%
MRSE ± 2.00 D	100 25 100%, 100%	100 15 100%, 100%	100 21 100%, 100%	100 1 100%, 100%
Safety Variables	N=25	N=16	N=21	N=1
Loss of ≥ 2 lines BSCVA	4.0 1 0.1%, 7.9%	0.0 0 0.0%, 0.0%	4.8 1 0.1%, 9.4%	0.0 0 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%, 0.0%	0.0 0 0.0%, 0.0%	4.8 1 0.1%, 9.4%	0.0 0 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