WaveLight® EX500

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 diopters (D) of sphere and up to - 6.00 diopters of astigmatism at spectacle plane,
- LASIK surgery for the elimination or reduction of **hyperopia** (farsightedness) of up to + 6.00 diopters of sphere and up to 5.00 diopters of astigmatism at the spectacle plane, with a maximum manifest refraction spherical equivalent of + 6.00 diopters,
- LASIK surgery for the elimination or reduction of **mixed astigmatism** of up to 6.00 diopters at the spectacle plane,
- Wavefront-guided LASIK surgery for the **wavefront-guided** reduction or elimination of up to - 7.00 diopters of spherical equivalent myopia or myopia with astigmatism, with up to 3.00 diopters of astigmatism at the spectacle plane,
- Who are 18 years (21 years for mixed astigmatism) 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.

CONTENTS

page

1. INTRODUCTION

This booklet has important information about **LASIK** and **wavefront-guided LASIK** surgery with the **WaveLight® EX500 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, FARSIGHTED AND ASTIGMATIC EYE

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

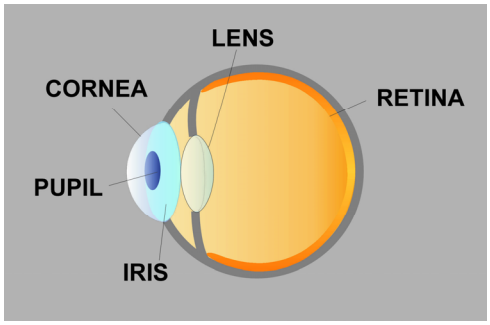

Figure 1: The Human Eye

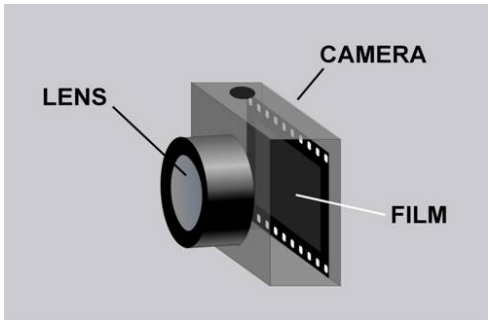

Figure 2: Camera

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**. Some eyes with astigmatism error show a special type of this error, called **mixed 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. Images of distant objects appear blurry on retina.

Figure 3 shows that distant vision is blurry when light focuses incorrectly in nearsighted eyes.

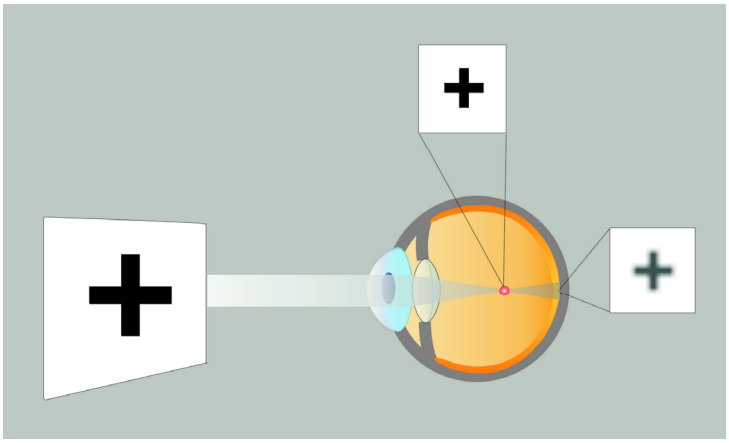

Figure 3: Nearsighted Eye Looking At A Black Cross

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 becomes evident later in life. Eyes of young people are often able to compensate for this condition. As we age, we loose this ability.

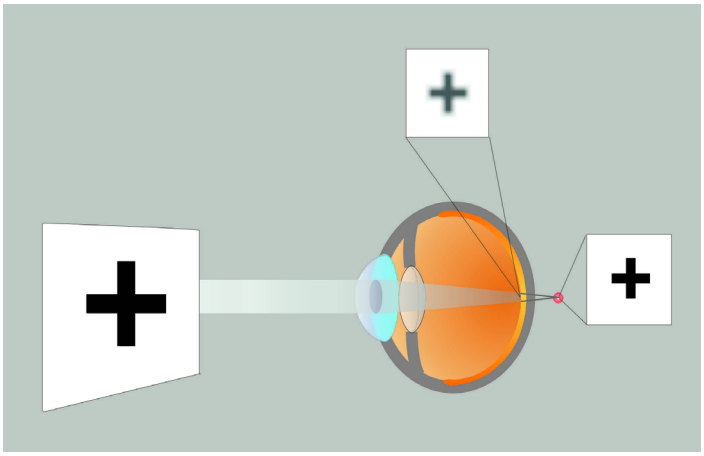

Figure 4: Farsighted Eye Looking At A Black Cross

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.

Mixed astigmatism is a condition of the human eye where people may see neither distant nor near objects clear. The image is focused twice in the eye, partially in front and partially behind the **retina**. A single focal point, which is where a sharp image appears, does not exist with mixed astigmatism.

Mixed astigmatism creates blurry images on the retina. If you look at objects with edges in various directions, 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. Light from a distant object is focused twice and not perfectly in each focal point. The image on the **retina** is blurry and distorted.

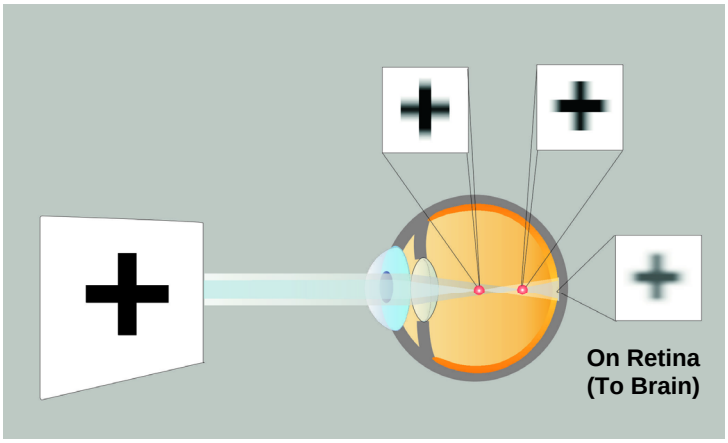

Figure 5: Nearsighted Eye With Astigmatism Looking At A Black Cross

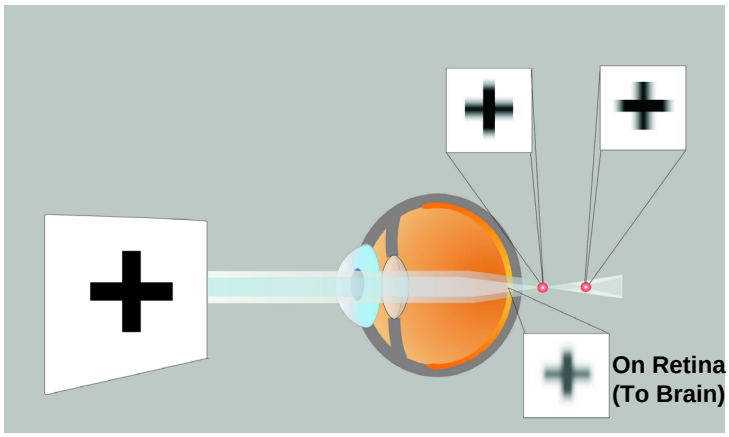

Figure 6: Farsighted Eye With Astigmatism Looking At A Black Cross

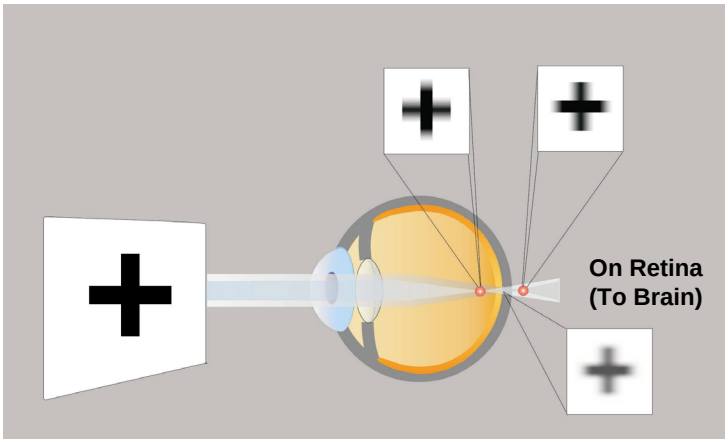

Figure 7: Eye With Mixed Astigmatism Looking At A Black Cross

The magnitude of all these errors is described by a single number called diopter.

Usually wearing glasses or contact lenses helps your eye focus light properly and on the retina. **LASIK** surgery is another way to improve this focusing property. 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 WAVELIGHT EX500 LASER SYSTEM?

The WaveLight® EX500 laser system consists of the laser console, which includes the laser and all control systems necessary for the surgeon to perform LASIK or wavefront-guided LASIK, such as control panels, monitors and a microscope. The WaveLight® EX500 laser system uses a very small laser beam to reshape the cornea. The system is equipped with 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 or wavefront-guided LASIK**, you will lie down on a bed. This bed is then moved under the laser and the LASIK or wavefront-guided LASIK treatment will be started.

The WaveLight® EX500 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.
- treating patients who have up to + 6 diopters of **farsightedness** with or without astigmatism of up to 5.0 diopters, with a maximum manifest refraction spherical equivalent of + 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.
- treating patients with **mixed astigmatism** error who have up to 6 diopters of astigmatism, who are 21 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.
- **wavefront-guided** treatments of patients who have up to - 7.00 diopters of nearsightedness with or without astigmatism of up to 3.00 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** or a **wavefront-guided LASIK** treatment is for you. Contraindications, warnings and precautions of the procedure are listed in this booklet. Check with your doctor which possible contraindications, precautions and warnings may apply to you. Make sure your doctor answers all your questions to your satisfaction before you agree to have LASIK or wavefront-guided LASIK treatment.

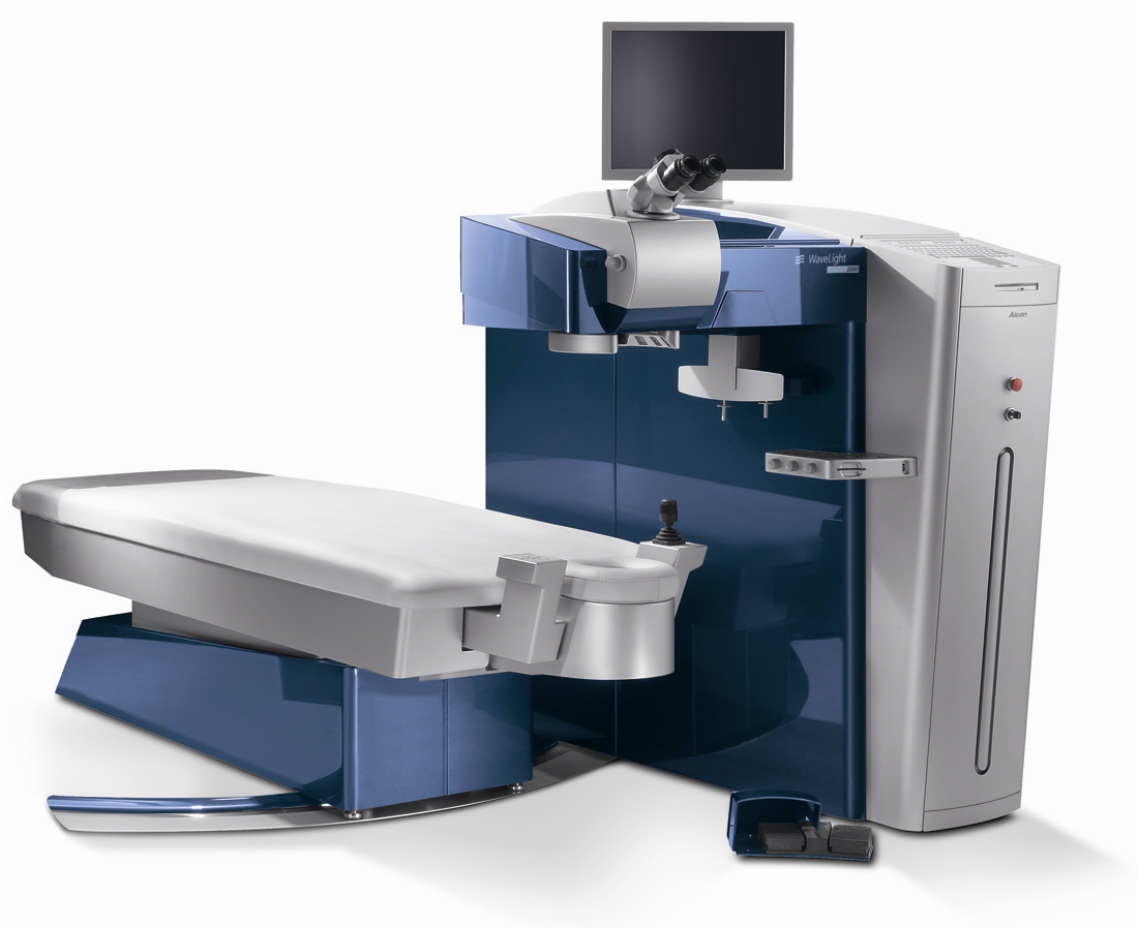

Figure 8: WaveLight® EX500

4. WHAT IS WAVEFRONT-GUIDED LASIK?

Glasses and contact lenses correct the main errors nearsightedness, farsightedness and astigmatism. They help your eye focus light properly and on the retina.
Wavefront-guided LASIK surgery is another way to focus light on the retina.
Besides the three main errors each eye has other imperfections or errors. They are usually smaller in magnitude but more complex. **Wavefront technology** can measure such errors in addition to nearsightedness, farsightedness and astigmatism.
A special **excimer laser** uses the measurement information for custom surgery. This laser will remove tiny amounts of tissue from the cornea. It does not change any other parts of the eye.
Wavefront-guided LASIK is a highly **customized surgery** compared to “off the shelf” **Wavefront Optimized LASIK**, **Standard LASIK** or **Traditional LASIK**.
Wavefront Optimized, Standard and Traditional LASIK are both terms referring to the same procedure. Wavefront Optimized (“standard” or “traditional”) LASIK is different than wavefront-guided LASIK. Wavefront Optimized LASIK does not use individual wavefront measurements.

Wavefront Measurement:

Wavefront measurement of an eye is a different way to measure its errors.
Wavefronts may be understood as images of light waves traveling through an eye.
Wavefronts can be used to determine the errors of an eye.
Wavefront measurement devices are called **wavefront analyzers** or **aberrometers**.
Such devices are able to provide highly detailed information for a custom wavefront-guided LASIK treatment:
Wavefront measurements will provide maps of the wavefront error. Such wavefront error maps include simple errors like nearsightedness and astigmatism as well as the more complex individual errors. In healthy eyes nearsightedness, farsightedness and astigmatism are usually much more than the complex individual errors.

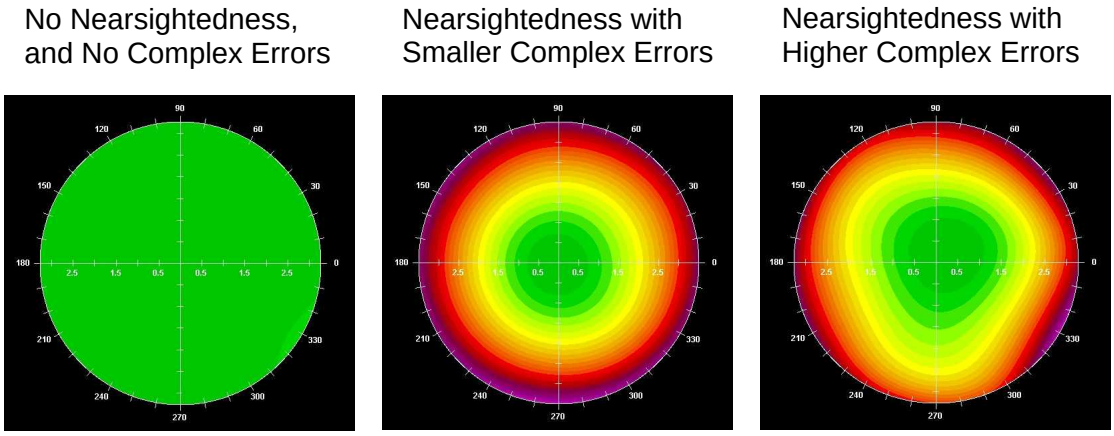

Figure 9: Examples For Wavefront Error Maps

An ideal eye has no wavefront error, the wavefront map would be flat. The higher the errors, the higher are the “elevations” of the wavefront map. Different colors represent different elevations.

5. WHAT IS THE ALLEGRO ANALYZER?

The ALLEGRO Analyzer is a wavefront analyzer for measuring human eyes.
The patient will sit in front of the device. The head is placed in a head rest. A lit target will help the patient keep their eye steady during image capture.
Multiple red light spots flash once while the image is captured. The red lights are arranged in a regular grid. Errors of the eye distort the regular grid pattern and the patient sees the distorted grid. With the ALLEGRO Analyzer patients will be able to get an idea of their errors by distortion of the grid they see.
A special camera inside the device captures the wavefront and provides information about nature and magnitude of the measured errors.

Figure 10: ALLEGRO Analyzer Diagnostic Device

6. HOW DOES LASIK CORRECT NEARSIGHTEDNESS / FARSIGHTEDNESS WITH OR WITHOUT ASTIGMATISM AND MIXED 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.

For the correction of **farsightedness**, the **optical power** of the eye must be **increased**. Therefore, the surface of the **cornea** is steepened by removing tissue mainly from the outer areas of the cornea.

For correction of **mixed astigmatism**, the **optical power** of the eye must be increased in one direction and decreased in another direction perpendicular to the first one. In the first direction, the surface of the **cornea** is steepened by removing tissue mainly from the outer areas of the cornea while in the second direction the surface of the cornea is flattened by removing tissue mainly from the central part of the cornea.

For **wavefront-guided** correction of nearsightedness, the **optical power** of the eye must be decreased. The surface of the **cornea** is flattened by removing tissue mainly from the central part of the cornea.

Surgical procedure:

- Numbing **eye drops** are given before surgery.
- The **WaveLight® EX500 laser system** does not require a dilated **pupil** for treatment.
- As shown in figure 11, your doctor will use an instrument called a **microkeratome** to create a **flap** of tissue from the upper layer of your **cornea**. Your doctor may use a **mechanical microkeratome** or a **laser microkeratome**. The laser microkeratome is also called "**femtosecond laser**". You will feel slight pressure on your eye and your vision may get dark. Vision will reappear when your doctor removes the microkeratome.

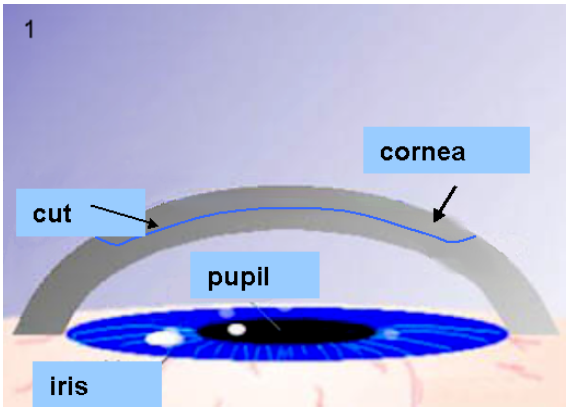

Figure 11: Cross Section Of Cornea

- Your doctor will fold the **flap** back to expose the inner layers of your **cornea** (see figure 12).

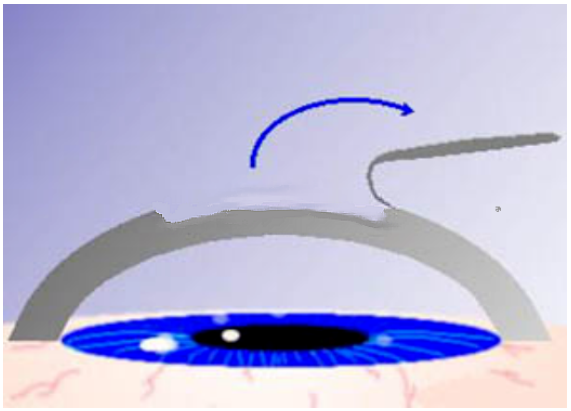

Figure 12: Flap Being Opened

- 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 WaveLight® EX500 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 13).

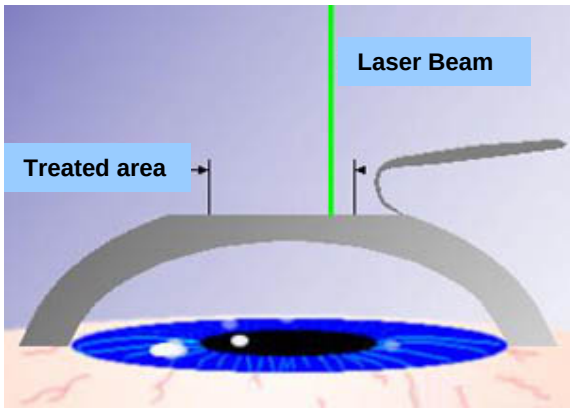

Figure 13: Cornea Being Shaped By Laser

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 WaveLight® EX500 laser system delivers 500 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 (see figure 14). Your vision will improve immediately, but it will be blurry or cloudy.

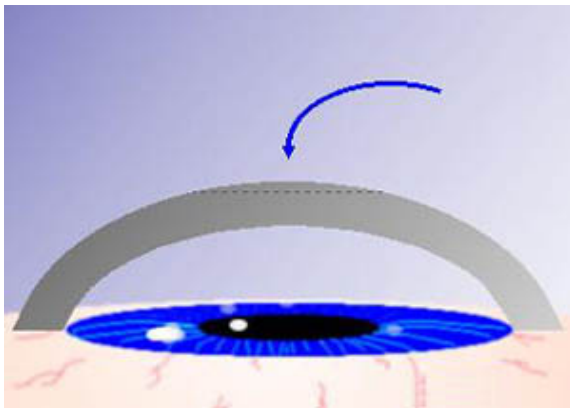

Figure 14: Flap Being Folded Back Into Position

The whole surgical procedure usually will take about 5-10 minutes per eye.

If you are going to have both of 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.

7. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Contraindications - When Can't You Have LASIK or wavefront-guided 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 Amiodarone 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 Wyeth Inc.

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

If you have any of the following conditions, you may have LASIK or wavefront-guided 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 or wavefront-guided 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, farsightedness, astigmatism or mixed astigmatism in the last 12 months, and your nearsightedness, farsightedness, astigmatism or mixed 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** (21 **years for mixed astigmatism**), because it is unknown whether LASIK is safe and effective for you.

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

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

- Physician Adjustments. Your doctor may modify the wavefront-calculated ablation program in order to give you a treatment that does not fully correct distance vision. You should discuss the risks in depth with your doctor for any LASIK corrections that do not fully correct for distance vision, especially if performed only in one eye.

- 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.

- Your **farsightedness** is worse than + 6.0 diopters or astigmatism is worse than 5 diopters, because it is unknown whether LASIK is safe and effective for you.

- Your **astigmatism** is worse than 6 diopters, because it is unknown whether LASIK is safe and effective for you.

- In **cylinder** amounts > 4 to ≤ 6 D **for mixed astigmatism** due to the lack of large numbers of patients in the general population, there are few subjects with cylinder amounts in this range to be studied. Not all complications, adverse events, and levels of effectiveness may have been determined.

- **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.

8. WHAT ARE ITS BENEFITS?

By using the WaveLight® EX500 laser system, your doctor can help eliminate or reduce your **nearsightedness**, **farsightedness**, **astigmatism** and **mixed astigmatism** and, therefore, your need to wear glasses or contact lenses.

The study data referenced below has been achieved using the ALLEGRETTO WAVE excimer laser system with 200 Hz. Testing data submitted to FDA show that the system with 500 Hz repetition rate is expected to show equivalent clinical results.

Please also refer to section:

- "Clinical Study for Farsightedness with or without Astigmatism" on page 25
- "Clinical Study for Mixed Astigmatism" on page 28
- "Clinical Study for Wavefront-guided LASIK" on page 31

Clinical Study for Nearsightedness with or without Astigmatism

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 chapter 11 "Frequently Asked Questions" on page 58.

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:	Asian	1.8%	Female	51.6%	Soft	55.6%
38 ± 10 years	Black	1.3%	Male	48.4%	RGP[1]	8.3%
Range:	Caucasian	92.6%			PMMA[2]	1.0%
18 to 67 years	Hispanic	2.9%			Glasses[3]	34.8%
	Other	1.2%				

Table 1: Demographics Of 901 Eyes Of 459 Subjects

[1] Rigid Gas Permeable

[2] Polymethylmethacrylate

[3] These subjects wore glasses or no method of correction.

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%

Table 2: Visual Acuity Without Glasses After Surgery For Nearsightedness

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 Comparison of Vision After Surgery (no glasses) with Vision Before Surgery (while wearing glasses)				
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%

Table 3: Comparison Of Vision After Surgery With Vision Before Surgery

[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

Clinical Study for Farsightedness with or without Astigmatism

A clinical study was done to evaluate the benefits and risks of the ALLEGRETTO WAVE laser system for LASIK. The study included 290 eyes treated for farsightedness with or without astigmatism. The study results are shown below and in chapter 11 “Frequently Asked Questions” on page 58.

Study Patient Demographics for Farsightedness:

Most patients were Caucasian. No patients were over 69 years old. **Table 4** shows the age, race, gender and contact lens history of patients in the study.

Table 4
Demographics of 290 Eyes of 151 Subjects

Age	Race		Gender		Contact Lens History	
Average:	Asian	0.0%	Female	51.0%	Soft	30.7%
52 ± 9 years	Black	0.0%	Male	49.0%	RGP[1]	3.4%
Range:	Caucasian	91.4%			PMMA[2]	0.3%
25 to 69 years	Hispanic	7.2%			Glasses[3]	65.5%
	Other	1.4%				

Table 4: Demographics Of 290 Eyes Of 151 Subjects

[1] Rigid Gas Permeable

[2] Polymethylmethacrylate

[3] These subjects wore glasses or no method of correction.

Visual Acuity *without* Glasses After Surgery for Farsightedness:

Visual Acuity measures the sharpness of vision using a letter chart. **Table 5** shows that at least 95% of study cases saw 20/40 or better without glasses after surgery. Most states require that your vision be 20/40 or better in order to drive without any glasses or contact lenses.

Table 5
Visual Acuity *without* Glasses After Surgery for Farsightedness

Time after Surgery	1 Month (N=232)	3 Months (N=225)	6 Months (N=212)	1 Year (N=80)
% of eyes with 20/20 or better	61.6%	68.9%	67.5%	67.5%
% of eyes with 20/40 or better	96.6%	96.4%	95.3%	98.8%

Table 5: Visual Acuity Without Glasses After Surgery For Farsightedness

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 6 shows how well patients were able to see without glasses after surgery. A comparison is shown to their vision with glasses prior to having surgery. The following table shows that at 6 months after surgery, 54.9% saw as well or better without glasses as they did with glasses before surgery.

Table 6
Comparison of Vision After Surgery (no glasses) with Vision Before Surgery (while wearing glasses)

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)			
	1 Month (N=285)	3 Months (N=276)	6 Months (N=260)	1 Year (N=98)
Gain of more than 2 lines[1]	0.0%	0.0%	0.0%	0.0%
Gain of 2 lines[1]	2.1%	2.2%	2.9%	4.7%
Gain of 1 line[1]	10.9%	15.1%	17.0%	21.3%
No change	35.1%	36.7%	35.0%	33.9%
Loss of 1 line[2]	22.8%	16.9%	15.9%	17.3%
Loss of 2 lines[2]	10.2%	11.5%	10.1%	7.9%
Loss of more than 2 lines[2]	19.0%	17.6%	19.1%	15.0%

Table 6: Comparison Of Vision After Surgery With Vision Before Surgery

[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

Clinical Study for Mixed Astigmatism

A clinical study was done to evaluate the benefits and risks of the ALLEGRETTO WAVE laser system for LASIK. The study included 162 eyes treated for mixed astigmatism. The study results are shown below and in chapter 11 “Frequently Asked Questions” on page 58.

Study Patient Demographics for Mixed Astigmatism:

Most patients were Caucasian. No patients were over 70 years old. **Table 7** shows the age, race, gender and contact lens history of patients in the study.

Table 7
Demographics of 162 Eyes of 96 Subjects

Age	Race		Gender		Contact Lens History	
Average:	Asian	0.0%	Female	32.7%	Soft	22.3%
39 years	Black	3.7%	Male	67.3%	RGP[1]	2.5%
Range:	Caucasian	85.8%			PMMA[2]	0.0%
22 to 70 years	Hispanic	8.0%			Glasses[3]	74.1%
	Other	2.4%				

Table 7: Demographics Of 162 Eyes Of 96 Subjects

[1] Rigid Gas Permeable

[2] Polymethylmethacrylate

[3] These subjects wore glasses or no method of correction.

Visual Acuity *without* Glasses After Surgery for Mixed Astigmatism:

Visual Acuity measures the sharpness of vision using a letter chart. **Table 8** shows that at least 95% of study cases saw 20/40 or better without glasses after surgery. Most states require that your vision be 20/40 or better in order to drive without any glasses or contact lenses.

Table 8
Visual Acuity *without* Glasses After Surgery for Mixed Astigmatism

Time after Surgery	1 Month (N=161)	3 Months (N=142)	6 Months (N=111)
% of eyes with 20/20 or better	59.6%	67.6%	69.4%
% of eyes with 20/40 or better	96.9%	95.8%	97.3%

Table 8: Visual Acuity Without Glasses After Surgery For Mixed Astigmatism

Visual Acuity *without* Glasses After Surgery and With Glasses Before Surgery:

Table 9 shows how well patients were able to see without glasses after surgery. A comparison is shown to their vision with glasses prior to having surgery. The following table shows that at 3 months after surgery, 64.4% saw as well or better without glasses as they did with glasses before surgery.

Table 9
Comparison of Vision After Surgery (no glasses) with Vision Before Surgery (while wearing glasses)

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)		
	1 Month (N=161)	3 Months (N=142)	6 Months (N=111)
Gain of more than 2 lines[1]	0.0%	0.7%	0.0%
Gain of 2 lines[1]	1.2%	2.8%	6.3%
Gain of 1 line[1]	14.3%	20.4%	19.8%
No change	39.8%	42.3%	46.9%
Loss of 1 line[2]	21.7%	19.0%	9.9%
Loss of 2 lines[2]	14.3%	8.5%	10.8%
Loss of more than 2 lines[2]	8.7%	6.3%	6.3%

Table 9: Comparison Of Vision After Surgery With Vision Before Surgery

[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

Clinical Study for Wavefront-guided LASIK

A clinical study was done to evaluate the benefits and risks of the ALLEGRETTO WAVE laser system for wavefront-guided LASIK. The study included 188 eyes treated wavefront-guided for nearsightedness. The study results are shown below and in chapter 11 “Frequently Asked Questions” on page 58.

Study Patient Demographics:

Most patients were Caucasian. No patients were over 52 years old. **Table 10** shows the age, race, gender and contact lens history of patients in the study.

Table 10
Demographics of 188 Eyes of 94 Subjects

Age	Race		Gender		Contact Lens History	
Average:	Asian	2.1%	Female	44.7%	Soft	66.0%
33.5 years	Black	3.2%	Male	55.3%	RGP[1]	5.3%
Range:	Caucasian	93.6%			PMMA[2]	0.0%
21 to 52 years	Hispanic	1.1%			Glasses[3]	28.7%
	Other	0.0%				

Table 10: Demographics Of 188 Eyes Of 94 Subjects

[1] Rigid Gas Permeable

[2] Polymethylmethacrylate

[3] These subjects wore glasses or no method of correction.

Visual Acuity *without* Glasses After Surgery for Nearsightedness:

Visual Acuity measures the sharpness of vision using a letter chart. **Table 11** shows that at least 99% of study cases saw 20/40 or better without glasses after surgery. Most states require that your vision be 20/40 or better in order to drive without any glasses or contact lenses.

Table 11
Visual Acuity *without* Glasses After Surgery for Nearsightedness

Time after Surgery	1 Month (N=182)	3 Months (N=180)	6 Months (N=166)
% of eyes with 20/20 or better	94.5%	95.0%	93.4%
% of eyes with 20/40 or better	99.5%	100%	99.4%

Table 11: Visual Acuity Without Glasses After Surgery For Nearsightedness

In the clinical study on wavefront-guided 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 12 shows how well patients were able to see without glasses after surgery. A comparison is shown to their vision with glasses prior to having surgery. The following table shows that at 3 months after surgery, 81.1% saw as well or better without glasses as they did with glasses before surgery.

Table 12
Comparison of Vision After Surgery (no glasses) with Vision Before Surgery (while wearing glasses)

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)		
	1 Month (N=182)	3 Months (N=180)	6 Months (N=166)
Gain of more than 2 lines[1]	0.0%	0.0%	0.6%
Gain of 2 lines[1]	4.4%	8.9%	9.0%
Gain of 1 line[1]	29.7%	29.4%	30.7%
No change	50.6%	42.8%	45.8%
Loss of 1 line[2]	13.2%	17.2%	9.0%
Loss of 2 lines[2]	1.7%	0.6%[3]	3.6%
Loss of more than 2 lines[2]	0.6%	1.1%[3]	1.2%

Table 12: Comparison Of Vision After Surgery With Vision Before Surgery

[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

[3] At 3 Months after surgery, 3 eyes had vision without glasses that was 2 or more lines worse than their vision with glasses before surgery. They are as follows:

1 case	Preoperative Vision with Glasses	20/20	3 Month Vision without Glasses	20/40
1 case	Preoperative Vision with Glasses	20/16	3 Month Vision without Glasses	20/32
1 case	Preoperative Vision with Glasses	20/20	3 Month Vision without Glasses	20/32

9. WHAT ARE ITS RISKS?

The study data referenced below has been achieved using the ALLEGRETTO WAVE excimer laser system with 200 Hz. Testing data submitted to FDA show that the system with 500 Hz repetition rate is expected to show equivalent clinical results.

Please also refer to section:

- “Clinical Study for Farsightedness with or without Astigmatism” on page 38
- “Clinical Study for Mixed Astigmatism” on page 43
- “Clinical Study for Wavefront-guided LASIK” on page 47

Clinical Study for Nearsightedness with or without Astigmatism

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 13** 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 13
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%

Table 13: Visual Acuity With Glasses After Surgery

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 14** shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses.

Table 14
Change in Eye's 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%

Table 14: Change in Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Nearsightedness

[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 mmsq, epithelium of > 1 mm^2 in the interface with loss of 2 lines or more of BSCVA, uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg, 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 epithelium 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** improved after LASIK. The percent of subjects reporting “none” or “mild” of these symptoms improved after treatment The results can be found in **Table 15**.

Table 15
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%
Visual Fluctuations	87.3%	10.3%	2.5%	71.4%	22.5%	6.1%
Night Driving Glare	50.5%	32.2%	17.4%	64.1%	24.0%	11.9%

Table 15: Patient Symptoms For Nearsightedness

Clinical Study for Farsightedness with or without Astigmatism

Visual Acuity *with* Glasses After Surgery for Farsightedness:

Best vision with glasses was measured before surgery and after surgery using the same chart to allow comparison of patient's visual acuities. **Table 16** 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 16
Visual Acuity with Glasses After Surgery

Time after Surgery	Preop (N=290)	1 Month (N=285)	3 Months (N=276)	6 Months (N=260)	1 Year (N=98)
% of eyes with 20/20 or better	91.4%	90.5%	91.7%	92.8%	96.1%
% of eyes with 20/40 or better	100%	99.3%	99.6%	98.9%	98.4%

Table 16: Visual Acuity With Glasses After Surgery

Change in Visual Acuity *with* Glasses After Surgery for Farsightedness

Table 17 shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses. Table 6 provided a comparison of visual acuity without glasses after surgery with visual acuity with glasses before surgery while this table is with glasses for both measurements.

Table 17
Change in Eye's Visual Acuity *with* Glasses After Surgery Compared with Before Surgery for Farsightedness

Change in Visual Acuity with Glasses	Time After Surgery (Number of Eyes Examined)			
	1 Month (N=285)	3 Months (N=276)	6 Months (N=260)	1 Year (N=98)
Gain of more than 2 lines[1]	0.4%	0.4%	0.4%	0.0%
Gain of 2 lines[1]	4.2%	6.2%	9.6%	9.2%
Gain of 1 line[1]	27.7%	29.0%	31.2%	34.7%
No change	52.6%	53.6%	48.5%	50.0%
Loss of 1 line[2]	11.9%	9.1%	8.9%	5.1%
Loss of 2 lines[2]	2.5%	1.5%	1.5%	1.0%
Loss of more than 2 lines[2]	0.7%	0.4%	0.0%	0.0%

Table 17: Change in Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Farsightedness

[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 Farsightedness:

Certain adverse events and complications occurred after the LASIK surgery. Only one adverse event occurred during the clinical study, one eye (0.4%) had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following adverse events did **not** occur: corneal infiltrate or ulcer requiring treatment, lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month, 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 mmsq, epithelium of > 1 mm² the interface with loss of 2 lines or more of BSCVA, uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg and decrease in best spectacle corrected visual acuity of > 10 letters not due to irregular astigmatism.

The following complications occurred 6 months after LASIK during this clinical trial: 0.8% (2/262) of eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

The following complications did **not** occur 6 months following LASIK in this clinical trial: corneal edema, foreign body sensation, pain, ghosting or double images, and need for lifting and/or reseating of the flap/cap.

Subjects were asked to complete a patient questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively. **Table 18** details cases in which the patient's response to the survey question indicated a worsening in a symptom.

Table 18
Change in Patient Symptoms for Patients with Worsening of Symptoms

	Much Worse		Somewhat Worse	
	%	n	%	n
	N=260		N=260	
Glare from Bright Lights	3.0	8	8.0	21
Halos	6.4	17	6.8	18
Light Sensitivity	4.9	13	8.0	21
Visual Fluctuations	6.1	16	23.5	61
Night Driving Glare	4.2	11	11.8	31

Table 18: Change In Patient Symptoms For Patients With Worsening Of Symptoms

Subjective Results for Farsightedness:

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** and **night driving glare** improved after LASIK. The percent of subjects reporting “none” or “mild” of these symptoms improved after treatment. The results can be found in **Table 19**.

Table 19
Patient Symptoms

	Preoperative						6 Months					
	None-Mild		Moderate		Marked-Severe		None-Mild		Moderate		Marked-Severe	
	%	n	%	n	%	n	%	n	%	n	%	n
	N=287		N=287		N=287		N=260		N=260		N=260	
Glare from Bright Lights	50.9	146	27.5	79	21.6	62	65.4	170	20.8	54	13.8	36
Halos	70.4	202	15.3	44	14.3	41	71.2	185	15.0	39	13.9	36
Light Sensitivity	61.7	177	17.8	51	20.6	59	61.5	160	23.5	61	15.0	55
Visual Fluctuations	71.1	204	24.7	71	4.2	12	55.4	144	28.5	74	16.2	42
Night Driving Glare	78.0	223	10.5	30	11.5	33	83.0	216	8.5	22	8.5	22

Table 19: Patient Symptoms For Farsightedness

Table 20 details changes in patient's responses to survey questions regarding symptoms. As can be seen in the table, in the majority of cases, there was no change in the patient's report of symptoms.

Table 20
Change in Patient Symptoms at 6 Months
(N=260)

	Much Worse		Somewhat Worse		No Change		Somewhat Better		Much Better	
	%	n	%	n	%	n	%	n	%	n
Glare from Bright Lights	3.0	8	8.0	21	62.9	163	19.7	51	6.4	17
Halos	6.4	17	6.8	18	68.6	178	13.6	35	4.5	12
Light Sensitivity	4.9	13	8.0	21	67.4	175	14.8	38	4.9	13
Visual Fluctuations	6.1	16	23.5	61	62.5	162	5.7	15	2.3	6
Night Driving Glare	4.2	11	11.8	31	61.2	159	12.9	34	9.9	25

Table 20: Change In Patient Symptoms At 6 Months

Clinical Study for Mixed Astigmatism

Change in Visual Acuity *with* Glasses After Surgery for Mixed Astigmatism:

Table 21 shows the percent of patient's eyes that changed visual acuity after LASIK surgery while wearing glasses. Table 9 provided a comparison of visual acuity without glasses after surgery with visual acuity with glasses before surgery while this table is with glasses for both measurements.

Table 21
Change in Eye's Visual Acuity *with* Glasses After Surgery Compared with Before Surgery for Mixed Astigmatism

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)		
	1 Month (N=161)	3 Months (N=142)	6 Months (N=111)
Gain of more than 2 lines[1]	0.0%	0.7%	0.0%
Gain of 2 lines[1]	5.0%	4.2%	6.3%
Gain of 1 line[1]	31.7%	35.9%	46.0%
No change	52.8%	48.6%	42.3%
Loss of 1 line[2]	8.1%	9.9%	4.5%
Loss of 2 lines[2]	1.9%	0.7%	0.0%
Loss of more than 2 lines[2]	0.6%	0.0%	0.9%

Table 21: Change In Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Mixed Astigmatism

[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 Mixed Astigmatism:

Certain adverse events and complications occurred after the LASIK surgery. No protocol defined adverse events occurred during the clinical study. However, two events occurred which were reported to the FDA as Adverse Events.
The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. The second event involved the treatment of an incorrect axis of astigmatism which required retreatment.

The following adverse events did **not** occur: corneal infiltrate or ulcer requiring treatment, corneal epithelial defect involving the keratectomy at 1 month or later, corneal edema at 1 month or later visible in the slit lamp exam, epithelium of > 1 mm^2 the interface with loss of 2 lines or more of BSCVA, lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month, decrease in best spectacle corrected visual acuity of > 10 letters not due to irregular astigmatism, any complication leading to intraocular surgery, melting of the flap of > 1 mmsq, uncontrolled IOP rise and retinal detachment or retinal vascular accident.

None of the following complications occurred at 3 months after LASIK during this clinical trial: corneal edema, corneal epithelial defect, any epithelium in the interface, foreign body sensation, pain, ghosting or double images, and need for lifting and/or reseating of the flap/cap.

Subjects were asked to complete a patient questionnaire preoperatively and at 3-months, 6-months, and 1-year postoperatively.

Subjective Results for Mixed Astigmatism:

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** and **night driving glare** improved after LASIK. The percent of subjects reporting “none” or “mild” of these symptoms improved after treatment. The results can be found in **Table 22**.

Table 22
Patient Symptoms for Mixed Astigmatism

	Preoperative			6 Months		
	None-Mild	Moderate	Marked-Severe	None-Mild	Moderate	Marked-Severe
	% n	% n	% n	% n	% n	% n
	N=162	N=162	N=162	N=142	N=142	N=142
Glare from Bright Lights	40.1 65	32.7 53	27.2 44	45.8 65	37.3 53	16.9 24
Halos	63.0 102	17.9 29	19.1 31	57.8 82	16.9 24	25.4 36
Light Sensitivity	56.8 92	19.8 32	23.5 38	47.2 67	25.4 36	27.5 39
Visual Fluctuations	67.9 110	19.1 31	13.0 21	57.0 81	24.7 35	18.3 26
Night Driving Glare	45.7 74	27.8 45	26.5 43	58.5 83	21.8 31	19.7 28

Table 22: Patient Symptoms For Mixed Astigmatism

Table 23 details changes in patient's responses to survey questions regarding symptoms. As can be seen in the table, in the majority of cases, there was no change in the patient's report of symptoms.

Table 23
Change in Patient Symptoms at 3 Months
(N=142)

	Much Worse		Somewhat Worse		No Change		Somewhat Better		Much Better	
	%	n	%	n	%	n	%	n	%	n
Glare from Bright Lights	2.1	3	14.1	20	48.6	69	33.1	47	2.1	3
Halos	9.9	14	19.7	28	42.3	60	26.8	38	1.4	2
Light Sensitivity	3.5	5	17.6	25	58.5	83	18.3	26	2.1	3
Visual Fluctuations	2.1	3	21.1	30	64.1	91	12.7	18	0	0
Night Driving Glare	4.2	6	10.6	15	56.3	80	26.1	37	2.8	4

Table 23: Change In Patient Symptoms At 3 Months

Clinical Study for Wavefront-guided LASIK

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 24** shows the percent of patient's eyes that achieved 20/20 or better and 20/40 or better visual acuity after wavefront-guided LASIK surgery while wearing glasses.

Table 24
Visual Acuity *with* Glasses After Surgery for Nearsightedness

Time after Surgery	Preop (N=188)	1 Month (N=182)	3 Months (N=180)
% of eyes with 20/20 or better	99.5%	100%	100%
% of eyes with 20/40 or better	100%	100%	100%

Table 24: Visual Acuity With Glasses After Surgery For Nearsightedness

Change in Visual Acuity *with* Glasses After Surgery for Nearsightedness:

Table 25 shows the percent of patient's eyes that changed visual acuity after wavefront-guided LASIK surgery while wearing glasses. Table 12 provided a comparison of visual acuity without glasses after surgery with visual acuity with glasses before surgery while this table is with glasses for both measurements.

Table 25
Change in Eye's Visual Acuity *with* Glasses After Surgery Compared with Before Surgery for Nearsightedness

Change in Visual Acuity	Time After Surgery (Number of Eyes Examined)		
	1 Month (N=182)	3 Months (N=180)	6 Months (N=166)
Gain of more than 2 lines[1]	0.0%	0.0%	1.8%
Gain of 2 lines[1]	5.5%	8.9%	9.6%
Gain of 1 line[1]	41.8%	42.8%	42.2%
No change	46.7%	41.7%	44.6%
Loss of 1 line[2]	6.0%	6.7%	1.8%
Loss of 2 lines[2]	0.0%	0.0%	0.0%
Loss of more than 2 lines[2]	0.0%	0.0%	0.0%

Table 25: Change In Eye's Visual Acuity With Glasses After Surgery Compared With Before Surgery For Nearsightedness

[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 wavefront-guided LASIK surgery. No adverse event occurred during wavefront-guided treatments during this clinical study.

The following adverse events did **not** occur: corneal infiltrate or ulcer requiring treatment, lost, misplaced or misaligned flap or any flap/cap problems requiring surgical intervention beyond 1 month, 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 mmsq, epithelium of > 1 mm^2 in the interface with loss of 2 lines or more of BSCVA, uncontrolled IOP rise with increase of > 5 mmHg or any reading above 25 mmHg and decrease in best spectacle corrected visual acuity of > 10 letters not due to irregular astigmatism.

The following complications occurred 3 months after wavefront-guided LASIK during this clinical trial: corneal epithelial defect (0.6%), foreign body sensation (0.6%), and pain (0.6%).

The following complications did not occur 3 months following wavefront-guided LASIK in this clinical trial: corneal edema, any epithelium in the interface, ghosting or double images, and need for lifting and/or reseating of 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 (e.g. never on one end, all the time on the other end) and a mark in the middle indicated a scaled response between the extremes.

Looking at the data in another way as shown in **Table 26**, also shows that patient reports of **glare** from **bright lights** and **night driving glare** improved after wavefront-guided LASIK. The percent of subjects reporting “none” or “mild” of these symptoms improved after treatment. Using a 10 point scale, responses were rated as None-Mild if the patient marked 1 - 3. Moderate if the response was 4 - 6 and Marked-Severe if the response was 7 - 10.

Table 26
Patient Symptoms

	Preoperative						3 Months					
	None-Mild		Moderate		Marked-Severe		None-Mild		Moderate		Marked-Severe	
	%	n	%	n	%	n	%	n	%	n	%	n
	N=188		N=188		N=188		N=180		N=180		N=180	
Glare from Bright Lights	52.1	98	27.7	52	20.2	38	60.0	108	31.1	56	8.9	16
Halos	63.8	120	23.4	44	12.8	24	66.7	120	17.8	32	15.6	28
Light Sensitivity	62.8	118	26.6	50	10.6	20	52.2	94	30.0	54	17.8	32
Visual Fluctuations	86.2	162	11.7	22	2.1	4	80.0	144	14.4	26	5.6	10
Night Driving Glare	56.9	107	25.0	47	18.1	34	68.9	124	22.2	40	8.9	16

Table 26: Patient Symptoms

Table 27 details changes in patient's responses to survey questions regarding symptoms. As can be seen in the table, in the majority of cases, there was no change in the patient's report of symptoms. Patients completed a questionnaire in which they rated symptoms on a 10 point scale. Results were considered to be "much worse" than before surgery if the response changed by 7 or more points on the 10 point scale and were considered to be "somewhat worse" if the response changed by 3 to 6 points. Results were considered to be "much better" than before surgery if the response improved by 7 or more points on the 10 point scale and were considered to be "somewhat better" if the response changed by 3 to 6 points.

Table 27
Change in Patient Symptoms at 3 Months
(N=180)

	Much Worse %	Somewhat Worse %	No Change %	Somewhat Better %	Much Better %
Glare from Bright Lights	0.0%	7.8%	67.8%	22.2%	2.2%
Halos	4.4%	14.4%	66.7%	14.4%	0.0%
Light Sensitivity	2.2%	24.4%	61.1%	12.2%	0.0%
Visual Fluctuations	0.0%	14.4%	76.7%	8.9%	0.0%
Night Driving Glare	0.0%	8.9%	70.6%	20.6%	0.0%

Table 27: Change In Patient Symptoms At 3 Months

10. 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 or wavefront-guided 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 or wavefront-guided 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. For evaluation and wavefront-guided LASIK treatment your eyes will get wavefront examination with a wavefront analyzer.

IMPORTANT

Stop wearing your contact lenses several days before your LASIK or wavefront-guided 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 make-up 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.

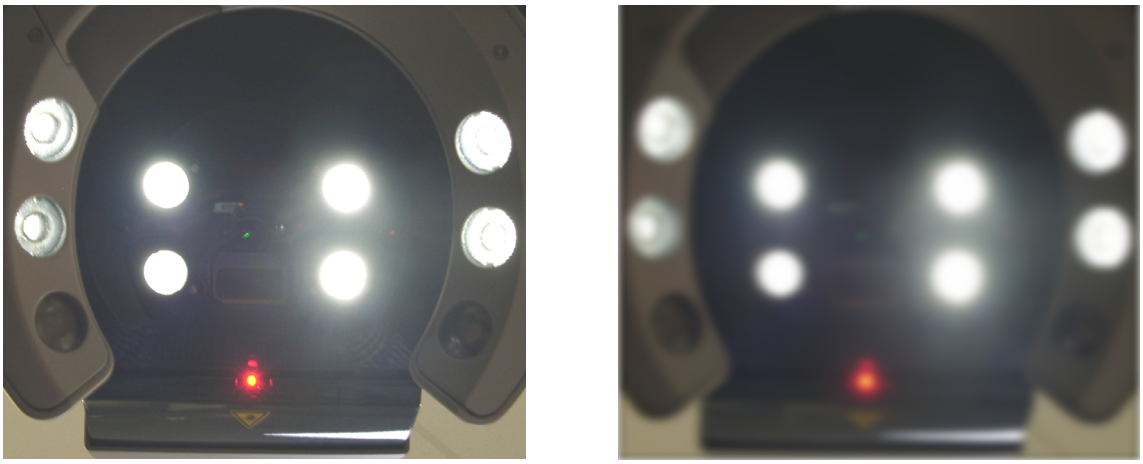

Figure 15: Examples Of Patients View Under The Laser (Crisp And Blurred)

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 or wavefront-guided 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 He may perform the cut with either a mechanical or a laser **microkeratome**. Mechanical microkeratomes usually makes a weak buzzing sound. Laser microkeratome are usually noiseless. 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 or wavefront-guided LASIK procedure will take about 5-10 minutes per eye.

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, 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 or wavefront-guided LASIK.

IMPORTANT

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.

11. FREQUENTLY ASKED QUESTIONS

Is LASIK or wavefront-guided 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 WaveLight® EX500 for treatment showed that the treatment was unchanged at 12 months (6 months for mixed astigmatism and wavefront-guided LASIK) after LASIK. However, it is unknown what will happen to you after that, because the study did not look at patient's conditions beyond 12 months after they had LASIK or wavefront-guided 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 or wavefront-guided LASIK?

In the clinical study of the ALLEGRETTO WAVE device for **myopia**, **myopic** and **astigmatism**, there were various defects in patient's 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.

In the clinical study of the ALLEGRETTO WAVE device for **hyperopia** and **hyperopic astigmatism**, there were various defects in patient's corrections:

- The visual acuity with glasses was worse than 20/40 in 0.4% (1/260). That means that even with glasses, their vision was worse than 20/40. In some States, with a visual acuity worse than 20/40 you may not be able to get a driving license.
- No patients (0/79) had a worsening of their astigmatism (increase of 2 or more diopters in their refractive cylinder) when they were treated for farsightedness (spherical hyperopia).
- 1.5% (4/260) 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.
- In no instance (0/260) did the LASIK procedure remove too much or too little of a patient's cornea, leaving them with an error in correction of 2 diopters or more.

In the clinical study of the ALLEGRETTO WAVE device for **mixed astigmatism**, there were various defects in patient's corrections:

- The visual acuity with glasses was worse than 20/40 in 0.0% (0 of 142). That means that even with glasses, their vision was worse than 20/40. In some States, with a visual acuity worse than 20/40 you may not be able to get a driving license.
- 0.7% (1 of 142) 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.
- In no instance (0 of 142) did the LASIK procedure remove too much or too little of a patient's cornea, leaving them with an error in correction of 2 diopters or more.

In the clinical study of the ALLEGRETTO WAVE device for nearsightedness with **wavefront-guided LASIK**, there were various defects in patients" corrections:

- The visual acuity with glasses was worse than 20/40 in 0.0% (0 of 180). That means that even with glasses, their vision was worse than 20/40. In some States, with a visual acuity worse than 20/40 you may not be able to get a driving license. This did not occur in this study of wavefront-guided LASIK.
- No patients (0 of 111) had a worsening of their astigmatism (increase of 2 or more diopters in their refractive cylinder) when they were treated for wavefront-guided LASIK.
- 0.0% (0 of 180) 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.
- In 0.6% (1 of 180) the wavefront-guided LASIK procedure removed too much or too little of a patient's cornea, leaving them with an error in correction of 2 diopters or more.

Will I need reading glasses after LASIK or wavefront-guided 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 or wavefront-guided 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.

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 suction ring used with the mechanical or laser 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 the pressure may cause closing of small blood vessels inside the eye. Once the Suction Ring 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.
- An unsatisfactory flap 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 WaveLight® EX500 laser device on implantable medical devices are unknown.

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 or wavefront-guided 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.

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 (Myopia):

- 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 mmHg.

At 6 months after treatment, the following events were reported in patients included in US clinical studies (Hyperopia):

- 0.8% (2/262) of cases had a defect in the top layer of the cornea (Corneal epithelial defect).
- 0.8% (2/262) of cases had an ingrowth of surface cells in the interface (Epithelial ingrowth).
- 4.5% (11/245) of cases had an increased intraocular pressure of > 5 mmHg.
- In one case, retinal detachment or retinal vascular accident occurred.

At 3 months after treatment, the following events were reported in patients included in US clinical studies (Mixed Asitgmatism):

- 4.2% (6 of 142) of cases had an increased intraocular pressure of > 5 mmHg.

At 3 months after treatment, the following events were reported in patients included in US clinical studies (Wavefront Myopia):

- 0.6% (1 of 180) of cases had a defect in the top layer of the cornea (Corneal epithelial defect).
- 0.6% (1 of 180) of cases of foreign body sensations.
- 0.6% (1 of 180) of cases of pain.

12. 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.

13. WHAT SHOULD YOU ASK YOUR DOCTOR?

You may want to ask your doctor the following questions to help you decide if LASIK or wavefront-guided 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 or wavefront-guided LASIK for my amount of nearsightedness, farsightedness with or without astigmatism or mixed astigmatism?
- What vision can I expect the first few months after surgery?
- If LASIK or wavefront-guided 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 or wavefront-guided 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 or wavefront-guided LASIK?
- Should I have LASIK or wavefront-guided LASIK in both eyes?
- How long will I have to wait till I get LASIK or wavefront-guided LASIK on the second eye?
- What vision problems may I experience, if I have LASIK or wavefront-guided 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.

14. SUMMARY OF IMPORTANT INFORMATION

- LASIK or wavefront-guided LASIK is a permanent operation to the cornea and cannot be reversed.
- LASIK or wavefront-guided 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 or wavefront-guided LASIK surgery.
- Your vision must be stable at least one year before the pre-op examination. You will need written evidence that your nearsightedness, farsightedness, astigmatism and mixed astigmatism have changed only 0.5 diopter or less.
- Pregnant or nursing women do not qualify for LASIK or wavefront-guided LASIK surgery.
- You are not a good candidate for LASIK or wavefront-guided LASIK surgery if you have a collagen vascular disease or autoimmune disease or have a condition that makes wound healing difficult.
- LASIK or wavefront-guided 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 or wavefront-guided LASIK is not a laser version of RK, these surgeries are completely different from each other.
- Alternatives to LASIK or wavefront-guided LASIK include, but are not limited to glasses, contact lenses, PRK and RK.
- Some professions prohibit refractive surgery including LASIK or wavefront-guided LASIK.
- Before considering LASIK or wavefront-guided 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 or wavefront-guided LASIK. You should also discuss the time needed for healing and the discomfort you may experience or problems that may occur during this time.

15. 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 or wavefront-guided LASIK is a permanent procedure.	☐	☐
b) LASIK or wavefront-guided LASIK is free of risks.	☐	☐
c) LASIK or wavefront-guided 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 or wavefront-guided LASIK.	☐	☐
f) There is a risk that I may lose some vision after LASIK or wavefront-guided LASIK.	☐	☐
g) It's ok to have LASIK or wavefront-guided 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 WaveLight® EX500 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 or wavefront-guided LASIK.	☐	☐
l) Wavefront-guided LASIK is the same as Wavefront Optimized LASIK	☐	☐

You can find the answers in chapter 17 "Answers To Self-Test Questions" on page 70.

16. 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 GmbH
Am Wolfsmantel 5
91058 Erlangen
Germany

Distribution and Support in the U.S.A.:

ALCON Laboratories, Inc.
6201 S. Freeway
Fort Worth, TX 76134, USA
Toll Free: 800-832-7827
Phone: 949-753-6614
Internet: ALCONLABS.COM

17. ANSWERS TO SELF-TEST QUESTIONS

a) True (see page 58 and page 67)

b) False (see page 18, page 19, pages 34-37, page 61, page 62 and page 67)

c) False (see page 17 and page 67)

d) False (see page 52)

e) True (see page 59, page 60, page 61 and page 67)

f) True (see page 20, pages 34-37, page 60, page 61 and page 62)

g) False (see page 18 and page 67)

h) True (see page 18 and page 20)

i) True (see pages 22-24, page 58 and page 67)

j) False (see page 10, page 15, page 17 and pages 54-56)

k) False (see page 20 and page 67)

l) False (see page 12 and page 75)

18. GLOSSARY

Aberrometer	Wavefront Analyzer
Ablation, Ablate	Removal of tissue with an excimer laser.
WaveLight® EX500 Laser System	Modern high speed laser system with eyetracker for treatment of nearsightedness, farsightedness (both with or without astigmatism) and mixed astigmatism, manufactured by WaveLight GmbH in Germany.
ALLEGRO Analyzer	Measurement device for measurements of wavefront errors in human eyes.
Analgesic Medication	Pain relieving medication.
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.
Cataract Surgery	Surgical removal of the opaque lens and replacement with artificial lens (“IOL”).
Clear Lens Exchange	Refractive surgery similar to cataract surgery where the clear lens of the eye is removed.

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.
Customized Treatment	LASIK treatment that is based on more information than just the amount of nearsightedness, farsightedness and / or astigmatism.
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. Mixed Astigmatism is measured in terms of positive and negative 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.
Femtosecond Laser	Precision infrared laser instrument that can divide corneal tissue without heat or impact to surrounding cornea. This laser is used as laser microkeratome for making a corneal flap.

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.
IOL	Artificial lens used to replace the natural lens of the eye.
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.
Lamellar Keratitis	Inflammation under the flap.

Laser In-situ Keratomileusis	Refractive surgery that removes corneal tissue after creating a flap.
Laser Microkeratome	Precision laser instrument used to crate a flap during LASIK surgery. Also referred to as femtosecond laser
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).
Lens	Flexible lens behind the iris that helps to focus images on the retina.
Mechanical 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”.
Mixed Astigmatism	Special type of Astigmatism. Refractive condition creating two only partially focused images. One in front and one behind the retina. Mixed Astigmatism may create ghost or double images. The cornea or the lens is too flat in one direction and too steep in another direction (much like the shape of a football). The amount of mixed astigmatism is measured in diopters.
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.
Ptosis	Drooping of the upper eye lid.

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.
Standard LASIK	Wavefront Optimized LASIK
Steroids	Drugs used to reduce inflammation or the body's healing response after injury or disease.
Striae	Minute grove/lines of a parallel series on the cornea.
Suction Ring	Microkeratome component used to stabilize the eye and hold the Microkeratome in the proper position while creating the corneal flap.
Treatment Zone	Area on the cornea where tissue is removed during laser treatment.
Traditional LASIK	Wavefront Optimized LASIK
Vitreous, Vitreous body	Gel-like fluid that fills the center of the eyeball behind the lens.
Wavefront	Image of light waves. Can be used to determine errors of an eye.
Wavefront-guided LASIK	LASIK treatment based on wavefront measurements.
Wavefront Analyzer	Measurement device designed to measure optical errors by means of wavefront measurement.
Wavefront Optimized LASIK	LASIK which is based just on amount of nearsightedness, farsightedness or astigmatism.

Table 28: Glossary

19. INDEX

page

page

- End -